

ANIMAL ALLERGENS, AP CATTLE HAIR AND DANDER- cattle hair and dander injection, solution

ANIMAL ALLERGENS, AP DOG HAIR AND DANDER CANIS SPP- animal allergens, dog dander canis spp injection, solution

ANIMAL ALLERGENS, DOG HAIR AND DANDER CANIS SPP.- dog hair canis spp. injection, solution

ANIMAL ALLERGENS, AP HORSE HAIR AND DANDER- ap horse hair and dander injection, solution

ANIMAL ALLERGENS, FEATHER MIX- feather mix injection, solution

ANIMAL ALLERGENS, GUINEA PIG HAIR AND DANDER- guinea pig hair and dander injection, solution

FOOD - ANIMAL PRODUCTS AND POULTRY PRODUCTS, BEEF BOVINE SPP.- beef bovine spp. injection, solution

FOOD - ANIMAL PRODUCTS AND POULTRY PRODUCTS, CHICKEN MEAT GALLUS SP.- chicken meat gallus sp. injection, solution

POLLENS - TREES, OLIVE OLEA EUROPAEA- olive olea europaea injection, solution

POLLENS - TREES, PALM, QUEEN COCOS PLUMOSA- palm, queen cocos plumosa injection, solution

POLLENS - TREES, PALO VERDE CERCIDIUM FLORIDUM- palo verde cercidium floridum injection, solution

POLLENS - TREES, PECAN CARYA CARYA ILLINOENSIS- pecan carya carya illinoensis injection, solution

POLLENS - TREES, PEPPER TREE, CALIFORNIA SCHINUS MOLLE- pepper tree, california schinus molle injection, solution

POLLENS - TREES, PINE MIX- pine mix injection, solution

POLLENS - TREES, PRIVET LIGUSTRUM VULGARE- privet ligustrum vulgare injection, solution

POLLENS - TREES, RUSSIAN OLIVE ELAEAGNUS ANGUSTIFOLIA- russian olive elaeagnus angustifolia injection, solution

POLLENS - TREES, SYCAMORE, AMERICAN EASTERN PLATANUS OCCIDENTALLIS- sycamore, american eastern platanus occidentallis injection, solution

POLLENS - TREES, TREE MIX 11- tree mix 11 injection, solution

POLLENS - TREES, TREE MIX 5- tree mix 5 injection, solution

POLLENS - TREES, TREE MIX 6- tree mix 6 injection, solution

POLLENS - TREES, TREE OF HEAVEN AILANTHUS ALTISSIMA- tree of heaven ailanthus altissima injection, solution

POLLENS - TREES, WALNUT, BLACK JUGLANS NIGRA- walnut, black juglans nigra injection, solution

POLLENS - TREES, WILLOW, BLACK SALIX NIGRA- willow, black salix nigra injection, solution

POLLENS - WEEDS AND GARDEN PLANTS, COCKLEBUR XANTHIUM STRUMARIUM- cocklebur xanthium strumarium injection, solution

POLLENS - WEEDS AND GARDEN PLANTS, DOG FENNEL, EASTERN EUPATORIUM CAPILLIFOLIUM- dog fennel, eastern eupatorium capillifolium injection, solution

POLLENS - WEEDS AND GARDEN PLANTS, GOLDENROD SOLIDAGO CANADENSIS- goldenrod solidago canadensis injection, solution

POLLENS - WEEDS AND GARDEN PLANTS, LAMBS QUARTERS CHENOPODIUM ALBUM- lambs quarters chenopodium album injection, solution

POLLENS - WEEDS AND GARDEN PLANTS, NETTLE URTICA DIOICA- nettle urtica dioica injection, solution

POLLENS - WEEDS AND GARDEN PLANTS, PIGWEED, ROUGH REDROOT AMARANTHUS RETROFLEXUS- pigweed, rough redroot amaranthus retroflexus injection, solution

POLLENS - WEEDS AND GARDEN PLANTS, PLANTAIN, ENGLISH PLANTAGO LANCEOLATA- plantain, english plantago lanceolata injection, solution

POLLENS - WEEDS AND GARDEN PLANTS, RAGWEED, GIANT AMBROSIA TRIFIDA- ragweed, giant ambrosia trifida injection, solution

POLLENS - WEEDS AND GARDEN PLANTS, RAGWEED. WESTERN AMBROSIA PSILOSTACHYA- ragweed. western ambrosia psilostachya injection, solution

POLLENS - WEEDS AND GARDEN PLANTS, RUSSIAN THISTLE SALSOLA KALI- russian thistle salsola kali injection, solution

POLLENS - WEEDS AND GARDEN PLANTS, SAGEBRUSH, MUGWORT ARTEMISIA VULGARIS- sagebrush, mugwort artemisia vulgaris injection, solution

POLLENS - WEEDS AND GARDEN PLANTS, SCALE, WING SHAD ATRIPLEX CANESCENS- scale, wing shad atriplex canescens injection, solution

POLLENS - WEEDS AND GARDEN PLANTS, SCOTCH BROOM CYTISUS SCOPARIUS- scotch broom cytiscus scoparius injection, solution

POLLENS - WEEDS AND GARDEN PLANTS, SORREL, SHEEP RUMEX ACETOSELLA- sorrel, sheep rumex acetosella injection, solution

POLLENS - WEEDS, CARELESS WEED AMARANTHUS PALMERI- careless weed amaranthus palmeri injection, solution

POLLENS - WEEDS, CARELESS/PIGWEED MIX- careless/pigweed mix injection, solution

POLLENS - WEEDS, DOCK/SORREL MIX- pollens - weeds, dock/sorrel mix injection, solution

POLLENS - WEEDS, GIANT, SHORT, WESTERN RAGWEED MIX- giant, short, western ragweed mix injection, solution

POLLENS - WEEDS, KOCHIA SCOPARIA- kochia scoparia injection, solution

POLLENS - WEEDS, MARSHELDER/POVERTY MIX- pollens - weeds, marshelder/poverty mix injection, solution

POLLENS - WEEDS, WEED MIX 2630- weed mix 2630 injection, solution

FOOD - ANIMAL PRODUCTS AND POULTRY PRODUCTS, EGG, WHITE GALLUS SP.- egg, white gallus sp. injection, solution

FOOD - ANIMAL PRODUCTS AND POULTRY PRODUCTS, EGG, YOLK GALLUS SP.- egg, yolk gallus sp. injection, solution

FOOD - ANIMAL PRODUCTS AND POULTRY PRODUCTS, PORK SUS SP.- pork sus sp. injection, solution

FOOD - DAIRY PRODUCTS, CASEIN, COW MILK- casein, cow milk injection, solution

FOOD - DAIRY PRODUCTS, MILK, WHOLE COW- milk, whole cow injection, solution

FOOD - FISH AND SHELLFISH, CLAM- clam injection, solution

FOOD - FISH AND SHELLFISH, CODFISH GADUS CALLARIAS- codfish gadus callarias injection, solution

FOOD - FISH AND SHELLFISH, CRAB XIPHOSURUS SOWERBYI- crab xiphosurus sowerbyi injection, solution

FOOD - FISH AND SHELLFISH, LOBSTER HOMARUS AMERICANUS- lobster homarus americanus injection, solution

FOOD - FISH AND SHELLFISH, SALMON SALMO SALAR- salmon salmo salar injection, solution

FOOD - FISH AND SHELLFISH, SHRIMP CRAGO SP.- shrimp crago sp. injection, solution

FOOD - FISH AND SHELLFISH, TUNA THUNNUS SP.- tuna thunnus sp. injection, solution

FOOD - PLANT SOURCE, ALMOND PRUNUS AMYGDALUS- almond prunus amygdalus injection, solution

FOOD - PLANT SOURCE, APPLE MALUS SP.- apple malus sp. injection, solution

FOOD - PLANT SOURCE, BANANA MUSA SAPIENTUM- banana musa

sapientum injection, solution

FOOD - PLANT SOURCE, BRAZIL NUT BERTHOLLETIA EXCELSA- brazil nut

bertholletia excelsa injection, solution

FOOD - PLANT SOURCE, CARROT DAUCUS CAROTA- carrot daucus

carota injection, solution

FOOD - PLANT SOURCE, CASHEW NUT ANACARDIUM OCCIDENTALIE- cashew

nut anacardium occidentale injection, solution

FOOD - PLANT SOURCE, CELERY APIUM GRAVEOLENS- celery apium

graveolens injection, solution

FOOD - PLANT SOURCE, CORN ZEA MAYS- corn zea mays injection, solution

FOOD - PLANT SOURCE, HAZELNUT FILBERT CORYLUS SPP.- hazelnut filbert

corylus spp. injection, solution

FOOD - PLANT SOURCE, MELON, CANTALOUPE CUCUMIS MELO- cantaloupe

cucumis melo injection, solution

FOOD - PLANT SOURCE, ORANGE CITRUS SINENSIS- orange citrus

sinensis injection, solution

FOOD - PLANT SOURCE, PEA, GREEN OR ENGLISH PISUM SATIVUM- pea,

green or english pisum sativum injection, solution

FOOD - PLANT SOURCE, PEACH PRUNUS PERSICA- peach prunus

persica injection, solution

FOOD - PLANT SOURCE, PEANUT ARACHIS HYPOGAEA- peanut arachis

hypogaea injection, solution

FOOD - PLANT SOURCE, PECAN CARYA ILLINOENSIS- pecan carya

illinoensis injection, solution

FOOD - PLANT SOURCE, POTATO, WHITE SOLANUM TUBEROSUM- potato,

white solanum tuberosum injection, solution

FOOD - PLANT SOURCE, RICE, WHOLE GRAIN- rice, whole grain injection,

solution

FOOD - PLANT SOURCE, RYE GRAIN- rye grain injection, solution

FOOD - PLANT SOURCE, SOYBEAN GLYCINE SOJA- soybean glycine

soja injection, solution

FOOD - PLANT SOURCE, STRAWBERRY FRAGARIA CHILOENSIS- strawberry

fragaria chiloensis injection, solution

FOOD - PLANT SOURCE, STRING BEAN MIX- string bean mix injection,

solution

FOOD - PLANT SOURCE, TOMATO NICOTIANA SPP.- tomato nicotiana

spp. injection, solution

FOOD - PLANT SOURCE, WALNUT, BLACK JUGLANS NIGRA- walnut, black

juglans nigra injection, solution

FOOD - PLANT SOURCE, YEAST, BAKER SACCHAROMYCES CEREVISIAE- yeast,

baker saccharomyces cerevisiae injection, solution

FOOD - PLANT SOURCE, YEAST, BREWER SACCHAROMYCES CEREVISIAE-

yeast, brewer saccharomyces cerevisiae injection, solution

INSECTS WHOLE BODY COCKROACH, AMERICAN PERIPLANETA AMERICANA-

insects whole body cockroach, american periplaneta americana injection,

solution

INSECTS WHOLE BODY COCKROACH, GERMAN BLATELLA GERMANICA- insects

whole body cockroach, german blatella germanica injection, solution

INSECTS WHOLE BODY COCKROACH MIX- insects whole body cockroach

mix injection, solution

INSECTS WHOLE BODY, FIRE ANT MIX- insects whole body, fire ant

mix injection, solution

MOLDS - ALTERNARIA/HORMODENDRUM MIX- molds -

alternaria/hormodendrum mix injection, solution

MOLDS - MOLD MIX 10- molds - mold mix 10 injection, solution

MOLDS - MOLD MIX 4- molds - mold mix 4 injection, solution

MOLDS - TRICHOPHYTON MIX- molds - trichophyton mix injection, solution
MOLDS, PENICILLIUM MIX- molds, penicillium mix injection, solution
MOLDS, RUSTS AND SMUTS, ALTERNARIA TENUIS- alternaria tenuis injection, solution
MOLDS, RUSTS AND SMUTS, ASPERGILLUS FUMIGATUS- aspergillus fumigatus injection, solution
MOLDS, RUSTS AND SMUTS, ASPERGILLUS NIGER- aspergillus niger injection, solution
MOLDS, RUSTS AND SMUTS, BOTRYTIS CINEREA- botrytis cinerea injection, solution
INSECTS WHOLE BODY, ANT, FIRE SOLENOPSIS INVICTA- ant, fire solenopsis invicta injection, solution
MOLDS, RUSTS AND SMUTS, CANDIDA ALBICANS- candida albicans injection, solution
MOLDS, RUSTS AND SMUTS, CEPHALOSPORIUM ACREMONIUM- cephalosporium acremonium injection, solution
MOLDS, RUSTS AND SMUTS, CURVULARIA SPICIFERA- curvularia spicifera injection, solution
MOLDS, RUSTS AND SMUTS, EPICOCCUM NIGRUM- epicoccum nigrum injection, solution
MOLDS, RUSTS AND SMUTS, EPIDERMOPHYTON FLOCCOSUM- epidermophyton floccosum injection, solution
MOLDS, RUSTS AND SMUTS, FUSARIUM VASINFECTUM- fusarium vasinfectum injection, solution
MOLDS, RUSTS AND SMUTS, HELMINTHOSPORIUM INTERSEMINATUM- helminthosporium interseminatum injection, solution
MOLDS, RUSTS AND SMUTS, HORMODENDRUM CLADOSPORIOIDES- hormodendrum cladosporioides injection, solution
MOLDS, RUSTS AND SMUTS, MUCOR RACEMOSUS- mucor racemosus injection, solution
MOLDS, RUSTS AND SMUTS, PENICILLIUM NOTATUM- penicillium notatum injection, solution
MOLDS, RUSTS AND SMUTS, PHOMA HERBARUM- phoma herbarum injection, solution
MOLDS, RUSTS AND SMUTS, PULLULARIA PULLULANS- pullularia pullulans injection, solution
MOLDS, RUSTS AND SMUTS, RHIZOPUS NIGRICANS- rhizopus nigricans injection, solution
MOLDS, RUSTS AND SMUTS, STEMPHYLIUM BOTRYOSUM- stemphylium botryosum injection, solution
POLLENS - GRASSES, BAHIA GRASS PASPALUM NOTATUM- bahia grass paspalum notatum injection, solution
POLLENS - GRASSES, BROME, SMOOTH BROMUS INERMIS- brome, smooth bromus inermis injection, solution
POLLENS - GRASSES, CORN, CULTIVATED ZEA MAYS- corn, cultivated zea mays injection, solution
POLLENS - GRASSES, JOHNSON GRASS SORGHUM HALEPENSE- johnson grass sorghum halepense injection, solution
POLLENS - GRASSES, OATS, COMMON, CULTIVATED AVENA SATIVA- oats, common, cultivated avena sativa injection, solution
POLLENS - GRASSES, GRASS MIX 8- grass mix 8 injection, solution
POLLENS - GRASSES, SOUTHERN GRASS MIX- pollens - grasses, southern grass mix injection, solution
POLLENS - TREES, ACACIA ACACIA LONGIFOLIA- acacia longifolia injection, solution
POLLENS - TREES, ALDER, RED ALNUS RUBRA- alder, red alnus rubra injection,

solution

POLLENS - TREES, ASH, WHITE FRAXINUS AMERICANA- ash, white fraxinus americana injection, solution

POLLENS - TREES, BEECH, AMERICAN FAGUS GRANDIFOLIA- beech, american fagus grandifolia injection, solution

POLLENS - TREES, BIRCH MIX- birch mix injection, solution

POLLENS - TREES, BOTTLE BRUSH CALLISTEMON SPP.- bottle brush callistemon spp. injection, solution

POLLENS - TREES, BOXELDER/MAPLE MIX- boxelder/maple mix injection, solution

POLLENS - TREES, CEDAR, MOUNTAIN JUNIPERUS ASHEI- cedar, mountain juniperus ashei injection, solution

POLLENS - TREES, CEDAR, RED JUNIPERUS VIRGINIANA- cedar, red juniperus virginiana injection, solution

POLLENS - TREES, COTTONWOOD, COMMON POPULUS DELTOIDES- cottonwood, common populus deltoides injection, solution

POLLENS - TREES, CYPRESS, ARIZONA CUPRESSUS ARIZONICA- cypress, arizona cupressus arizonica injection, solution

POLLENS - TREES, CYPRESS, BALD TAXODIUM DISTICHUM- cypress, bald taxodium distichum injection, solution

POLLENS - TREES, ELM, AMERICAN ULMUS AMERICANA- elm, american ulmus americana injection, solution

POLLENS - TREES, ELM, CHINESE ULMUS PARVIFOLIA- elm, chinese ulmus parvifolia injection, solution

POLLENS - TREES, EUCALYPTUS, EUCALYPTUS GLOBULUS- eucalyptus, eucalyptus globulus injection, solution

POLLENS - TREES, GUM, SWEET LIQUIDAMBAR STYRACIFLUA- gum, sweet liquidambar styraciflua injection, solution

POLLENS - TREES, HACKBERRY CELTIS OCCIDENTALIS- hackberry celtis occidentalis injection, solution

POLLENS - TREES, HICKORY, SHAGBARK CARYA OVATA- hickory, shagbark carya ovata injection, solution

POLLENS - TREES, LINDEN BASSWOOD TILIA AMERICANA- linden basswood tilia americana injection, solution

POLLENS - TREES, MAPLE, HARD ACER SACCHARUM- maple, hard acer saccharum injection, solution

POLLENS - TREES, MELALEUCA PUNK TREE MELALEUCA QUINQUENERVIA- melaleuca punk tree melaleuca quinquenervia injection, solution

POLLENS - TREES, MESQUITE, PROSOPIS JULIFLORA- mesquite, prosopis juliflora injection, solution

POLLENS - TREES, MULBERRY MIX- mulberry mix injection, solution

POLLENS - TREES, OAK MIX- oak mix injection, solution

POLLENS - TREES, OAK, RED QUERCUS RUBRA- oak, red quercus rubra injection, solution

ANIMAL ALLERGENS, UF DOG HAIR-DANDER CANIS SPP- animal allergens, dog dander canis spp injection, solution

Jubilant HollisterStier LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use **NON-STANDARDIZED ALLERGENIC EXTRACTS (POLLENS, MOLDS, EPIDERMALS AND INSECTS)** safely and effectively. See full prescribing information for **NON-STANDARDIZED ALLERGENIC EXTRACTS (POLLENS, MOLDS, EPIDERMALS AND INSECTS)**.

NON-STANDARDIZED ALLERGENIC EXTRACTS (POLLENS, MOLDS, EPIDERMALS AND INSECTS)

Solution for percutaneous, intradermal, or subcutaneous administration Initial U.S. Approval: 1925

WARNING: ANAPHYLAXIS

See full prescribing information for complete boxed warning.

- Non-standardized allergenic extracts can cause anaphylaxis, including anaphylactic shock and death.(5.1)
- Do not administer to individuals with severe, unstable or uncontrolled asthma, history of severe systemic reaction to the allergen extract when administered for diagnosis or treatment, or with medical conditions that reduce the ability to survive anaphylaxis.(4)
- Observe individuals for at least 30 minutes following administration. Emergency measures and personnel trained in their use must be available in the event of a life-threatening reaction.(5.1)
- Individuals with extreme sensitivity to these products, on an accelerated immunotherapy build-up, switching to another lot, receiving high doses of these products, or exposed to similar allergens may be at increased risk of anaphylaxis.(5.1)
- These products may not be suitable for individuals who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.(5.1)

INDICATIONS AND USAGE

Non-standardized allergenic extracts are indicated for:

- Skin test diagnosis of patients with a clinical history of allergy to the specific corresponding allergens.(1)
- Immunotherapy for the reduction of allergen-induced allergic symptoms confirmed by positive skin test or by *in vitro* testing for allergen-specific IgE antibodies.(1)

DOSAGE AND ADMINISTRATION

For percutaneous, intradermal, or subcutaneous use only.

Administration:

- Percutaneous for diagnostic testing.
- Intradermal for diagnostic testing.
- Subcutaneous for immunotherapy.

See full prescribing information for details on dosing and dilution preparation. (2)

DOSAGE FORMS AND STRENGTHS

Non-standardized allergenic extract solutions: stock concentrates, labeled in weight/volume, in a glycerin-preserved extracting fluid, supplied in 5, 10, 30, and 50 mL vials. (3, 16) Refer to the vial label for the product concentration. (11)

CONTRAINDICATIONS

- Severe, unstable or uncontrolled asthma.(4)
- History of any severe systemic reaction to the allergen extract when administered for diagnosis or treatment.(4)
- Medical conditions that reduce the ability to survive anaphylaxis.(4)

WARNINGS AND PRECAUTIONS

The risk of anaphylaxis may be increased in the following situations:

- Extreme sensitivity to non-standardized allergenic extracts.
- Concomitant environmental exposure to similar allergens.
- Receipt of high concentrations and volumes of non-standardized allergenic extracts.
- Receipt of an accelerated build-up schedule (e.g., "rush" immunotherapy).
- Changing to another lot of allergen.(5)

ADVERSE REACTIONS

Common adverse reactions reported for non-standardized allergenic extracts are:

- Local adverse reactions, occurring in 26 to 82% of all patients who receive subcutaneous immunotherapy (e.g., erythema, swelling, pruritus, tenderness and pain at the injection site).(6)
- Systemic adverse reactions, occurring in $\leq 7\%$ of patients who receive subcutaneous immunotherapy (e.g., generalized skin erythema, urticaria, pruritus, angioedema, rhinitis, wheezing, laryngeal edema, and hypotension). Systemic reactions may be fatal.(6)

To report SUSPECTED ADVERSE REACTIONS, contact Jubilant HollisterStier at 1-800-495-7437 or Adverse.Reactions@jhs.jubl.com; or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Certain medications may decrease skin test wheal and erythema responses, including antihistamines, topical corticosteroids, topical anesthetics, and tricyclic antidepressants.(7)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 11/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

WARNING: ANAPHYLAXIS

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

2.1 Preparation for Administration

2.2 Diagnostic Testing

2.3 Immunotherapy

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

5.1 Anaphylaxis

5.2 Cross-reactions and Dose Sensitivity

6 ADVERSE REACTIONS

7 DRUG INTERACTIONS

7.1 Antihistamines

7.2 Topical Corticosteroids and Topical Anesthetics

7.3 Tricyclic Antidepressants

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.2 Lactation

8.4 Pediatric Use

8.5 Geriatric Use

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

14 CLINICAL STUDIES

15 REFERENCES

16 HOW SUPPLIED

16.2 Storage and Handling

17 PATIENT COUNSELING INFORMATION

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: ANAPHYLAXIS

- Non-standardized allergenic extracts can cause anaphylaxis, including anaphylactic shock and death.(5.1)
- Do not administer to individuals with:
 - severe, unstable or uncontrolled asthma;
 - history of severe systemic reaction to the allergen extract when administered for diagnosis of treatment;
 - medical conditions that reduce the ability to survive anaphylaxis.(4)
- Observe individuals for at least 30 minutes following administration. Emergency measures and personnel trained in their use must be available in the event of a life-threatening reaction.(5.1)
- Individuals with extreme sensitivity to these products, on an accelerated immunotherapy build-up, switching to another lot, receiving high doses of these products, or exposed to similar allergens may be at increased risk of anaphylaxis.(5.1)
- These products may not be suitable for individuals who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.(5.1)

1 INDICATIONS AND USAGE

NON-STANDARDIZED ALLERGENIC EXTRACTS are indicated for:

- Skin test diagnosis of individuals with a clinical history of allergy to the specific corresponding allergens.

NON-STANDARDIZED ALLERGENIC EXTRACTS are indicated for:

- Immunotherapy for the reduction of allergen-induced allergic symptoms confirmed by positive skin test or by *in vitro* testing for allergen specific IgE antibodies for the specific corresponding allergens.

2 DOSAGE AND ADMINISTRATION

For percutaneous, intradermal, or subcutaneous administration only. Do not inject intravenously.

2.1 Preparation for Administration

Appearance is clear to slightly opalescent. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Discard solution if either of these conditions exist.

Non-standardized allergenic extracts diluted with Albumin Saline with Phenol (0.4%) (stabilized diluent) may be more potent than extracts diluted with diluents that do not contain albumin. When switching from non-stabilized to stabilized diluent, consider less concentrated initial dilutions for both intradermal testing and immunotherapy.

Different formulations, preparations, or new lots of non-standardized allergenic extracts are not interchangeable. Dosing should be adjusted appropriately when formulations, preparations, or lots of non-standardized allergenic extracts are changed [see *Immunotherapy (2.3)* and *Dosage Forms and Strengths (3)*].

Allergenic extracts may be prepared for intradermal (diagnosis) or subcutaneous (immunotherapy) administration by diluting stock concentrates.

- For diluent, use sterile albumin saline with phenol or sterile normal saline with phenol.

- Dilute stock concentrates by a minimum of 100-fold for intradermal testing. Dilutions of 1,000-fold or greater are appropriate starting points for patients with a clinical history of adverse reaction.

To prepare dilutions for intradermal testing and immunotherapy, start with a stock concentrate, and prepare a ten-fold (1:10) dilution by adding 0.5 mL of concentrate to 4.5 mL of sterile aqueous diluent. Prepare subsequent dilutions in a similar manner. (see Table 1).

Table 1: 10-fold Dilution Series

| Dilution | Extract | Milliliters of Diluent | Dilution Strength (w/v) | Dilution Strength (w/v) | Dilution Strength (w/v) | Dilution Strength (w/v) | Dilution Strength (w/v) |
|----------|--------------------|------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| 0 | Concentrate | | 1:10 | 1:20 | 1:50 | 1:100 | 1:650 |
| 1 | 0.5 mL Concentrate | 4.5 | 1:100 | 1:200 | 1:500 | 1:1,000 | 1:6,500 |
| 2 | 0.5 mL Dilution | 4.5 | 1:1,000 | 1:2,000 | 1:5,000 | 1:10,000 | 1:65,000 |
| 3 | 0.5 mL Dilution 2 | 4.5 | 1:10,000 | 1:20,000 | 1:50,000 | 1:100,000 | 1:650,000 |
| 4 | 0.5 mL Dilution 3 | 4.5 | 1:100,000 | 1:200,000 | 1:500,000 | 1:1,000,000 | 1:6,500,000 |
| 5 | 0.5 mL Dilution 4 | 4.5 | 1:1,000,000 | 1:2,000,000 | 1:5,000,000 | 1:10,000,000 | 1:65,000,000 |
| 6 | 0.5 mL Dilution 5 | 4.5 | 1:10,000,000 | 1:20,000,000 | 1:50,000,000 | 1:100,000,000 | 1:650,000,000 |

Note: A lower starting dose and/or less concentrated dilutions may be necessary for highly sensitive patients with a clinical history of sensitivity, or for those who display severe symptoms. [see *Diagnostic Testing (2.2)*, *Percutaneous Skin Testing (2.2.1)* and *Intradermal (Intracutaneous) Skin Test (2.2.2)*].

2.2 Diagnostic Testing

Testing is performed to identify patients that exhibit an allergic response at the site of administration. False positive reactions may occur. A positive skin test reaction must be interpreted in the context of the individual's clinical history and known exposure to the allergen.

- Administer percutaneous tests prior to administration of intradermal tests to identify highly sensitive patients.
- Do not use allergen mixes for diagnostic testing because a positive reaction would not permit specific identification of the allergen(s) that elicited the reaction. In addition, a negative reaction would fail to indicate whether an individual component allergen would have elicited a positive reaction at full strength.

2.2.1 Percutaneous Skin Testing

Dose

Unless an individual is suspected to be at greater risk for anaphylaxis, the initial starting dose is 1 drop (approximately 0.05 mL) of undiluted allergenic extract. For individuals suspected to be at greater risk for anaphylaxis (for example, as indicated by a history of allergen-induced anaphylaxis), initiate percutaneous testing with a sequence of serial 10-fold dilutions of undiluted allergenic extract spaced 15-20 minutes apart [see *Preparation for Administration (2.1)*].

Administration

- Percutaneous Test: Place one drop (approximately 0.05 mL) of allergen on the skin and pierce through drop superficially into the skin, lifting slightly. Use a skin test device, such as a sterile needle, lancet, or bifurcated needle.
- Percutaneous Test using self-loading devices: Refer to the manufacturer's product instructions.

Concurrently, use a positive histamine skin test control to identify patients whose recent use of drugs with antihistamine activity may result in a false negative skin test. Apply a 50% glycerin solution as a negative control, to identify false positive responses to the extracting fluid used in the manufacture of allergenic extracts, or due to dermatographism [see *Drug Interactions (7)*].

Interpreting Results

For interpretation of percutaneous skin tests, refer to the information provided in Allergy Diagnostic Testing: An Updated Practice Parameter.¹ In addition, follow the directions provided with the percutaneous skin test devices. Measure wheal responses for the histamine positive control test at 15 minutes and for the allergen tests at 15 to 20 minutes.

- The negative control (50% glycerin solution) response should measure < 3 mm wheal and \leq 10 mm flare.¹
- Response to positive controls should be at least 3 millimeters larger than the response to the negative control.
- If either the response to the histamine positive control or to the negative control do not meet the criteria above for acceptable wheal size, the results for the allergenic extracts tested at the same time should be considered invalid and be repeated.
- Fire Ant: Percutaneous testing is considered positive when the response occurs at a concentration of 1:100 w/v or less.⁴

2.2.2 Intradermal (Intracutaneous) Skin Test

Always perform percutaneous tests prior to intradermal skin tests.^{1, 2}

Dose

Perform intradermal tests with at least 100-fold less concentrated solutions than the stock concentrates used in percutaneous tests [see *Preparation and Administration (2.1)*].

Fire Ant: Use 0.02 mL of a 1:100,000 v/v dilution of the concentrate for intradermal tests. Very sensitive individuals such as those who have had nearly fatal anaphylactic reactions may not tolerate even 1:100,000 v/v dilution of concentrate as a starting point. These patients should be tested with a 1:10,000,000 v/v dilution of concentrate [see *Preparation for Administration (2.1)*].

Use intradermal tests following a negative or equivocal percutaneous test when the patient continues to report a history of symptoms following exposure to a specific allergen.

Administration

Intradermally inject 0.02 mL of the allergen using a 1 mL intradermal testing syringe with a 26 or 27 gauge, 1/2" or 3/8" needle with intradermal bevel, graduated in 0.01 units. Insert needle at a 30° angle, bevel down.

Test concurrently with a positive histamine control at intradermal strength (0.1 mg/mL of histamine base) and an aqueous buffer negative control (Sterile Albumin Saline with Phenol, Sterile Buffered Saline with Phenol).

Interpreting Results

For interpretation of intradermal skin tests, follow the information provided in Allergy Diagnostic Testing: An Updated Practice Parameter.¹

- Measure wheal responses for the histamine positive control test and allergen tests at 10-15 minutes after injection
- Response to the positive control should be at least 3 millimeters larger than the response to the negative control.
- The negative control (50% glycerin solution) response should measure < 3-mm wheal and \leq 10 mm flare (erythema).
- If either the response to the histamine positive control or to the negative control do not meet the criteria above for acceptable wheal size, the results for the allergenic extracts tested at the same time should be considered invalid and be repeated.
- Fire Ant: Intradermal testing is considered positive when the response occurs at a concentration of 1:1,000 w/v or less.⁴

2.3 Immunotherapy

For subcutaneous administration only.

Administration of Immunotherapy

Administer immunotherapy by subcutaneous injection in the lateral aspect of the arm or thigh. Avoid injection directly into any blood vessels. Administer injections with a sterile 1 mL allergy treatment syringe with a 26 or 27 gauge, 1/2", beveled needle, graduated in 0.01 units.

The optimal interval between doses of allergenic extract varies among individuals. Injections are usually given one or two times per week until the maintenance dose is reached, at which time the injection interval is increased to 2, 3, and finally 4 weeks.

Most adverse reactions occur within 30 minutes after injection. Therefore, observe patients for at least 30 minutes. For high risk patients, 30 minutes of observation may not be sufficient.²

Dosing of non-standardized allergenic extracts for allergen immunotherapy is highly individualized. Adjust dose according to the degree of sensitivity of the patient, tolerance to the extract administered during the early phases of an injection regimen, and the clinical response. Dosing is individualized by choice of an initial dose, the schedule of dose build-up, the target maintenance dose, the actual maintenance dose, and the duration of treatment.

The large volume of solution for immunotherapy may produce increased discomfort in the pediatric population. In order to achieve the total dose required, the volume of the dose may need to be divided into more than one injection per visit.²

2.3.1 Dose Build-up

Following the first administration of 0.03 mL of the selected initial dilution of allergenic extract, dosing is increased in 0.03 mL to 0.12 mL increments until 0.3 mL is reached, following which 0.03 mL is administered from the next most concentrated allergen extract or allergen mixture vial in the dilution series. The interval between doses is usually 3 to 7 days during dose build-up. Proceed in this manner until a maintenance dose is reached. The final maintenance dose may not be the target maintenance dose selected at the beginning of therapy.

The following adjustments may be necessary during dose build-up:

- If allergic symptoms or local reactions develop shortly after dose administration, decrease the dose volume to one-half or one-quarter of the maximum dose previously attained.

- If the patient is experiencing any seasonal allergy symptoms, decrease the dose volume to one-half or one-quarter of the maximum dose previously attained.
- Adjust the dose periodically based on the patient's tolerance and reaction.
- Decrease the dose if the previous injection resulted in a marked local reaction.
- Repeat the previous dose or reduce the dose at the next administration if local reactions persist for longer than 24 hours.
- Decrease the dose if the previous injection resulted in a systemic reaction. Any evidence of a systemic reaction is an indication for a significant (at least 75%) reduction in the subsequent dose or the cessation of immunotherapy.
- Repeated systemic reactions, however mild, are sufficient reason for the cessation of further attempts to increase the reaction-causing dose.

2.3.2 Maintenance Dose Selection, Adjustments, and Intervals

The maintenance dose is the dose that provides therapeutic efficacy without severe adverse local or systemic reactions. This dose may be limited by adverse reactions and may not be the original targeted maintenance dose. Select a maintenance dose based on the patient's clinical response and tolerance.

- Suggested maintenance dose is 0.3 mL of the undiluted allergen extract. Occasionally, higher doses are necessary to relieve symptoms.
- Maintenance doses larger than 0.3 mL of undiluted allergen extract may cause patient discomfort due to the 50% glycerin content.
- After the maintenance dose is achieved, increase the injection interval to 2 weeks, then 3 weeks, and finally 4 weeks, as tolerated. Administer the maintenance dose at a given interval three or four times before further increasing the interval to assure that no reactions occur. Protection may be lost rapidly if the interval between doses is more than 4 weeks.

The following adjustments to the maintenance dose may be necessary.

Withhold immunotherapy and/or reduce dosage, if any of the following conditions exist:

- Severe symptoms of rhinitis and/or asthma. Decrease dose to one-half or one-quarter of the maximum dose previously attained if the patient has any seasonal symptoms.
- Allergic symptoms or a local reaction following the prior dose.
- Infection accompanied by fever.
- Exposure to excessive amounts of clinically relevant allergen prior to a scheduled injection.

In situations prompting dose reduction, a cautious increase in dosage can be attempted once the reduced dose is tolerated.

Decrease the interval between doses if symptoms develop before the next injection is scheduled.

In some patients, the dosage may be increased and/or the dosing interval shortened based on individual responses and dosing requirements. If the onset of symptoms is soon after the initiation of immunotherapy, decrease the interval between each dose.

Changing to a different lot of extract: All extracts can lose allergenic activity over time and extracts vary in allergenic activity. Two different lots of extract could differ substantially in allergenic activity, even if they are the same formula and concentration. The volume of the first dose from the new vial should not exceed 50% of the previous dose. Do not use extracts beyond their expiry date.

Changing to a different formulation of extract or to an extract from a different manufacturer: Decrease the starting dose of the new extract when the extract is the same formula and dilution as the one previously used. In general, a volume dose reduction to 50% of the previous product dose is adequate, but each situation must be evaluated separately considering the patient's history of sensitivity, tolerance of previous injections, and other factors. If the patient tolerates the 50% decrease, then raise the next dose to the previous tolerated dose amount. To re-establish the maintenance dose the starting interval between doses should not be greater than one week.

Prolonged period has elapsed since the last injection: Patients may lose tolerance for allergen injections during prolonged intervals (> 4 weeks) between doses. The duration of tolerance is an individual characteristic and varies from patient to patient. In general, the longer the lapse in the injection schedule, the greater dose reduction required.

Changes made in the extract concentrate formula: Changes other than those listed above such as a difference in extracting fluid (e.g., change from non-glycerin extracts to 50% glycerin extracts), combining two or more stock concentrates, or any other change can affect a patient's tolerance of the treatment. Extra dilutions are recommended whenever starting a revised formula. The greater the change, the greater the number of dilutions required.

Duration of Treatment

The duration of treatment for immunotherapy has not been established. A period of two to three years of injection therapy constitutes an average minimum course of treatment. Evaluate patients for treatment response at least every 6 to 12 months while they receive immunotherapy.

3 DOSAGE FORMS AND STRENGTHS

Non-standardized allergenic extracts are solutions: stock concentrates, labeled in weight/volume, in a glycerin-preserved extracting fluid, supplied in 5, 10, 30, and 50 mL vials. (3, 16) Refer to the vial label for the product concentration. (11)

4 CONTRAINDICATIONS

Non-standardized allergenic extracts are contraindicated in individuals with the following conditions:

- Severe, unstable or uncontrolled asthma.
- History of any severe systemic reaction to the allergen extract when administered for diagnosis or treatment.
- Medical conditions that reduce the ability to survive anaphylaxis.

5 WARNINGS AND PRECAUTIONS

5.1 Anaphylaxis

Anaphylaxis, which may lead to death, can occur in individuals following the administration of non-standardized allergenic extracts, particularly in the following situations:

- Extreme sensitivity to the non-standardized allergenic extract.
- Concomitant environmental exposure to allergens.
- Receipt of high doses of the non-standardized allergenic extract.
- Receipt of an accelerated build-up schedule ("rush" immunotherapy).

- Change from one lot of a particular non-standardized allergenic extract to another lot of the same non-standardized allergenic extract.

Administer non-standardized allergenic extracts in a healthcare setting under the supervision of a physician prepared to manage anaphylaxis; management may include use of inhaled bronchodilators and use of epinephrine. Non-standardized allergenic extracts may not be suitable for individuals who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers. See prescribing information for epinephrine for complete information, particularly on medications that blunt or potentiate epinephrine activity. Individuals should remain in the physician's office for a minimum of 30 minutes after receiving an injection of non-standardized allergenic extracts, so that any adverse reaction can be observed and properly handled.

5.2 Cross-reactions and Dose Sensitivity

When determining the final dose of an allergen mixture for immunotherapy, consider cross-reactivity among component extracts.

Determine the initial dilution of allergenic extract, starting dose, and progression of dosage based on the patient's history and results of skin tests [see *Dosage and Administration (2)*]. Strongly positive skin tests can be indicators for potential adverse reactions.

6 ADVERSE REACTIONS

Common adverse reactions reported for non-standardized allergenic extracts are:

- Local reactions occurring in 26 to 82% of all patients who receive subcutaneous immunotherapy, at the injection site (e.g., erythema, swelling, pruritus, tenderness and pain).²
- Systemic adverse reactions, occurring in $\leq 7\%$ of patients who receive subcutaneous immunotherapy (e.g., generalized skin erythema, urticaria, pruritus, angioedema, rhinitis, wheezing, laryngeal edema, hypotension, and shock).³ Systemic reactions may be fatal.²

No clinical trials of non-standardized allergenic extracts have been conducted.

Published studies of non-standardized allergenic extracts report systemic reactions occurring in fewer than 1% in patients receiving conventional immunotherapy and greater than 36% in patients receiving rush immunotherapy. Most systemic reactions occurred within 30 minutes of injection. However, systemic reactions have been reported to occur up to 2 hours after the final injection with rush schedules. Some reactions have occurred up to 6 hours after skin tests or immunotherapy.^{2, 3}

7 DRUG INTERACTIONS

7.1 Antihistamines

Do not perform skin testing with non-standardized allergenic extracts within 3 to 10 days of first-generation H1-histamine receptor blockers (e.g., clemastine, diphenhydramine) and second-generation antihistamines (e.g., loratadine, fexofenadine) being used. These products suppress histamine skin test reactions and could mask a positive response.^{1, 2}

7.2 Topical Corticosteroids and Topical Anesthetics

Topical corticosteroids may suppress skin reactivity; therefore, discontinue use at the

skin test site for at least 2 to 3 weeks before skin testing. Avoid use of topical local anesthetics at skin test sites because they can suppress flare responses.^{1, 2}

7.3 Tricyclic Antidepressants

Tricyclic antidepressants, such as doxepin, can have potent antihistamine effects and may alter skin test results. Allow 7 to 14 days after discontinuation of tricyclic medication prior to skin testing.^{1, 2}

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively. There are no human or animal data to establish the presence or absence of non-standardized allergenic extracts-associated risks during pregnancy.

8.2 Lactation

Risk Summary

It is not known whether non-standardized allergenic extracts are present in human milk. Data are not available to assess the effects of these extracts on the breastfed child or on milk production/excretion. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for non-standardized allergenic extracts and any potential adverse effects on the breastfed child from the extracts or from the underlying maternal condition.

8.4 Pediatric Use

For use of these products in children younger than 5 years of age, consideration should be given to the patient's ability to comply and cooperate with receipt of the product and the potential for difficulty in communicating with the child regarding systemic reactions.²

The volume of a dose for immunotherapy may need to be divided for pediatric patients [see *Dosage and Administration* (2.3)]

8.5 Geriatric Use

Data are not available to determine if subjects 65 years of age and older respond differently to allergen immunotherapy than younger subjects.

11 DESCRIPTION

Non-standardized allergenic extracts are labeled "No U.S. Standard of Potency".

Non-standardized allergenic extracts are supplied in a Glycero Cocos extraction solution, which consists of 0.5% sodium chloride for isotonicity, 0.275% sodium bicarbonate as a buffer, and 50% glycerin (volume/volume) as preservative.

Non-standardized allergenic extracts are supplied as a weight to volume (w/v) solution of allergen in extraction solution. Product concentrations vary based on the source. Refer to the vial label for the product concentration.

Source material mold mycelia and *Candida albicans* cells are cultivated on liquid medium which may contain one or more of the following constituents: casein hydrolysate; malt

extract; yeast extract; maltose; dextrose; ammonium nitrate, calcium carbonate, calcium chloride, ammonium citrate, potassium phosphate, sodium citrate, citric acid; magnesium sulfate; or trace elements. Acetone and ether may be used as drying and de-fatting agents. *Candida albicans* cells are treated with phenol, which is removed by dialysis.

Dog Hair and Dander extracts are manufactured in 3 product forms:

- Dog Hair and Dander (Regular Process) is derived from extraction of the source material without additional processing, and is prepared at 1:10 w/v in Glycero-Cocas.
- Acetone Precipitated (AP) Dog Hair and Dander is derived from the acetone precipitated aqueous extract and is prepared at 1:100 w/v in Glycero-Cocas.
- Ultrafiltered (UF) Dog Hair and Dander is derived from the UF aqueous extract and is prepared at 1:650 w/v in Glycero-Cocas.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The skin test reaction results from interaction of the introduced allergen and allergen-specific IgE antibodies bound to mast cells, leading to mast cell degranulation and release of histamine, tryptase and other mediators, which results in the formation of the wheal and flare.

The precise mechanisms of action of allergen immunotherapy are not known. Immunologic responses to immunotherapy include changes in allergen-specific IgE levels, allergen-specific IgG levels, and regulatory T cell responses.²

14 CLINICAL STUDIES

Specific immunotherapy with allergenic extracts is helpful in reducing symptoms associated with exposure to the offending allergens. A summary of effectiveness by the Panel on Review of Allergenic Extracts, an advisory committee to the U.S. Food and Drug Administration, has been published.⁵

15 REFERENCES

1. Bernstein IL, Li JT, Bernstein DI, et al. Allergy diagnostic testing: and updated practice parameter. *Ann Allergy Asthma Immunol.* 2008 Mar;100:S1-148.
2. Cox L, Nelson H, Lockey R, Calabria C, Chacko T, Finegold I, et al. Allergen immunotherapy: A practice parameter third update. *J Allergy Clin Immunol.* 2011 Jan;127:S1-55.
3. Greineder DK. Risk management in allergen immunotherapy. *J Allergy Clin Immunol.* 1996 Dec;98(6 Pt 3):S330-4
4. Golden D B K, Demain J, Freeman T, Graft D, et al. Stinging insect hypersensitivity: A practice parameter update 2016. *Ann Allergy Asthma Immunol* 118 (2017) 28-54.
5. Federal Register Proposed Rule: Biological Products: Implementation of Efficacy Review, Allergenic Extracts, *Federal Register* 1985;50:3082-3288.

16 HOW SUPPLIED

Non-standardized allergenic extracts and mixes are supplied as 50% glycerin stock concentrates labeled in weight/volume and provided in 10 milliliter, 30 milliliter and 50 milliliter vials for use in percutaneous skin testing and subcutaneous

immunotherapy. These extracts may also be supplied in 5 milliliter dropper vials for percutaneous testing only.

These products are supplied as listed in Table 2.

| TABLE 2: AVAILABLE PRODUCTS |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| POLLEN - GRASS ALLERGENS |
| Bahia Grass, <i>Paspalum notatum</i> |
| Brome, Smooth <i>Bromus inermis</i> |
| Corn, Cultivated <i>Zea mays</i> |
| Grass Mix 8-100,000 BAU/mL each of <i>P. pratensis</i> ; <i>A. gigantean</i> ; <i>P. pretense</i> ; 10,000 BAU/mL of <i>C. dactylon</i> ; 1:20w/v of <i>S. halepense</i> |
| Johnson Grass, <i>Sorghum halepense</i> |
| Oats, Common Cultivated, <i>Avena sativa</i> |
| POLLEN - TREE ALLERGENS |
| Acacia, Golden, <i>Acacia longifolia</i> |
| Alder, Red, <i>Alnus rubra</i> |
| Ash, White, <i>Fraxinus americana</i> |
| Beech, American, <i>Fagus grandifolia</i> |
| Birch Mix (PRW)- <i>B. papyrifera</i> , <i>B. pendula</i> , <i>B. nigra</i> |
| Bottlebrush, <i>Melaleuca citrina</i> |
| Boxelder/Maple Mix (BHR)- <i>A. negundo</i> , <i>A. saccharum</i> , <i>A. rubrum</i> |
| Cedar, Mountain, <i>Juniperus ashei</i> |
| Cedar, Red, <i>Juniperus virginiana</i> |
| Cottonwood, Common, <i>Populus deltoides</i> |
| Cyprus, Arizona, <i>Cupressus arizonica</i> |
| Cyprus, Bald, <i>Taxodium distichum</i> |
| Elm, American, <i>Ulmus americana</i> |
| Elm, Chinese, <i>Ulmus parvifolia</i> |
| Gum, Sweet, <i>Liquidambar styraciflua</i> |
| Hackberry, <i>Celtis occidentalis</i> |
| Hickory, Shagbark, <i>Carya ovata</i> |
| Maple, Hard/Sugar, <i>Acer saccharum</i> |
| Melaleuca, <i>Melaleuca quinquenervia</i> |
| Mesquite, <i>Prosopis glandulosa</i> |
| Mulberry Mix (RW)- <i>M. rubra</i> , <i>M. alba</i> |
| Oak Mix (RVW)- <i>Q. rubra</i> , <i>Q. virginiana</i> , <i>Q. alba</i> |
| Oak, Red, <i>Quercus Rubra</i> |
| Olive Tree, <i>Olea europaea</i> |
| Palm, Queen, <i>Syagrus romanzoffiana</i> |
| Pecan Tree, <i>Carya illinoensis</i> |
| Pine Mix (LY)- <i>P. contorta</i> , <i>P. ponderosa</i> |
| Privet, Common, <i>Ligustrum vilgare</i> |
| Russian Olive, <i>Elaeagnus angustifolia</i> |
| Sycamore, American, <i>Platanus occidentalis</i> |
| Tree Mix 5-20% each of <i>F. Americana</i> ; <i>J. nigra</i> ; <i>P. deltoides</i> ; <i>U. Americana</i> ; 6.7% each of <i>B. papyrifera</i> ; <i>B. nigra</i> ; <i>B. pendula</i> |
| Tree Mix 6- Tree Mix 6-20% each of <i>F. Americana</i> ; <i>J. nigra</i> ; <i>P. deltoides</i> ; <i>U. Americana</i> ; 6.7% each of <i>B. papyrifera</i> ; <i>B. nigra</i> ; <i>B. pendula</i> |
| Tree Mix 11-10% each of <i>F. americana</i> ; <i>B. nigra</i> ; <i>J. nigra</i> ; <i>P. deltoides</i> ; <i>U. americana</i> ; <i>C. ovata</i> ; <i>A. saccharum</i> ; <i>Q. rubra</i> ; <i>P. occidentalis</i> ; <i>S. nigra</i> |
| Walnut, Black, <i>Juglans nigra</i> |
| Willow, Black, <i>Salix nigra</i> |
| POLLEN - WEED AND GARDEN PLANT ALLERGENS |

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Careless Weed, <i>Amaranthus palmeri</i> |
| Careless/Pigweed Mix (CR)- <i>A. palmeri</i> , <i>A. retroflexus</i> |
| Cocklebur, Common, <i>Xanthium strumarium</i> |
| Dock/Sorrel Mix (DS)- <i>R. crispus</i> , <i>R. acetosella</i> |
| Dog Fennel, Eastern, <i>Eupatorium capillifolium</i> |
| Goldenrod, <i>Solidago canadensis</i> |
| Kochia, <i>Kochia scoparia</i> |
| Lamb's Quarters, <i>Chenopodium album</i> |
| Marshelder/Poverty Mix (BPT)- <i>C. xanthifolia</i> , <i>I. annua</i> , <i>I. axillaris</i> |
| Nettle, <i>Urtica dioica</i> |
| Pigweed, Rough Redroot, <i>Amaranthus retroflexus</i> |
| Plantain, English, <i>Plantago lanceolata</i> |
| Ragweed, Giant, <i>Ambrosia trifida</i> |
| Ragweed Mix (GSW)- <i>A. trifida</i> , <i>A. artemisiifolia</i> , <i>A. psilostachya</i> |
| Ragweed, Western, <i>Ambrosia psilostachya</i> |
| Russian Thistle, <i>Salicaria kali</i> |
| Sagebrush, Mugwort, <i>Artemisia vulgaris</i> |
| Scale, Wing, <i>Atriplex canescens</i> |
| Sorrel, Sheep, <i>Rumex acetosella</i> |
| Weed Mix 2630-25% each of <i>X. strumarium</i> ; <i>C. album</i> ; <i>A. retroflexus</i> ; 12.5% each of <i>R. crispus</i> ; <i>R. acetosella</i> |
| MOLDS |
| Alternaria/Hormodendrum Mix- <i>A. tenuis</i> , <i>H. cladosporioides</i> |
| <i>Alternaria tenuis</i> (<i>Alternaria alternata</i>) |
| <i>Aspergillus fumigatus</i> |
| <i>Aspergillus niger</i> var. <i>niger</i> |
| <i>Botrytis cinerea</i> |
| <i>Candida albicans</i> |
| <i>Cephalosporium acremonium</i> (<i>Sarocladium strictum</i>) |
| <i>Curvularia spicifera</i> (<i>Cochliobolus spicifer</i>) |
| <i>Epicoccum nigrum</i> |
| <i>Epidermophyton floccosum</i> |
| <i>Fusarium vasinfectum</i> (<i>Fusarium oxysporum vasinfectum</i>) |
| <i>Helminthosporium interseminatum</i> (<i>Dendryphiella vinosa</i>) |
| <i>Hormodendrum cladosporioides</i> (<i>Cladosporium cladosporioides</i>) |
| Mold Mix 4-25% each of <i>A. alternata</i> ; <i>C. cladosporioides</i> ; 6.2% each of <i>A. fumigatus</i> ; <i>A. nidulans</i> ; <i>A. niger</i> var. <i>niger</i> ; <i>A. terreus</i> ; <i>P. digitatum</i> ; <i>P. expansum</i> ; <i>P. chrysogenum</i> var. <i>chrysogenum</i> ; <i>C. rosea</i> f. <i>rosea</i> |
| Mold Mix 10-2.5% each of <i>A. fumigatus</i> ; <i>A. nidulans</i> ; <i>A. niger</i> var. <i>niger</i> ; <i>A. terreus</i> ; <i>P. digitatum</i> ; <i>P. expansum</i> ; <i>P. chrysogenum</i> var. <i>chrysogenum</i> ; <i>C. rosea</i> f. <i>rosea</i> ; 10% each of <i>A. alternata</i> ; <i>F. oxysporum vasinfectum</i> ; <i>D. vinosa</i> ; <i>C. cladosporioides</i> ; <i>M. racemosus</i> ; <i>P. exigua</i> var. <i>exigua</i> ; <i>A. pullulans</i> var. <i>pullulans</i> ; <i>R. stolonifer</i> |
| <i>Mucor racemosus</i> |
| Penicillium Mix- <i>P. expansum</i> , <i>P. digitatum</i> , <i>P. chrysogenum</i> , <i>C. rosea</i> |
| <i>Penicillium notatum</i> (<i>Penicillium chrysogenum</i> var. <i>chrysogenum</i>) |
| <i>Phoma herbarum</i> (<i>Phoma exigua</i> var. <i>exigua</i>) |
| <i>Pullularia pullulans</i> (<i>Aerobasidium pullulans</i> var. <i>pullulans</i>) |
| <i>Rhizopus nigricans</i> (<i>Rhizopus stolonifer</i>) |
| <i>Stemphylium botryosum</i> (<i>Pleospora tarda</i>) |
| Trichophyton Mix- <i>T. tonsurans</i> , <i>T. rubrum</i> , <i>T. mentagrophytes</i> |
| EPIDERMALS |
| AP Horse Hair and Dander, <i>Equus caballus</i> |
| AP Cattle Hair and Dander, <i>Bos taurus</i> |
| AP Dog Hair and Dander, <i>Canis lupus familiaris</i> |

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|--------------------------------------------------------------------------|
| Dog Hair and Dander, <i>Canislupusfamiliaris</i> |
| UF Dog Hair and Dander, <i>Canislupusfamiliaris</i> |
| Feather Mix-G. <i>gallus</i> , <i>A. platyrhynchos</i> , <i>A. anser</i> |
| Guinea Pig Hair and Dander, <i>Caviaporcellus</i> |
| INSECTS |
| Cockroach, American, <i>Periplanetaamericana</i> |
| Cockroach, German, <i>Blatellagermanica</i> |
| Cockroach Mix- <i>P. americana</i> , <i>B. germanica</i> |
| Fire Ant, <i>Solenopsisinvicta</i> |

16.2 Storage and Handling

Store extracts at 2°C to 8°C (36°F to 46°F).

17 PATIENT COUNSELING INFORMATION

Instruct patients to remain in the office under observation for a minimum of 30 minutes after an injection or longer, if deemed necessary for the individual.

Inform patients that reactions may occur more than 30 minutes after skin testing or an injection.

Instruct patient to recognize the following symptoms as systemic adverse reactions and seek emergency medical care right away if any of these symptoms occur:

- Unusual swelling and/or tenderness at the injection site.
- Hives or itching of the skin.
- Swelling of face and/or mouth.
- Sneezing, coughing, or wheezing.
- Shortness of breath.
- Nausea.
- Dizziness or faintness.

Manufacturer:

Jubilant HollisterStier LLC

Spokane, WA 99207 U.S.A.

U.S. Lic. No. 1272

Version Date: February 24, 2022

PRINCIPAL DISPLAY PANEL

ALLERGENIC EXTRACT

Preservative:
50% Glycerin v/v

Inactive Ingredients:
0.5% Sodium chloride
0.275% Sodium
bicarbonate

**UF DOG
HAIR-DANDER
(ULTRAFILTERED)**
Canis lupus familiaris
hair & dander



(01)00000000000000
(17)190702
(10)S1234567
(21)00000000000001

1:650 w/v

Item: XXXXXX
Lot: S1234567
Exp: 2019Jul02

No U.S. standard of potency
Dose/Route: See Package Insert

NDC: 65044-4850-2
U.S. License No. 1272

10 mL Item: XXXXXX

Store at 2-8°C
Rx Only - Sterile

5000000XXXX - H01

Non-Returnable

5000000XXXX - H01

UF Dog Hair-Dander, 10 mL 1.650wv Carton Label

ALLERGENIC EXTRACT

**UF DOG HAIR-DANDER
(ULTRAFILTERED)**
Canis lupus familiaris hair & dander

10 mL **1:650 w/v**
Dose/Route: See Package Insert

Rx Only - Sterile
Store at 2-8°C

Preservative 50% Glycerin v/v
U.S. License No. 1272

Item: XXXXXX
Lot: S1234567
Exp: 2019Jul01

Jubilant HollisterStier LLC Spokane, WA 99207

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UF Dog Hair-Dander, 10 mL 1.650wv Vial Label

ANIMAL ALLERGENS, AP CATTLE HAIR AND DANDER

cattle hair and dander injection, solution

| Product Information | | | | |
|----------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-4811 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| BOS TAURUS HAIR (UNII: TOQ97Z8644) (BOS TAURUS HAIR - UNII:TOQ97Z8644) | | BOS TAURUS HAIR | 0.01 g in 1 mL | |
| BOS TAURUS DANDER (UNII: C8VYS72608) (BOS TAURUS DANDER - UNII:C8VYS72608) | | BOS TAURUS DANDER | 0.01 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-4811-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-4811-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-4811-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 01/30/1978 | | |

| ANIMAL ALLERGENS, AP DOG HAIR AND DANDER CANIS SPP | | | |
|----------------------------------------------------------------------------------------------------|-----------------------------|-------------------------------|--------------------|
| animal allergens, dog dander canis spp injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-4824 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| CANIS LUPUS FAMILIARIS HAIR (UNII: 05S7L91ZTR) (CANIS LUPUS FAMILIARIS HAIR - UNII:05S7L91ZTR) | | CANIS LUPUS FAMILIARIS HAIR | 0.005 g in 1 mL |
| CANIS LUPUS FAMILIARIS DANDER (UNII: 11JCK302I4) (CANIS LUPUS FAMILIARIS DANDER - UNII:11JCK302I4) | | CANIS LUPUS FAMILIARIS DANDER | 0.005 g in 1 mL |

| Inactive Ingredients | | | | |
|---------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-4824-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-4824-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-4824-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | | 08/24/1976 | |

| ANIMAL ALLERGENS, DOG HAIR AND DANDER CANIS SPP. | | | | |
|----------------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|-------------------------------|--------------------|
| dog hair canis spp. injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | | Item Code (Source) | NDC:65044-4083 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | | Basis of Strength | Strength |
| CANIS LUPUS FAMILIARIS HAIR (UNII: 05S7L91ZTR) (CANIS LUPUS FAMILIARIS HAIR - UNII:05S7L91ZTR) | | | CANIS LUPUS FAMILIARIS HAIR | 0.05 g in 1 mL |
| CANIS LUPUS FAMILIARIS DANDER (UNII: 11JCK302I4) (CANIS LUPUS FAMILIARIS DANDER - UNII:11JCK302I4) | | | CANIS LUPUS FAMILIARIS DANDER | 0.05 g in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-4083-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-4083-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| | NDC:65044- | 50 mL in 1 VIAL; Type 0: Not a Combination | | |

| | | | | |
|------------------------------|-------------------------------------------------|----------------------------------------------------|---------------------------|--|
| 3 | NDC:65044-4083-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

ANIMAL ALLERGENS, DOG HAIR AND DANDER CANIS SPP.

dog hair canis spp. injection, solution

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-4085 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| | | | |
|----------------------------------------|----------------------------------------------------------------------------------------------------|-------------------------------|-----------------|
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | CANIS LUPUS FAMILIARIS HAIR (UNII: 05S7L91ZTR) (CANIS LUPUS FAMILIARIS HAIR - UNII:05S7L91ZTR) | CANIS LUPUS FAMILIARIS HAIR | 0.05 g in 1 mL |
| | CANIS LUPUS FAMILIARIS DANDER (UNII: 11JCK302I4) (CANIS LUPUS FAMILIARIS DANDER - UNII:11JCK302I4) | CANIS LUPUS FAMILIARIS DANDER | 0.05 g in 1 mL |

| | |
|---------------------------------------|-----------------|
| Inactive Ingredients | |
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

| | | | | |
|------------------|------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-4085-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-4085-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-4085-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| | | | |
|------------------------------|-------------------------------------------------|-----------------------------|---------------------------|
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

ANIMAL ALLERGENS, AP HORSE HAIR AND DANDER

ap horse hair and dander injection, solution

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|----------------------------|
| Product Information |
|----------------------------|

| | | | | |
|------------------------------------------------------------------------------------|-------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-4855 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| EQUUS CABALLUS HAIR (UNII: 4F35XG0149) (EQUUS CABALLUS HAIR - UNII:4F35XG0149) | | EQUUS CABALLUS HAIR | 0.01 g in 1 mL | |
| EQUUS CABALLUS DANDER (UNII: J81SZ18495) (EQUUS CABALLUS DANDER - UNII:J81SZ18495) | | EQUUS CABALLUS DANDER | 0.01 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-4855-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-4855-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-4855-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 01/30/1978 | | |

ANIMAL ALLERGENS, FEATHER MIX

feather mix injection, solution

| | | | | |
|----------------------------------------------------------------------------------------------|-----------------------------|----------------------------|-----------------|--|
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-4349 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| GALLUS GALLUS FEATHER (UNII: 1FCM16V0FV) (GALLUS GALLUS FEATHER - UNII:1FCM16V0FV) | | GALLUS GALLUS FEATHER | 0.1 g in 1 mL | |
| ANAS PLATYRHYNCHOS FEATHER (UNII: 83B65P4796) (ANAS PLATYRHYNCHOS FEATHER - UNII:83B65P4796) | | ANAS PLATYRHYNCHOS FEATHER | 0.1 g in 1 mL | |
| ANSER ANSER FEATHER (UNII: 15XI414745) (ANSER ANSER FEATHER - UNII:15XI414745) | | ANSER ANSER FEATHER | 0.1 g in 1 mL | |

| Inactive Ingredients | | | | |
|---------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-4349-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-4349-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-4349-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

ANIMAL ALLERGENS, FEATHER MIX

feather mix injection, solution

| Product Information | | | | |
|----------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-4352 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| GALLUS GALLUS FEATHER (UNII: 1FCM16V0FV) (GALLUS GALLUS FEATHER - UNII:1FCM16V0FV) | | GALLUS GALLUS FEATHER | 0.1 g in 1 mL | |
| ANAS PLATYRHYNCHOS FEATHER (UNII: 83B65P4796) (ANAS PLATYRHYNCHOS FEATHER - UNII:83B65P4796) | | ANAS PLATYRHYNCHOS FEATHER | 0.1 g in 1 mL | |
| ANSER ANSER FEATHER (UNII: 15XI414745) (ANSER ANSER FEATHER - UNII:15XI414745) | | ANSER ANSER FEATHER | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-4352-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| | | | | |
|---|------------------|----------------------------------------------------|--|--|
| 2 | NDC:65044-4352-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-4352-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

ANIMAL ALLERGENS, GUINEA PIG HAIR AND DANDER

guinea pig hair and dander injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-4401 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | |
|--------------------------------------------------------------------------------------|------------------------|----------------|
| Ingredient Name | Basis of Strength | Strength |
| CAVIA PORCELLUS HAIR (UNII: KBA5Y6X57N) (CAVIA PORCELLUS HAIR - UNII:KBA5Y6X57N) | CAVIA PORCELLUS HAIR | 0.05 g in 1 mL |
| CAVIA PORCELLUS DANDER (UNII: 84Q71TU5SU) (CAVIA PORCELLUS DANDER - UNII:84Q71TU5SU) | CAVIA PORCELLUS DANDER | 0.05 g in 1 mL |

| Inactive Ingredients | |
|---------------------------------------|----------|
| Ingredient Name | Strength |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-4401-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

FOOD - ANIMAL PRODUCTS AND POULTRY PRODUCTS, BEEF BOVINE SPP.

beef bovine spp. injection, solution

| Product Information | | | | |
|--------------------------------------------------|-------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Product Type | | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3077 |
| Route of Administration | | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | | Basis of Strength | Strength |
| BEEF (UNII: 4PIB2155QP) (BEEF - UNII:4PIB2155QP) | | | BEEF | 0.1 g in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3077-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | | 04/19/1941 | |

| FOOD - ANIMAL PRODUCTS AND POULTRY PRODUCTS, CHICKEN MEAT GALLUS SP. | | | | |
|----------------------------------------------------------------------------------|--|-----------------------------|---------------------------|-----------------|
| chicken meat gallus sp. injection, solution | | | | |
| Product Information | | | | |
| Product Type | | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3173 |
| Route of Administration | | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | | Basis of Strength | Strength |
| POULTRY, UNSPECIFIED (UNII: L7WXO2P5HM) (POULTRY, UNSPECIFIED - UNII:L7WXO2P5HM) | | | POULTRY, UNSPECIFIED | 0.1 g in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3173-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

| POLLENS - TREES, OLIVE OLEA EUROPAEA | | | | |
|-----------------------------------------|----------------------------------------------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| olive olea europaea injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2053 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | OLEA EUROPAEA POLLEN (UNII: 43R41XZ627) (OLEA EUROPAEA POLLEN - UNII:43R41XZ627) | OLEA EUROPAEA POLLEN | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | PHENOL (UNII: 339NCG44TV) | | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2053-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2053-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2053-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - TREES, PALM, QUEEN COCOS PLUMOSA

palm, queen cocos plumosa injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2074 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------------------|------------------------------|-------------------|
| SYAGRUS ROMANZOFFIANA POLLEN (UNII: 84ZOM591BB) (SYAGRUS ROMANZOFFIANA POLLEN - UNII:84ZOM591BB) | SYAGRUS ROMANZOFFIANA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2074-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2074-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2074-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, PALO VERDE CERCIDIUM FLORIDUM

palo verde cercidium floridum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2018 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------------------------------------------------------------------------------------|----------------------------|-------------------|
| PARKINSONIA FLORIDA POLLEN (UNII: 57586C96ZL) (PARKINSONIA FLORIDA POLLEN - UNII:57586C96ZL) | PARKINSONIA FLORIDA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | | Strength | | |
|---------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2018-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2018-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2018-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - TREES, PECAN CARYA CARYA ILLINOENSIS

pecan carya carya illinoensis injection, solution

| Product Information | | | | |
|----------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2098 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| CARYA ILLINOINENSIS POLLEN (UNII: PYO4JR720Y) (CARYA ILLINOINENSIS POLLEN - UNII:PYO4JR720Y) | CARYA ILLINOINENSIS POLLEN | 0.05 g in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2098-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2098-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2098-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, PECAN CARYA CARYA ILLINOENSIS

pecan carya carya illinoensis injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2101 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------------------------------------------------------------------------|----------------------------|------------------|
| CARYA ILLINOINENSIS POLLEN (UNII: PYO4JR720Y) (CARYA ILLINOINENSIS POLLEN - UNII:PYO4JR720Y) | CARYA ILLINOINENSIS POLLEN | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2101-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2101-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2101-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, PEPPER TREE, CALIFORNIA SCHINUS MOLLE

pepper tree, califomia schinus molle injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2107 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | | |
|----------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | | Basis of Strength | Strength |
| SCHINUS MOLLE POLLEN (UNII: M0G28FH9K1) (SCHINUS MOLLE POLLEN - UNII:M0G28FH9K1) | | | SCHINUS MOLLE POLLEN | 0.05 g in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2107-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2107-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2107-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - TREES, PINE MIX

pine mix injection, solution

| Product Information | | | |
|--------------------------------------------------------------------------------------|-----------------------------|------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2203 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| PINUS CONTORTA POLLEN (UNII: FB7IP650ET) (PINUS CONTORTA POLLEN - UNII:FB7IP650ET) | | PINUS CONTORTA POLLEN | 0.05 g in 1 mL |
| PINUS PONDEROSA POLLEN (UNII: 042SUA2DS9) (PINUS PONDEROSA POLLEN - UNII:042SUA2DS9) | | PINUS PONDEROSA POLLEN | 0.05 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2203-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2203-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2203-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, PRIVET LIGUSTRUM VULGARE

privet ligustrum vulgare injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2251 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | |
|------------------------------------------------------------------------------------------|--------------------------|----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| LIGUSTRUM VULGARE POLLEN (UNII: Y3FRX92Z0E) (LIGUSTRUM VULGARE POLLEN - UNII:Y3FRX92Z0E) | LIGUSTRUM VULGARE POLLEN | 0.05 g in 1 mL | |

| Inactive Ingredients | |
|---------------------------------------|----------|
| Ingredient Name | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2251-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2251-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2251-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, RUSSIAN OLIVE ELAEAGNUS ANGUSTIFOLIA

russian olive elaeagnus angustifolia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2359 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------------------------------------------------------------------------------------------|----------------------------------|-------------------|
| ELAEAGNUS ANGUSTIFOLIA POLLEN (UNII: 68P4F4M6VD) (ELAEAGNUS ANGUSTIFOLIA POLLEN - UNII:68P4F4M6VD) | ELAEAGNUS ANGUSTIFOLIA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2359-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2359-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2359-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, SYCAMORE, AMERICAN EASTERN PLATANUS OCCIDENTALLIS

sycamore, american eastern platanus occidentallis injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2563 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------------------|---------------------------------|-------------------|
| PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK) | PLATANUS OCCIDENTALIS POLLEN | 0.05 g in 1 mL |

| Inactive Ingredients | | | | |
|---------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2563-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2563-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2563-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| POLLENS - TREES, TREE MIX 11 | | | | |
|--------------------------------------------------------------------------------------------------|-----------------------------|------------------------------|----------------|--|
| tree mix 11 injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2619 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q) | | FRAXINUS AMERICANA POLLEN | 0.05 g in 1 mL | |
| BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P) | | BETULA NIGRA POLLEN | 0.05 g in 1 mL | |
| JUGLANS NIGRA POLLEN (UNII: 1BV28146ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28146ZR) | | JUGLANS NIGRA POLLEN | 0.05 g in 1 mL | |
| POPULUS DELTOIDES POLLEN (UNII: 476DVV63WP) (POPULUS DELTOIDES POLLEN - UNII:476DVV63WP) | | POPULUS DELTOIDES POLLEN | 0.05 g in 1 mL | |
| ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | | ULMUS AMERICANA POLLEN | 0.05 g in 1 mL | |
| CARYA OVATA POLLEN (UNII: 54UN9R2798) (CARYA OVATA POLLEN - UNII:54UN9R2798) | | CARYA OVATA POLLEN | 0.05 g in 1 mL | |
| ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861) | | ACER SACCHARUM POLLEN | 0.05 g in 1 mL | |
| QUERCUS RUBRA POLLEN (UNII: SVW19ET93C) (QUERCUS RUBRA POLLEN - UNII:SVW19ET93C) | | QUERCUS RUBRA POLLEN | 0.05 g in 1 mL | |
| PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK) | | PLATANUS OCCIDENTALIS POLLEN | 0.05 g in 1 mL | |
| SALIX NIGRA POLLEN (UNII: 6M2JIH93ZN) (SALIX NIGRA POLLEN - UNII:6M2JIH93ZN) | | SALIX NIGRA POLLEN | 0.05 g in 1 mL | |

| Inactive Ingredients | | | | |
|---------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2619-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2619-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2619-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | | 04/19/1941 | |

| POLLENS - TREES, TREE MIX 11 | | | |
|--------------------------------------------------------------------------------------------------|-----------------------------|------------------------------|----------------|
| tree mix 11 injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2622 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q) | | FRAXINUS AMERICANA POLLEN | 0.1 g in 1 mL |
| BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P) | | BETULA NIGRA POLLEN | 0.1 g in 1 mL |
| JUGLANS NIGRA POLLEN (UNII: 1BV28146ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28146ZR) | | JUGLANS NIGRA POLLEN | 0.1 g in 1 mL |
| POPULUS DELTOIDES POLLEN (UNII: 476DVV63WP) (POPULUS DELTOIDES POLLEN - UNII:476DVV63WP) | | POPULUS DELTOIDES POLLEN | 0.1 g in 1 mL |
| ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | | ULMUS AMERICANA POLLEN | 0.1 g in 1 mL |
| CARYA OVATA POLLEN (UNII: 54UN9R2798) (CARYA OVATA POLLEN - UNII:54UN9R2798) | | CARYA OVATA POLLEN | 0.1 g in 1 mL |
| ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861) | | ACER SACCHARUM POLLEN | 0.1 g in 1 mL |
| QUERCUS RUBRA POLLEN (UNII: SVW19ET93C) (QUERCUS RUBRA POLLEN - UNII:SVW19ET93C) | | QUERCUS RUBRA POLLEN | 0.1 g in 1 mL |
| PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK) | | PLATANUS OCCIDENTALIS POLLEN | 0.1 g in 1 mL |
| SALIX NIGRA POLLEN (UNII: 6M2JIH93ZN) (SALIX NIGRA POLLEN - UNII:6M2JIH93ZN) | | SALIX NIGRA POLLEN | 0.1 g in 1 mL |
| Inactive Ingredients | | | |

| Ingredient Name | | Strength | | |
|---------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| PHENOL (UNII: 339NCG44TV) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2622-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2622-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2622-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - TREES, TREE MIX 11

tree mix 11 injection, solution

| Product Information | | | |
|--------------------------------------------------------------------------------------------------|------------------------------|---------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2624 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q) | FRAXINUS AMERICANA POLLEN | 20000 [PNU] in 1 mL | |
| BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P) | BETULA NIGRA POLLEN | 20000 [PNU] in 1 mL | |
| JUGLANS NIGRA POLLEN (UNII: 1BV28146ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28146ZR) | JUGLANS NIGRA POLLEN | 20000 [PNU] in 1 mL | |
| POPULUS DELTOIDES POLLEN (UNII: 476DVV63WP) (POPULUS DELTOIDES POLLEN - UNII:476DVV63WP) | POPULUS DELTOIDES POLLEN | 20000 [PNU] in 1 mL | |
| ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | ULMUS AMERICANA POLLEN | 20000 [PNU] in 1 mL | |
| CARYA OVATA POLLEN (UNII: 54UN9R2798) (CARYA OVATA POLLEN - UNII:54UN9R2798) | CARYA OVATA POLLEN | 20000 [PNU] in 1 mL | |
| ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861) | ACER SACCHARUM POLLEN | 20000 [PNU] in 1 mL | |
| QUERCUS RUBRA POLLEN (UNII: SVW19ET93C) (QUERCUS RUBRA POLLEN - UNII:SVW19ET93C) | QUERCUS RUBRA POLLEN | 20000 [PNU] in 1 mL | |
| PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK) | PLATANUS OCCIDENTALIS POLLEN | 20000 [PNU] in 1 mL | |
| SALIX NIGRA POLLEN (UNII: 6M2JIH93ZN) (SALIX NIGRA POLLEN - UNII:6M2JIH93ZN) | SALIX NIGRA POLLEN | 20000 [PNU] in 1 mL | |
| Inactive Ingredients | | | |
| Ingredient Name | Strength | | |

| PHENOL (UNII: 339NCG44TV) | | | | |
|----------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2624-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2624-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2624-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - TREES, TREE MIX 11

tree mix 11 injection, solution

| Product Information | | | |
|---------------------------------------------------------------------------------------------------------|------------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2623 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q) | FRAXINUS AMERICANA POLLEN | 40000 [PNU] in 1 mL | |
| BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P) | BETULA NIGRA POLLEN | 40000 [PNU] in 1 mL | |
| JUGLANS NIGRA POLLEN (UNII: 1BV28146ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28146ZR) | JUGLANS NIGRA POLLEN | 40000 [PNU] in 1 mL | |
| POPULUS DELTOIDES POLLEN (UNII: 476DVV63WP) (POPULUS DELTOIDES POLLEN - UNII:476DVV63WP) | POPULUS DELTOIDES POLLEN | 40000 [PNU] in 1 mL | |
| ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | ULMUS AMERICANA POLLEN | 40000 [PNU] in 1 mL | |
| CARYA OVATA POLLEN (UNII: 54UN9R2798) (CARYA OVATA POLLEN - UNII:54UN9R2798) | CARYA OVATA POLLEN | 40000 [PNU] in 1 mL | |
| ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861) | ACER SACCHARUM POLLEN | 40000 [PNU] in 1 mL | |
| QUERCUS RUBRA POLLEN (UNII: SVW19ET93C) (QUERCUS RUBRA POLLEN - UNII:SVW19ET93C) | QUERCUS RUBRA POLLEN | 40000 [PNU] in 1 mL | |
| PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK) | PLATANUS OCCIDENTALIS POLLEN | 40000 [PNU] in 1 mL | |
| SALIX NIGRA POLLEN (UNII: 6M2JIH93ZN) (SALIX NIGRA POLLEN - UNII:6M2JIH93ZN) | SALIX NIGRA POLLEN | 40000 [PNU] in 1 mL | |
| Inactive Ingredients | | | |
| Ingredient Name | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | | |

SODIUM CHLORIDE (UNII: 451W47IQ8X)

SODIUM BICARBONATE (UNII: 8MDF5V39QO)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2623-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2623-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2623-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, TREE MIX 5

tree mix 5 injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2854 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------------------|------------------------------|-----------------|
| CARYA ILLINOINENSIS POLLEN (UNII: PYO4JR720Y) (CARYA ILLINOINENSIS POLLEN - UNII:PYO4JR720Y) | CARYA ILLINOINENSIS POLLEN | 0.05 g in 1 mL |
| ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861) | ACER SACCHARUM POLLEN | 0.017 g in 1 mL |
| ACER NEGUNDO POLLEN (UNII: P6K070AR8V) (ACER NEGUNDO POLLEN - UNII:P6K070AR8V) | ACER NEGUNDO POLLEN | 0.017 g in 1 mL |
| ACER RUBRUM POLLEN (UNII: 700NK45C76) (ACER RUBRUM POLLEN - UNII:700NK45C76) | ACER RUBRUM POLLEN | 0.017 g in 1 mL |
| QUERCUS RUBRA POLLEN (UNII: SVW19ET93C) (QUERCUS RUBRA POLLEN - UNII:SVW19ET93C) | QUERCUS RUBRA POLLEN | 0.017 g in 1 mL |
| QUERCUS VIRGINIANA POLLEN (UNII: 8KDG09A4GO) (QUERCUS VIRGINIANA POLLEN - UNII:8KDG09A4GO) | QUERCUS VIRGINIANA POLLEN | 0.017 g in 1 mL |
| QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK) | QUERCUS ALBA POLLEN | 0.017 g in 1 mL |
| PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK) | PLATANUS OCCIDENTALIS POLLEN | 0.05 g in 1 mL |
| SALIX NIGRA POLLEN (UNII: 6M2JIH93Z N) (SALIX NIGRA POLLEN - UNII:6M2JIH93Z N) | SALIX NIGRA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2854-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2854-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2854-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, TREE MIX 5

tree mix 5 injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2856 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | |
|---------------------------------------------------------------------------------------------------------|------------------------------|-----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| CARYA ILLINOINENSIS POLLEN (UNII: PYO4JR720Y) (CARYA ILLINOINENSIS POLLEN - UNII:PYO4JR720Y) | CARYA ILLINOINENSIS POLLEN | 0.1 g in 1 mL | |
| ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861) | ACER SACCHARUM POLLEN | 0.033 g in 1 mL | |
| ACER NEGUNDO POLLEN (UNII: P6K070AR8V) (ACER NEGUNDO POLLEN - UNII:P6K070AR8V) | ACER NEGUNDO POLLEN | 0.033 g in 1 mL | |
| ACER RUBRUM POLLEN (UNII: 700NK45C76) (ACER RUBRUM POLLEN - UNII:700NK45C76) | ACER RUBRUM POLLEN | 0.033 g in 1 mL | |
| QUERCUS RUBRA POLLEN (UNII: SVW19ET93C) (QUERCUS RUBRA POLLEN - UNII:SVW19ET93C) | QUERCUS RUBRA POLLEN | 0.033 g in 1 mL | |
| QUERCUS VIRGINIANA POLLEN (UNII: 8KDG09A4GO) (QUERCUS VIRGINIANA POLLEN - UNII:8KDG09A4GO) | QUERCUS VIRGINIANA POLLEN | 0.033 g in 1 mL | |
| QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK) | QUERCUS ALBA POLLEN | 0.033 g in 1 mL | |
| PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK) | PLATANUS OCCIDENTALIS POLLEN | 0.1 g in 1 mL | |
| SALIX NIGRA POLLEN (UNII: 6M2JH93ZN) (SALIX NIGRA POLLEN - UNII:6M2JH93ZN) | SALIX NIGRA POLLEN | 0.1 g in 1 mL | |

| Inactive Ingredients | |
|----------------------------------------------|----------|
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2856-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2856-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2856-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, TREE MIX 5

tree mix 5 injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2855 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | |
|---------------------------------------------------------------------------------------------------------|------------------------------|---------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| CARYA ILLINOINENSIS POLLEN (UNII: PYO4JR720Y) (CARYA ILLINOINENSIS POLLEN - UNII:PYO4JR720Y) | CARYA ILLINOINENSIS POLLEN | 20000 [PNU] in 1 mL | |
| ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861) | ACER SACCHARUM POLLEN | 20000 [PNU] in 1 mL | |
| ACER NEGUNDO POLLEN (UNII: P6K070AR8V) (ACER NEGUNDO POLLEN - UNII:P6K070AR8V) | ACER NEGUNDO POLLEN | 20000 [PNU] in 1 mL | |
| ACER RUBRUM POLLEN (UNII: 700NK45C76) (ACER RUBRUM POLLEN - UNII:700NK45C76) | ACER RUBRUM POLLEN | 20000 [PNU] in 1 mL | |
| QUERCUS RUBRA POLLEN (UNII: SVW19ET93C) (QUERCUS RUBRA POLLEN - UNII:SVW19ET93C) | QUERCUS RUBRA POLLEN | 20000 [PNU] in 1 mL | |
| QUERCUS VIRGINIANA POLLEN (UNII: 8KDG09A4GO) (QUERCUS VIRGINIANA POLLEN - UNII:8KDG09A4GO) | QUERCUS VIRGINIANA POLLEN | 20000 [PNU] in 1 mL | |
| QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK) | QUERCUS ALBA POLLEN | 20000 [PNU] in 1 mL | |
| PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK) | PLATANUS OCCIDENTALIS POLLEN | 20000 [PNU] in 1 mL | |
| SALIX NIGRA POLLEN (UNII: 6M2JIH93ZN) (SALIX NIGRA POLLEN - UNII:6M2JIH93ZN) | SALIX NIGRA POLLEN | 20000 [PNU] in 1 mL | |

| Inactive Ingredients | |
|----------------------------------------------|----------|
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

| Packaging | | | | |
|-----------|------------|--------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044- | 10 mL in 1 VIAL; Type 0: Not a Combination | | |

| | | | | |
|---|------------------|----------------------------------------------------|--|--|
| 1 | 2855-2 | Product | | |
| 2 | NDC:65044-2855-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2855-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, TREE MIX 6

tree mix 6 injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2863 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------------|---------------------------|-----------------|
| FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q) | FRAXINUS AMERICANA POLLEN | 0.05 g in 1 mL |
| BETULA PAPYRIFERA POLLEN (UNII: 3538FNV8AY) (BETULA PAPYRIFERA POLLEN - UNII:3538FNV8AY) | BETULA PAPYRIFERA POLLEN | 0.017 g in 1 mL |
| BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P) | BETULA NIGRA POLLEN | 0.017 g in 1 mL |
| BETULA PENDULA POLLEN (UNII: ZL5TV40C5Y) (BETULA PENDULA POLLEN - UNII:ZL5TV40C5Y) | BETULA PENDULA POLLEN | 0.017 g in 1 mL |
| JUGLANS NIGRA POLLEN (UNII: 1BV28146ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28146ZR) | JUGLANS NIGRA POLLEN | 0.05 g in 1 mL |
| POPULUS DELTOIDES POLLEN (UNII: 476DVV63WP) (POPULUS DELTOIDES POLLEN - UNII:476DVV63WP) | POPULUS DELTOIDES POLLEN | 0.05 g in 1 mL |
| ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | ULMUS AMERICANA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2863-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2863-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2863-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, TREE MIX 6

tree mix 6 injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2861 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------------|---------------------------|-----------------|
| FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q) | FRAXINUS AMERICANA POLLEN | 0.1 g in 1 mL |
| BETULA PAPYRIFERA POLLEN (UNII: 3538FNV8AY) (BETULA PAPYRIFERA POLLEN - UNII:3538FNV8AY) | BETULA PAPYRIFERA POLLEN | 0.033 g in 1 mL |
| BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P) | BETULA NIGRA POLLEN | 0.033 g in 1 mL |
| BETULA PENDULA POLLEN (UNII: ZL5TV40C5Y) (BETULA PENDULA POLLEN - UNII:ZL5TV40C5Y) | BETULA PENDULA POLLEN | 0.033 g in 1 mL |
| JUGLANS NIGRA POLLEN (UNII: 1BV28146ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28146ZR) | JUGLANS NIGRA POLLEN | 0.1 g in 1 mL |
| POPULUS DELTOIDES POLLEN (UNII: 476DVV63WP) (POPULUS DELTOIDES POLLEN - UNII:476DVV63WP) | POPULUS DELTOIDES POLLEN | 0.1 g in 1 mL |
| ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | ULMUS AMERICANA POLLEN | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2861-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2861-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2861-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, TREE MIX 6

tree mix 6 injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2862 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------------|---------------------------|---------------------|
| FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q) | FRAXINUS AMERICANA POLLEN | 20000 [PNU] in 1 mL |
| BETULA PAPYRIFERA POLLEN (UNII: 3538FNV8AY) (BETULA PAPYRIFERA POLLEN - UNII:3538FNV8AY) | BETULA PAPYRIFERA POLLEN | 20000 [PNU] in 1 mL |
| BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P) | BETULA NIGRA POLLEN | 20000 [PNU] in 1 mL |
| BETULA PENDULA POLLEN (UNII: ZL5TV40C5Y) (BETULA PENDULA POLLEN - UNII:ZL5TV40C5Y) | BETULA PENDULA POLLEN | 20000 [PNU] in 1 mL |
| JUGLANS NIGRA POLLEN (UNII: 1BV28146ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28146ZR) | JUGLANS NIGRA POLLEN | 20000 [PNU] in 1 mL |
| POPULUS DELTOIDES POLLEN (UNII: 476DVV63WP) (POPULUS DELTOIDES POLLEN - UNII:476DVV63WP) | POPULUS DELTOIDES POLLEN | 20000 [PNU] in 1 mL |
| ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | ULMUS AMERICANA POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2862-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2862-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2862-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, TREE OF HEAVEN AILANTHUS ALTISSIMA

tree of heaven ailanthus altissima injection, solution

Product Information

| | | | | |
|----------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2599 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| AILANTHUS ALTISSIMA POLLEN (UNII: 2A64U81OQ3) (AILANTHUS ALTISSIMA POLLEN - UNII:2A64U81OQ3) | | AILANTHUS ALTISSIMA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2599-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2599-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2599-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - TREES, WALNUT, BLACK JUGLANS NIGRA

walnut, black juglans nigra injection, solution

| | | | |
|----------------------------------------------------------------------------------|-----------------------------|---------------------------|-------------------|
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2626 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| JUGLANS NIGRA POLLEN (UNII: 1BV28146ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28146ZR) | | JUGLANS NIGRA POLLEN | 0.05 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2626-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2626-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2626-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, WALNUT, BLACK JUGLANS NIGRA

walnut, black juglans nigra injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2629 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------------------------------------------------------------------------|----------------------|---------------|
| JUGLANS NIGRA POLLEN (UNII: 1BV28146ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28146ZR) | JUGLANS NIGRA POLLEN | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2629-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2629-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2629-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| Category | Citation | Date | Date |
|----------|-----------|------------|------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, WILLOW, BLACK SALIX NIGRA

willow, black salix nigra injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2677 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | |
|--------------------------------------------------------------------------------|--------------------|----------------|
| Ingredient Name | Basis of Strength | Strength |
| SALIX NIGRA POLLEN (UNII: 6M2JIH93Z N) (SALIX NIGRA POLLEN - UNII:6M2JIH93Z N) | SALIX NIGRA POLLEN | 0.05 g in 1 mL |

| Inactive Ingredients | |
|---------------------------------------|----------|
| Ingredient Name | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2677-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2677-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2677-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, COCKLEBUR XANTHIUM STRUMARIUM

cocklebur xanthium strumarium injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1405 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | | |
|----------------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | Basis of Strength | Strength | |
| XANTHIUM STRUMARIUM POLLEN (UNII: 2QOF601J1M) (XANTHIUM STRUMARIUM POLLEN - UNII:2QOF601J1M) | | XANTHIUM STRUMARIUM POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1405-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1405-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1405-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | | 04/19/1941 | |

| POLLENS - WEEDS AND GARDEN PLANTS, COCKLEBUR XANTHIUM STRUMARIUM | | | | |
|----------------------------------------------------------------------------------------------|-----------------------------|----------------------------|----------------------|--------------------|
| cocklebur xanthium strumarium injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1408 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| XANTHIUM STRUMARIUM POLLEN (UNII: 2QOF601J1M) (XANTHIUM STRUMARIUM POLLEN - UNII:2QOF601J1M) | | XANTHIUM STRUMARIUM POLLEN | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1408-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1408-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1408-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, COCKLEBUR XANTHIUM STRUMARIUM

cocklebur xanthium strumarium injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1409 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------------------------------------------------------------------------------------|----------------------------|---------------------|
| XANTHIUM STRUMARIUM POLLEN (UNII: 2QOF601J1M) (XANTHIUM STRUMARIUM POLLEN - UNII:2QOF601J1M) | XANTHIUM STRUMARIUM POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1409-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1409-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1409-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, DOG FENNEL, EASTERN EUPATORIUM CAPILLIFOLIUM

dog fennel, eastern eupatorium capillifolium injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2057 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------|
| EUPATORIUM CAPILLIFOLIUM POLLEN (UNII: B67NF86HF0) (EUPATORIUM CAPILLIFOLIUM POLLEN - UNII:B67NF86HF0) | EUPATORIUM CAPILLIFOLIUM POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2057-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2057-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2057-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, GOLDENROD SOLIDAGO CANADENSIS

goldenrod solidago canadensis injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1630 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------------------------------------------------------------------------------------|----------------------------|-------------------|
| SOLIDAGO CANADENSIS POLLEN (UNII: 644CZ16IR5) (SOLIDAGO CANADENSIS POLLEN - UNII:644CZ16IR5) | SOLIDAGO CANADENSIS POLLEN | 0.05 g in 1 mL |

| Inactive Ingredients | | | | |
|---------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1630-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1630-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1630-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| POLLENS - WEEDS AND GARDEN PLANTS, LAMBS QUARTERS CHENOPODIUM ALBUM | | | | |
|------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------|--------------------|
| lams quarters chenopodium album injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1786 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CHENOPODIUM ALBUM POLLEN (UNII: 098LKX5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKX5NCN) | | CHENOPODIUM ALBUM POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1786-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1786-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| | | | | |
|------------------------------|-------------------------------------------------|----------------------------------------------------|---------------------------|--|
| 3 | NDC:65044-1786-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - WEEDS AND GARDEN PLANTS, LAMBS QUARTERS CHENOPODIUM ALBUM
lams quarters chenopodium album injection, solution

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1789 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| | | | |
|----------------------------------------|------------------------------------------------------------------------------------------|--------------------------|-----------------|
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | CHENOPODIUM ALBUM POLLEN (UNII: 098LKX5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKX5NCN) | CHENOPODIUM ALBUM POLLEN | 0.1 g in 1 mL |

| | |
|---------------------------------------|-----------------|
| Inactive Ingredients | |
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

| | | | | |
|------------------|------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1789-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1789-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1789-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| | | | |
|------------------------------|-------------------------------------------------|-----------------------------|---------------------------|
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, LAMBS QUARTERS CHENOPODIUM ALBUM
lams quarters chenopodium album injection, solution

| Product Information | | | | |
|------------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1790 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CHENOPODIUM ALBUM POLLEN (UNII: 098LKX5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKX5NCN) | | CHENOPODIUM ALBUM POLLEN | 40000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1790-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1790-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1790-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| POLLENS - WEEDS AND GARDEN PLANTS, LAMBS QUARTERS CHENOPODIUM ALBUM | | | |
|------------------------------------------------------------------------------------------|-----------------------------|--------------------------|---------------------|
| lams quarters chenopodium album injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1791 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| CHENOPODIUM ALBUM POLLEN (UNII: 098LKX5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKX5NCN) | | CHENOPODIUM ALBUM POLLEN | 20000 [PNU] in 1 mL |
| Inactive Ingredients | | | |

| Ingredient Name | | Strength | | |
|---------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| PHENOL (UNII: 339NCG44TV) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1791-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1791-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1791-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| POLLENS - WEEDS AND GARDEN PLANTS, NETTLE URTICA DIOICA | | | | |
|----------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------|--------------------|
| nettle urtica dioica injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1945 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| URTICA DIOICA POLLEN (UNII: DNB59M1NVU) (URTICA DIOICA POLLEN - UNII:DNB59M1NVU) | URTICA DIOICA POLLEN | 0.05 g in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1945-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1945-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1945-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, NETTLE URTICA DIOICA

nettle urtica dioica injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1947 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------------------------------------------------------------|----------------------|------------------|
| URTICA DIOICA POLLEN (UNII: DNB59M1NVU) (URTICA DIOICA POLLEN - UNII:DNB59M1NVU) | URTICA DIOICA POLLEN | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1947-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1947-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1947-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, PIGWEED, ROUGH REDROOT AMARANTHUS RETROFLEXUS

pigweed, rough redroot amaranthus retroflexus injection, solution

Product Information

| | | | |
|--------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2125 |
|--------------|-----------------------------|--------------------|----------------|

| | | | | |
|----------------------------------------|----------------------------------------------------------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW) | AMARANTHUS RETROFLEXUS POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | GLYCERIN (UNII: PDC6A3C00X) | | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2125-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2125-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2125-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| | | | |
|---------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|----------------------------|-----------------|
| POLLENS - WEEDS AND GARDEN PLANTS, PLANTAIN, ENGLISH PLANTAGO LANCEOLATA | | | |
| plantain, english plantago lanceolata injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2212 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | PLANTAGO LANCEOLATA POLLEN (UNII: DO87T1U2CI) (PLANTAGO LANCEOLATA POLLEN - UNII:DO87T1U2CI) | PLANTAGO LANCEOLATA POLLEN | 0.05 g in 1 mL |
| Inactive Ingredients | | | |
| | Ingredient Name | Strength | |
| | GLYCERIN (UNII: PDC6A3C00X) | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2212-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2212-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2212-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, PLANTAIN, ENGLISH PLANTAGO LANCEOLATA

plantain, english plantago lanceolata injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2215 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------------------------------------------------------------------------------------|----------------------------|---------------|
| PLANTAGO LANCEOLATA POLLEN (UNII: DO87T1U2CI) (PLANTAGO LANCEOLATA POLLEN - UNII:DO87T1U2CI) | PLANTAGO LANCEOLATA POLLEN | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2215-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2215-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2215-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
|--------------------|------------------------------------------|----------------------|--------------------|

| | | | |
|-----|-----------|------------|--|
| BLA | BLA103888 | 04/19/1941 | |
|-----|-----------|------------|--|

POLLENS - WEEDS AND GARDEN PLANTS, PLANTAIN, ENGLISH PLANTAGO LANCEOLATA

plantain, english plantago lanceolata injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2217 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------------------------------------------------------------------------------------|----------------------------|---------------------|
| PLANTAGO LANCEOLATA POLLEN (UNII: DO87T1U2CI) (PLANTAGO LANCEOLATA POLLEN - UNII:DO87T1U2CI) | PLANTAGO LANCEOLATA POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2217-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2217-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2217-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, PLANTAIN, ENGLISH PLANTAGO LANCEOLATA

plantain, english plantago lanceolata injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2216 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|----------------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| PLANTAGO LANCEOLATA POLLEN (UNII: DO87T1U2CI) (PLANTAGO LANCEOLATA POLLEN - UNII:DO87T1U2CI) | | PLANTAGO LANCEOLATA POLLEN | 40000 [PNU] in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2216-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2216-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2216-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - WEEDS AND GARDEN PLANTS, RAGWEED, GIANT AMBROSIA TRIFIDA

ragweed, giant ambrosia trifida injection, solution

| Product Information | | | | |
|----------------------------------------------------------------------------------------|-----------------------------|-------------------------|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2293 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| AMBROSIA TRIFIDA POLLEN (UNII: KU1V1898XX) (AMBROSIA TRIFIDA POLLEN - UNII:KU1V1898XX) | | AMBROSIA TRIFIDA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2293-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2293-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2293-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, RAGWEED, GIANT AMBROSIA TRIFIDA

ragweed, giant ambrosia trifida injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2296 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------------------------------------------------------------------------------|-------------------------|---------------|
| AMBROSIA TRIFIDA POLLEN (UNII: KU1V1898XX) (AMBROSIA TRIFIDA POLLEN - UNII:KU1V1898XX) | AMBROSIA TRIFIDA POLLEN | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2296-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2296-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2296-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, RAGWEED. WESTERN AMBROSIA PSILOSTACHYA

ragweed. western ambrosia psilostachya injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2308 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------------------|------------------------------|-----------------|
| AMBROSIA PSILOSTACHYA POLLEN (UNII: RX18M46K8L) (AMBROSIA PSILOSTACHYA POLLEN - UNII:RX18M46K8L) | AMBROSIA PSILOSTACHYA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|-----------------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|----------------------------------------------------|-----------------------------|---------------------------|
| 1 | NDC:65044-2308-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2308-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2308-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|-------------------------------------------------|-----------------------------|---------------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, RAGWEED. WESTERN AMBROSIA PSILOSTACHYA

ragweed. western ambrosia psilostachya injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2311 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------------------|------------------------------|-----------------|
| AMBROSIA PSILOSTACHYA POLLEN (UNII: RX18M46K8L) (AMBROSIA PSILOSTACHYA POLLEN - UNII:RX18M46K8L) | AMBROSIA PSILOSTACHYA POLLEN | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2311-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2311-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2311-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, RUSSIAN THISTLE SALSOLA KALI

russian thistle salsola kali injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2362 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--------------------------------------------------------------------------------|---------------------|----------------|
| SALSOLA KALI POLLEN (UNII: 2MH135KC6G) (SALSOLA KALI POLLEN - UNII:2MH135KC6G) | SALSOLA KALI POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2362-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| | | | | |
|---|------------------|----------------------------------------------------|--|--|
| 2 | NDC:65044-2362-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2362-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, SAGEBRUSH, MUGWORT ARTEMISIA VULGARIS
sagebrush, mugwort artemisia vulgaris injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2413 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | |
|---------------------------------|--------------------------------------------------------------------------------------------|---------------------------|----------------|
| | Ingredient Name | Basis of Strength | Strength |
| | ARTEMISIA VULGARIS POLLEN (UNII: ANT994T71D) (ARTEMISIA VULGARIS POLLEN - UNII:ANT994T71D) | ARTEMISIA VULGARIS POLLEN | 0.05 g in 1 mL |

| Inactive Ingredients | | |
|----------------------|---------------------------------------|----------|
| | Ingredient Name | Strength |
| | GLYCERIN (UNII: PDC6A3C0OX) | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2413-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2413-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2413-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, SAGEBRUSH, MUGWORT ARTEMISIA VULGARIS

sagebrush, mugwort artemisia vulgaris injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2416 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------------|---------------------------|------------------|
| ARTEMISIA VULGARIS POLLEN (UNII: ANT994T71D) (ARTEMISIA VULGARIS POLLEN - UNII:ANT994T71D) | ARTEMISIA VULGARIS POLLEN | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2416-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2416-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2416-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, SAGEBRUSH, MUGWORT ARTEMISIA VULGARIS

sagebrush, mugwort artemisia vulgaris injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2417 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------------|---------------------------|------------------------|
| ARTEMISIA VULGARIS POLLEN (UNII: ANT994T71D) (ARTEMISIA VULGARIS POLLEN - UNII:ANT994T71D) | ARTEMISIA VULGARIS POLLEN | 40000 [PNU] in 1 mL |

| Inactive Ingredients | | | | |
|---------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | | | Strength |
| PHENOL (UNII: 339NCG44TV) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2417-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2417-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2417-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | | 04/19/1941 | |

| POLLENS - WEEDS AND GARDEN PLANTS, SCALE, WING SHAD ATRIPLEX CANESCENS | | | | |
|--------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------|--------------------|
| scale, wing shad atriplex canescens injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2482 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| ATRIPLEX CANESCENS POLLEN (UNII: 26U0BU8G83) (ATRIPLEX CANESCENS POLLEN - UNII:26U0BU8G83) | | ATRIPLEX CANESCENS POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2482-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2482-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044- | 50 mL in 1 VIAL; Type 0: Not a Combination | | |

| 2482-4 | Product | | |
|------------------------------|------------------------------------------|----------------------|--------------------|
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, SCALE, WING SHAD ATRIPLEX CANESCENS
scale, wing shad atriplex canescens injection, solution

| Product Information | | | |
|----------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2485 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | |
|---------------------------------------------------------------------------------------------------|---------------------------|---------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ATRIPLEX CANESCENS POLLEN (UNII: 26U0BU8G83) (ATRIPLEX CANESCENS POLLEN - UNII:26U0BU8G83) | ATRIPLEX CANESCENS POLLEN | 0.1 g in 1 mL | |

| Inactive Ingredients | |
|----------------------------------------------|----------|
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

| Packaging | | | | |
|------------------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2485-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2485-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2485-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|------------------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, SCOTCH BROOM CYTISUS SCOPARIUS
scotch broom cytissus scoparius injection, solution

Product Information

| | | | | |
|--------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2487 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CYTISUS SCOPARIUS FLOWERING TOP (UNII: XZC6H8R666) (CYTISUS SCOPARIUS FLOWERING TOP - UNII:XZC6H8R666) | | CYTISUS SCOPARIUS FLOWERING TOP | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2487-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2487-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2487-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - WEEDS AND GARDEN PLANTS, SORREL, SHEEP RUMEX ACETOSELLA

sorrel, sheep rumex acetosella injection, solution

| | | | |
|----------------------------------------------------------------------------------------|-----------------------------|---------------------------|-------------------|
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2506 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW) | | RUMEX ACETOSELLA POLLEN | 0.05 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |

SODIUM BICARBONATE (UNII: 8MDF5V39QO)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2506-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2506-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2506-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS AND GARDEN PLANTS, SORREL, SHEEP RUMEX ACETOSELLA

sorrel, sheep rumex acetosella injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2508 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------------------------------------------------------------------------------|-------------------------|---------------|
| RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW) | RUMEX ACETOSELLA POLLEN | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2508-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2508-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2508-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS, CARELESS WEED AMARANTHUS PALMERI

careless weed amaranthus palmeri injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1297 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|------------------------------------------------------------------------------------------|---------------------------|----------------|
| AMARANTHUS PALMERI POLLEN (UNII: 1GH3W23KH) (AMARANTHUS PALMERI POLLEN - UNII:1GH3W23KH) | AMARANTHUS PALMERI POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1297-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1297-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1297-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS, CARELESS/PIGWEED MIX

careless/pigweed mix injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1300 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|----------------------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| AMARANTHUS PALMERI POLLEN (UNII: 1GH3W23KH) (AMARANTHUS PALMERI POLLEN - UNII:1GH3W23KH) | | AMARANTHUS PALMERI POLLEN | 0.05 g in 1 mL | |
| AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW) | | AMARANTHUS RETROFLEXUS POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1300-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1300-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1300-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - WEEDS, CARELESS/PIGWEED MIX

careless/pigweed mix injection, solution

| Product Information | | | |
|----------------------------------------------------------------------------------------------------|-----------------------------|-------------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1303 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| AMARANTHUS PALMERI POLLEN (UNII: 1GH3W23KH) (AMARANTHUS PALMERI POLLEN - UNII:1GH3W23KH) | | AMARANTHUS PALMERI POLLEN | 0.1 g in 1 mL |
| AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW) | | AMARANTHUS RETROFLEXUS POLLEN | 0.1 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1303-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1303-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1303-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

| POLLENS - WEEDS, DOCK/SORREL MIX | | | | |
|----------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| pollens - weeds, dock/sorrel mix injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1516 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| RUMEX CRISPUS POLLEN (UNII: V825XJG64G) (RUMEX CRISPUS POLLEN - UNII:V825XJG64G) | | RUMEX CRISPUS POLLEN | 0.05 g in 1 mL | |
| RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW) | | RUMEX ACETOSELLA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1516-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1516-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1516-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - WEEDS, DOCK/SORREL MIX

pollens - weeds, dock/sorrel mix injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1519 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------------------------------------------------------------------------------|-------------------------|---------------|
| RUMEX CRISPUS POLLEN (UNII: V825XJG64G) (RUMEX CRISPUS POLLEN - UNII:V825XJG64G) | RUMEX CRISPUS POLLEN | 0.1 g in 1 mL |
| RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW) | RUMEX ACETOSELLA POLLEN | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1519-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1519-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1519-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS, DOCK/SORREL MIX

pollens - weeds, dock/sorrel mix injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1520 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | | | |
|-----------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| RUMEX CRISPUS POLLEN (UNII: V825XJG64G) (RUMEX CRISPUS POLLEN - UNII:V825XJG64G) | RUMEX CRISPUS POLLEN | 20000 [PNU] in 1 mL | | |
| RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW) | RUMEX ACETOSELLA POLLEN | 20000 [PNU] in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1520-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1520-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1520-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| | | | | |
|------------------------------------------------------------------------------------------------------|-----------------------------|--------------------------------|-----------------|--|
| POLLENS - WEEDS, GIANT, SHORT, WESTERN RAGWEED MIX | | | | |
| giant, short, western ragweed mix injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2320 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| AMBROSIA TRIFIDA POLLEN (UNII: KU1V1898XX) (AMBROSIA TRIFIDA POLLEN - UNII:KU1V1898XX) | | AMBROSIA TRIFIDA POLLEN | 0.05 g in 1 mL | |
| AMBROSIA ARTEMISIIFOLIA POLLEN (UNII: K20Y81ACO3) (AMBROSIA ARTEMISIIFOLIA POLLEN - UNII:K20Y81ACO3) | | AMBROSIA ARTEMISIIFOLIA POLLEN | 0.05 g in 1 mL | |
| AMBROSIA PSILOSTACHYA POLLEN (UNII: RX18M46K8L) (AMBROSIA PSILOSTACHYA POLLEN - UNII:RX18M46K8L) | | AMBROSIA PSILOSTACHYA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2320-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2320-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2320-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

| POLLENS - WEEDS, KOCHIA SCOPARIA | | | | |
|--------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| kochia scoparia injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1780 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| BASSIA SCOPARIA POLLEN (UNII: 07A108ZKW5) (BASSIA SCOPARIA POLLEN - UNII:07A108ZKW5) | | BASSIA SCOPARIA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1780-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1780-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1780-5 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - WEEDS, KOCHIA SCOPARIA

kochia scoparia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1783 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------|------------------------|------------------|
| BASSIA SCOPARIA POLLEN (UNII: 07A108ZKW5) (BASSIA SCOPARIA POLLEN - UNII:07A108ZKW5) | BASSIA SCOPARIA POLLEN | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1783-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1783-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1783-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS, MARSHELDER/POVERTY MIX

pollens - weeds, marshelder/poverty mix injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1858 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------------------------------------------------------------------------|----------------------|-------------------|
| IVA AXILLARIS POLLEN (UNII: 13KFG30UBR) (IVA AXILLARIS POLLEN - UNII:13KFG30UBR) | IVA AXILLARIS POLLEN | 0.05 g in 1 mL |
| IVA ANNUA POLLEN (UNII: Y2U5S5PF22) (IVA ANNUA POLLEN - | IVA ANNUA POLLEN | 0.05 g |

| | | | | |
|-------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| UNII:Y2U5S5PF22) | IVA ANNUA POLLEN | in 1 mL | | |
| CYCLACHAENA XANTHIFOLIA POLLEN (UNII: V80TPZ0T6J) (CYCLACHAENA XANTHIFOLIA POLLEN - UNII:V80TPZ0T6J) | CYCLACHAENA XANTHIFOLIA POLLEN | 0.05 g in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1858-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1858-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1858-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - WEEDS, MARSHELDER/POVERTY MIX

pollens - weeds, marshelder/poverty mix injection, solution

| | | | |
|------------------------------------------------------------------------------------------------------|-----------------------------|--------------------------------|------------------|
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1861 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| IVA AXILLARIS POLLEN (UNII: 13KFG30UBR) (IVA AXILLARIS POLLEN - UNII:13KFG30UBR) | | IVA AXILLARIS POLLEN | 0.1 g in 1 mL |
| IVA ANNUA POLLEN (UNII: Y2U5S5PF22) (IVA ANNUA POLLEN - UNII:Y2U5S5PF22) | | IVA ANNUA POLLEN | 0.1 g in 1 mL |
| CYCLACHAENA XANTHIFOLIA POLLEN (UNII: V80TPZ0T6J) (CYCLACHAENA XANTHIFOLIA POLLEN - UNII:V80TPZ0T6J) | | CYCLACHAENA XANTHIFOLIA POLLEN | 0.1 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1861-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1861-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1861-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

| POLLENS - WEEDS, WEED MIX 2630 | | | | |
|----------------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------|--------------------|
| weed mix 2630 injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2634 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| XANTHIUM STRUMARIUM POLLEN (UNII: 2QOF601J1M) (XANTHIUM STRUMARIUM POLLEN - UNII:2QOF601J1M) | | XANTHIUM STRUMARIUM POLLEN | 0.05 g in 1 mL | |
| CHENOPODIUM ALBUM POLLEN (UNII: 098LKX5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKX5NCN) | | CHENOPODIUM ALBUM POLLEN | 0.05 g in 1 mL | |
| AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW) | | AMARANTHUS RETROFLEXUS POLLEN | 0.05 g in 1 mL | |
| RUMEX CRISPIUS POLLEN (UNII: V825XJG64G) (RUMEX CRISPIUS POLLEN - UNII:V825XJG64G) | | RUMEX CRISPIUS POLLEN | 0.025 g in 1 mL | |
| RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW) | | RUMEX ACETOSELLA POLLEN | 0.025 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2634-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2634-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2634-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS, WEED MIX 2630

weed mix 2630 injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2632 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------------------------------------------------------------------------------------------|-------------------------------|----------------|
| XANTHIUM STRUMARIUM POLLEN (UNII: 2QOF601J1M) (XANTHIUM STRUMARIUM POLLEN - UNII:2QOF601J1M) | XANTHIUM STRUMARIUM POLLEN | 0.1 g in 1 mL |
| CHENOPODIUM ALBUM POLLEN (UNII: 098LKX5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKX5NCN) | CHENOPODIUM ALBUM POLLEN | 0.1 g in 1 mL |
| AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW) | AMARANTHUS RETROFLEXUS POLLEN | 0.1 g in 1 mL |
| RUMEX CRISPUS POLLEN (UNII: V825XJG64G) (RUMEX CRISPUS POLLEN - UNII:V825XJG64G) | RUMEX CRISPUS POLLEN | 0.05 g in 1 mL |
| RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW) | RUMEX ACETOSELLA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2632-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2632-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2632-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - WEEDS, WEED MIX 2630

weed mix 2630 injection, solution

| Product Information | | | | |
|-----------------------------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2635 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| XANTHIUM STRUMARIUM POLLEN (UNII: 2QOF601J1M) (XANTHIUM STRUMARIUM POLLEN - UNII:2QOF601J1M) | XANTHIUM STRUMARIUM POLLEN | 20000 [PNU] in 1 mL | | |
| CHENOPODIUM ALBUM POLLEN (UNII: 098LKX5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKX5NCN) | CHENOPODIUM ALBUM POLLEN | 20000 [PNU] in 1 mL | | |
| AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW) | AMARANTHUS RETROFLEXUS POLLEN | 20000 [PNU] in 1 mL | | |
| RUMEX CRISPUS POLLEN (UNII: V825XJG64G) (RUMEX CRISPUS POLLEN - UNII:V825XJG64G) | RUMEX CRISPUS POLLEN | 20000 [PNU] in 1 mL | | |
| RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW) | RUMEX ACETOSELLA POLLEN | 20000 [PNU] in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| PHENOL (UNII: 339NCG44TV) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2635-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2635-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2635-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - WEEDS, WEED MIX 2630

weed mix 2630 injection, solution

| Product Information | | | |
|---------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2633 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |

| | | |
|-----------------------------------------------------------------------------------------------------------|-------------------------------|---------------------|
| XANTHIUM STRUMARIUM POLLEN (UNII: 2QOF601J1M) (XANTHIUM STRUMARIUM POLLEN - UNII:2QOF601J1M) | XANTHIUM STRUMARIUM POLLEN | 40000 [PNU] in 1 mL |
| CHENOPODIUM ALBUM POLLEN (UNII: 098LKX5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKX5NCN) | CHENOPODIUM ALBUM POLLEN | 40000 [PNU] in 1 mL |
| AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW) | AMARANTHUS RETROFLEXUS POLLEN | 40000 [PNU] in 1 mL |
| RUMEX CRISPUS POLLEN (UNII: V825XJG64G) (RUMEX CRISPUS POLLEN - UNII:V825XJG64G) | RUMEX CRISPUS POLLEN | 40000 [PNU] in 1 mL |
| RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW) | RUMEX ACETOSELLA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-2633-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2633-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2633-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

FOOD - ANIMAL PRODUCTS AND POULTRY PRODUCTS, EGG, WHITE GALLUS SP.

egg, white gallus sp. injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3248 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------|-------------------|----------------|
| EGG WHITE (UNII: 3E0I92Z2GR) (EGG WHITE - UNII:3E0I92Z2GR) | EGG WHITE | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-3248-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

FOOD - ANIMAL PRODUCTS AND POULTRY PRODUCTS, EGG, YOLK GALLUS SP.

egg, yolk gallus sp. injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3254 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------------------------------------|-------------------|----------------|
| EGG YOLK (UNII: 4IPS17B70T) (EGG YOLK - UNII:4IPS17B70T) | EGG YOLK | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-3254-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

FOOD - ANIMAL PRODUCTS AND POULTRY PRODUCTS, PORK SUS SP.

pork sus sp. injection, solution

| Product Information | | | | |
|--------------------------------------------------|-------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Product Type | | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3509 |
| Route of Administration | | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| PORK (UNII: O138UB266J) (PORK - UNII:O138UB266J) | | PORK | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3509-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | | 04/19/1941 | |

| FOOD - DAIRY PRODUCTS, CASEIN, COW MILK | | | | |
|------------------------------------------------------|--|-----------------------------|---------------------------|----------------|
| casein, cow milk injection, solution | | | | |
| Product Information | | | | |
| Product Type | | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3380 |
| Route of Administration | | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CASEIN (UNII: 48268V50D5) (CASEIN - UNII:48268V50D5) | | CASEIN | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3380-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

| FOOD - DAIRY PRODUCTS, MILK, WHOLE COW | | | | |
|----------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| milk, whole cow injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3389 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| COW MILK (UNII: 917J3173FT) (COW MILK - UNII:917J3173FT) | | COW MILK | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3389-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| FOOD - FISH AND SHELLFISH, CLAM | | | |
|---------------------------------|-----------------------------|--------------------|----------------|
| clam injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3191 |

| | | | | |
|----------------------------------------|--------------------------------------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | QUAHOG, UNSPECIFIED (UNII: 226LY0AFR9) (QUAHOG, UNSPECIFIED - UNII:226LY0AFR9) | QUAHOG, UNSPECIFIED | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | GLYCERIN (UNII: PDC6A3C00X) | | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3191-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| | | | |
|-----------------------------------------------------------|--------------------------------------------------------------------------|---------------------------|-----------------|
| FOOD - FISH AND SHELLFISH, CODFISH GADUS CALLARIAS | | | |
| codfish gadus callarias injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3203 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | COD, UNSPECIFIED (UNII: 8D6Q5LNG3D) (COD, UNSPECIFIED - UNII:8D6Q5LNG3D) | COD, UNSPECIFIED | 0.1 g in 1 mL |
| Inactive Ingredients | | | |
| | Ingredient Name | Strength | |
| | GLYCERIN (UNII: PDC6A3C00X) | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | |
| Packaging | | | |

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-3203-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

| FOOD - FISH AND SHELLFISH, CRAB XIPHOSURUS SOWERBYI | | | | |
|------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| crab xiphosurus sowerbyi injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3215 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CRAB LEG, UNSPECIFIED (UNII: S1VF61QLO9) (CRAB LEG, UNSPECIFIED - UNII:S1VF61QLO9) | | CRAB LEG, UNSPECIFIED | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3215-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| FOOD - FISH AND SHELLFISH, LOBSTER HOMARUS AMERICANUS | | | |
|-------------------------------------------------------|-----------------------------|--------------------|----------------|
| lobster homarus americanus injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3362 |

| | | | | |
|----------------------------------------|-----------------------------------------------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | LOBSTER, UNSPECIFIED (UNII: ZQ6LG2C39M) (LOBSTER, UNSPECIFIED - UNII:ZQ6LG2C39M) | LOBSTER, UNSPECIFIED | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | GLYCERIN (UNII: PDC6A3C00X) | | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3362-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| | | | |
|------------------------------------------------------|---------------------------------------------------------------------------------------|---------------------------|------------------|
| FOOD - FISH AND SHELLFISH, SALMON SALMO SALAR | | | |
| salmon salmo salar injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3565 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | SALMON, UNSPECIFIED (UNII: 6122W2M0GB) (SALMON, UNSPECIFIED - UNII:6122W2M0GB) | SALMON, UNSPECIFIED | 0.1 g in 1 mL |
| Inactive Ingredients | | | |
| | Ingredient Name | Strength | |
| | GLYCERIN (UNII: PDC6A3C00X) | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | |
| Packaging | | | |

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-3565-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

| FOOD - FISH AND SHELLFISH, SHRIMP CRAGO SP. | | | | |
|--------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| shrimp crago sp. injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3584 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| SHRIMP, UNSPECIFIED (UNII: 1891LE191T) (SHRIMP, UNSPECIFIED - UNII:1891LE191T) | | SHRIMP, UNSPECIFIED | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3584-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| FOOD - FISH AND SHELLFISH, TUNA THUNNUS SP. | | | |
|---------------------------------------------|-----------------------------|--------------------|----------------|
| tuna thunnus sp. injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3674 |

| | | | | |
|----------------------------------------|-----------------------------------------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | TUNA, UNSPECIFIED (UNII: V2T3IHT3E2) (TUNA, UNSPECIFIED - UNII:V2T3IHT3E2) | TUNA, UNSPECIFIED | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | GLYCERIN (UNII: PDC6A3C00X) | | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3674-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| | | | | |
|-----------------------------------------------------|-------------------------------------------------------------|----------------------------|-----------------------------|---------------------------|
| FOOD - PLANT SOURCE, ALMOND PRUNUS AMYGDALUS | | | | |
| almond prunus amygdalus injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3014 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | ALMOND (UNII: 3Z252A2K9G) (ALMOND - UNII:3Z252A2K9G) | ALMOND | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | GLYCERIN (UNII: PDC6A3C00X) | | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |

| | | | | |
|------------------------------|-------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| 1 | NDC:65044-3014-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | | 04/19/1941 | |

FOOD - PLANT SOURCE, APPLE MALUS SP.

apple malus sp. injection, solution

| | | | | |
|----------------------------------------------------|-------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | | Item Code (Source) | NDC:65044-3020 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | | Basis of Strength | Strength |
| APPLE (UNII: B423VGH5S9) (APPLE - UNII:B423VGH5S9) | | | APPLE | 0.1 g in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3020-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | | 04/19/1941 | |

FOOD - PLANT SOURCE, BANANA MUSA SAPIENTUM

banana musa sapientum injection, solution

| | | | | |
|--------------------------------|-----------------------------|--|---------------------------|----------------|
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | | Item Code (Source) | NDC:65044-3041 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |

| Active Ingredient/Active Moiety | | | | |
|------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | Basis of Strength | Strength | |
| BANANA (UNII: 4AJZ4765R9) (BANANA - UNII:4AJZ4765R9) | | BANANA | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3041-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| FOOD - PLANT SOURCE, BRAZIL NUT BERTHOLLETIA EXCELSA | | | | |
|--------------------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------|--------------------|
| brazil nut bertholletia excelsa injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3107 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| BRAZIL NUT (UNII: XKR79OET1K) (BRAZIL NUT - UNII:XKR79OET1K) | | BRAZIL NUT | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3107-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

FOOD - PLANT SOURCE, CARROT DAUCUS CAROTA

carrot daucus carota injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3125 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|------------------------------------------------------|-------------------|---------------|
| CARROT (UNII: L56Z1JK48B) (CARROT - UNII:L56Z1JK48B) | CARROT | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-3125-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

FOOD - PLANT SOURCE, CASHEW NUT ANACARDIUM OCCIDENTALIE

cashew nut anacardium occidentale injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3134 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|------------------------------------------------------|-------------------|---------------|
| CASHEW (UNII: 3H5U5CX7KO) (CASHEW - UNII:3H5U5CX7KO) | CASHEW | 0.1 g in 1 mL |

| Inactive Ingredients | | | | |
|---------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3134-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| FOOD - PLANT SOURCE, CELERY APIUM GRAVEOLENS | | | | |
|------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| celery apium graveolens injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3140 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CELERY (UNII: 44IDY6DTKX) (CELERY - UNII:44IDY6DTKX) | | CELERY | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3140-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

FOOD - PLANT SOURCE, CORN ZEA MAYS

corn zea mays injection, solution

| Product Information | | | | |
|--------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3212 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CORN (UNII: 0N86727070) (CORN - UNII:0N86727070) | | CORN | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3212-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

FOOD - PLANT SOURCE, HAZELNUT FILBERT CORYLUS SPP.

hazelnut filbert corylus spp. injection, solution

| Product Information | | | | |
|------------------------------------------------------------------------------------|-----------------------------|-----------------------|----------------|--|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3305 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| HAZELNUT, UNSPECIFIED (UNII: IW00M96F60) (HAZELNUT, UNSPECIFIED - UNII:IW00M96F60) | | HAZELNUT, UNSPECIFIED | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |

| Ingredient Name | | | Strength | |
|---------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3305-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| FOOD - PLANT SOURCE, MELON, CANTALOUPE CUCUMIS MELO | | | | |
|--------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| cantaloupe cucumis melo injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3116 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| CANTALOUPE (UNII: 8QF5D5H6UH) (CANTALOUPE - UNII:8QF5D5H6UH) | CANTALOUPE | 0.1 g in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3116-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

FOOD - PLANT SOURCE, ORANGE CITRUS SINENSIS

orange citrus sinensis injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3428 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------|--------------------------|-----------------|
| ORANGE (UNII: 5EVU04N5QU) (ORANGE - UNII:5EVU04N5QU) | ORANGE | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|-----------------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|----------------------------------------------------|-----------------------------|---------------------------|
| 1 | NDC:65044-3428-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|-------------------------------------------------|-----------------------------|---------------------------|
| BLA | BLA103888 | 04/19/1941 | |

FOOD - PLANT SOURCE, PEA, GREEN OR ENGLISH PISUM SATIVUM

pea, green or english pisum sativum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3449 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------|--------------------------|-----------------|
| PEA (UNII: W4X7H8GYFM) (PEA - UNII:W4X7H8GYFM) | PEA | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|-----------------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3449-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

| FOOD - PLANT SOURCE, PEACH PRUNUS PERSICA | | | | |
|----------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| peach prunus persica injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3452 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| PEACH (UNII: 3OKE88I3QG) (PEACH - UNII:3OKE88I3QG) | PEACH | 0.1 g in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3452-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| FOOD - PLANT SOURCE, PEANUT ARACHIS HYPOGAEA | | | |
|----------------------------------------------|--|--|--|
| peanut arachis hypogaea injection, solution | | | |
| Product Information | | | |

| | | | | |
|------------------------------------------------------|-------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3455 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| PEANUT (UNII: QE1QX6B99R) (PEANUT - UNII:QE1QX6B99R) | | PEANUT | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3455-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

FOOD - PLANT SOURCE, PECAN CARYA ILLINOENSIS

pecan carya illinoensis injection, solution

| | | | | |
|----------------------------------------------------|-----------------------------|----------------------------|-----------------------------|---------------------------|
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3461 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| PECAN (UNII: F14P91GB5F) (PECAN - UNII:F14P91GB5F) | | PECAN | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |

| | | | | |
|------------------------------|-------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| 1 | NDC:65044-3461-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | | 04/19/1941 | |

FOOD - PLANT SOURCE, POTATO, WHITE SOLANUM TUBEROSUM
potato, white solanum tuberosum injection, solution

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3518 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| | | |
|------------------------------------------------------|--------------------------|-----------------|
| Active Ingredient/Active Moiety | | |
| Ingredient Name | Basis of Strength | Strength |
| POTATO (UNII: CFE1S8DYWD) (POTATO - UNII:CFE1S8DYWD) | POTATO | 0.1 g in 1 mL |

| | |
|---------------------------------------|-----------------|
| Inactive Ingredients | |
| Ingredient Name | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

| | | | | |
|------------------|------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3518-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| | | | | |
|------------------------------|-------------------------------------------------|--|-----------------------------|---------------------------|
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | | 04/19/1941 | |

FOOD - PLANT SOURCE, RICE, WHOLE GRAIN
rice, whole grain injection, solution

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3548 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | | |
|--------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | Basis of Strength | Strength | |
| BROWN RICE (UNII: 659G217HPG) (BROWN RICE - UNII:659G217HPG) | | BROWN RICE | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3548-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | | 04/19/1941 | |

| FOOD - PLANT SOURCE, RYE GRAIN | | | | |
|------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------|--------------------|
| rye grain injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | | Item Code (Source) | NDC:65044-3554 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| RYE (UNII: 0R4AQI398X) (RYE - UNII:0R4AQI398X) | | RYE | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3554-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

FOOD - PLANT SOURCE, SOYBEAN GLYCINE SOJA

soybean glycine soja injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3596 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--------------------------------------------------------|-------------------|---------------|
| SOYBEAN (UNII: L7HT8F1ZOD) (SOYBEAN - UNII:L7HT8F1ZOD) | SOYBEAN | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-3596-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

FOOD - PLANT SOURCE, STRAWBERRY FRAGARIA CHILOENSIS

strawberry fragaria chiloensis injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3626 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--------------------------------------------------------------|-------------------|----------------|
| STRAWBERRY (UNII: 4J2TY8Y81V) (STRAWBERRY - UNII:4J2TY8Y81V) | STRAWBERRY | 0.05 g in 1 mL |

| Inactive Ingredients | | | | |
|---------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3626-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| FOOD - PLANT SOURCE, STRING BEAN MIX | | | | |
|----------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| string bean mix injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3074 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| STRING BEAN (UNII: N9D69B2Q7Y) (STRING BEAN - UNII:N9D69B2Q7Y) | | STRING BEAN | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3074-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

FOOD - PLANT SOURCE, TOMATO NICOTIANA SPP.

tomato nicotiana spp. injection, solution

| Product Information | | | | |
|------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3656 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| TOMATO (UNII: Z4KHF2C175) (TOMATO - UNII:Z4KHF2C175) | | TOMATO | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-3656-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | | 04/19/1941 | |

FOOD - PLANT SOURCE, WALNUT, BLACK JUGLANS NIGRA

walnut, black juglans nigra injection, solution

| Product Information | | | | |
|------------------------------------------------------------------|-----------------------------|--------------------|----------------|--|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3695 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| BLACK WALNUT (UNII: 02WM57RXZJ) (BLACK WALNUT - UNII:02WM57RXZJ) | | BLACK WALNUT | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |

SODIUM BICARBONATE (UNII: 8MDF5V39QO)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-3695-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

FOOD - PLANT SOURCE, YEAST, BAKER SACCHAROMYCES CEREVISIAE

yeast, baker saccharomyces cerevisiae injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3713 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------------------------------|-------------------|---------------|
| YEAST (UNII: 3NY3SM6B8U) (YEAST - UNII:3NY3SM6B8U) | YEAST | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-3713-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

FOOD - PLANT SOURCE, YEAST, BREWER SACCHAROMYCES CEREVISIAE

yeast, brewer saccharomyces cerevisiae injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-3716 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------------------------------------------|-------------------|---------------|
| YEAST (UNII: 3NY3SM6B8U) (YEAST - UNII:3NY3SM6B8U) | YEAST | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-3716-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

INSECTS WHOLE BODY COCKROACH, AMERICAN PERIPLANETA AMERICANA

insects whole body cockroach, american periplaneta americana injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-6580 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------------------------|-----------------------|---------------|
| PERIPLANETA AMERICANA (UNII: 2RQ1L9N089) (PERIPLANETA AMERICANA - UNII:2RQ1L9N089) | PERIPLANETA AMERICANA | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |

SODIUM BICARBONATE (UNII: 8MDF5V39QO)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-6580-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-6580-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-6580-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

INSECTS WHOLE BODY COCKROACH, GERMAN BLATELLA GERMANICA

insects whole body cockroach, german blatella germanica injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-6581 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------------------|--------------------|------------------|
| BLATELLA GERMANICA (UNII: G9O67I0A8Q) (BLATELLA GERMANICA - UNII:G9O67I0A8Q) | BLATELLA GERMANICA | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-6581-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-6581-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-6581-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

INSECTS WHOLE BODY COCKROACH MIX

insects whole body cockroach mix injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-6584 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------------------------|-----------------------|---------------|
| PERIPLANETA AMERICANA (UNII: 2RQ1L9N089) (PERIPLANETA AMERICANA - UNII:2RQ1L9N089) | PERIPLANETA AMERICANA | 0.1 g in 1 mL |
| BLATTELLA GERMANICA (UNII: G9O67I0A8Q) (BLATTELLA GERMANICA - UNII:G9O67I0A8Q) | BLATTELLA GERMANICA | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47I08X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-6584-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-6584-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-6584-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

INSECTS WHOLE BODY COCKROACH MIX

insects whole body cockroach mix injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-6587 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------------------------|-----------------------|---------------|
| PERIPLANETA AMERICANA (UNII: 2RQ1L9N089) (PERIPLANETA AMERICANA - UNII:2RQ1L9N089) | PERIPLANETA AMERICANA | 0.1 g in 1 mL |
| BLATTELLA GERMANICA (UNII: G9O67I0A8Q) (BLATTELLA GERMANICA - UNII:G9O67I0A8Q) | BLATTELLA GERMANICA | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-6587-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-6587-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-6587-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

INSECTS WHOLE BODY COCKROACH MIX

insects whole body cockroach mix injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-6588 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------------------------|-----------------------|---------------------|
| PERIPLANETA AMERICANA (UNII: 2RQ1L9N089) (PERIPLANETA AMERICANA - UNII:2RQ1L9N089) | PERIPLANETA AMERICANA | 20000 [PNU] in 1 mL |
| BLATTELLA GERMANICA (UNII: G9O67I0A8Q) (BLATTELLA GERMANICA - UNII:G9O67I0A8Q) | BLATTELLA GERMANICA | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |

SODIUM CHLORIDE (UNII: 451W47IQ8X)

SODIUM BICARBONATE (UNII: 8MDF5V39QO)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-6588-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-6588-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-6588-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

INSECTS WHOLE BODY COCKROACH MIX

insects whole body cockroach mix injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-6589 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|------------------------------------------------------------------------------------|-----------------------|---------------------|
| PERIPLANETA AMERICANA (UNII: 2RQ1L9N089) (PERIPLANETA AMERICANA - UNII:2RQ1L9N089) | PERIPLANETA AMERICANA | 20000 [PNU] in 1 mL |
| BLATTELLA GERMANICA (UNII: G9O67I0A8Q) (BLATTELLA GERMANICA - UNII:G9O67I0A8Q) | BLATTELLA GERMANICA | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-6589-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-6589-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-6589-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

INSECTS WHOLE BODY COCKROACH MIX

insects whole body cockroach mix injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-6590 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------------------------|-----------------------|--------------------|
| PERIPLANETA AMERICANA (UNII: 2RQ1L9N089) (PERIPLANETA AMERICANA - UNII:2RQ1L9N089) | PERIPLANETA AMERICANA | 5000 [PNU] in 1 mL |
| BLATTELLA GERMANICA (UNII: G9O67I0A8Q) (BLATTELLA GERMANICA - UNII:G9O67I0A8Q) | BLATTELLA GERMANICA | 5000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-6590-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-6590-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-6590-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

INSECTS WHOLE BODY, FIRE ANT MIX

insects whole body, fire ant mix injection, solution

Product Information

| | | | |
|--------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-6518 |
|--------------|-----------------------------|--------------------|----------------|

| | | | | |
|----------------------------------------|---------------------------------------------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | SOLENOPSIS RICHTERI (UNII: 739684T11W) (SOLENOPSIS RICHTERI - UNII:739684T11W) | SOLENOPSIS RICHTERI | 0.1 g in 1 mL | |
| | SOLENOPSIS INVICTA (UNII: 507CR4P444) (SOLENOPSIS INVICTA - UNII:507CR4P444) | SOLENOPSIS INVICTA | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | GLYCERIN (UNII: PDC6A3C0OX) | | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-6518-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-6518-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-6518-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| | | | |
|------------------------------------------------------|---------------------------------------------------------------------------------------|---------------------------|-----------------|
| INSECTS WHOLE BODY, FIRE ANT MIX | | | |
| insects whole body, fire ant mix injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-6517 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | SOLENOPSIS RICHTERI (UNII: 739684T11W) (SOLENOPSIS RICHTERI - UNII:739684T11W) | SOLENOPSIS RICHTERI | 0.1 g in 1 mL |
| | SOLENOPSIS INVICTA (UNII: 507CR4P444) (SOLENOPSIS INVICTA - UNII:507CR4P444) | SOLENOPSIS INVICTA | 0.1 g in 1 mL |
| Inactive Ingredients | | | |
| | Ingredient Name | Strength | |

| PHENOL (UNII: 339NCG44TV) | | | | |
|----------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-6517-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-6517-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-6517-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| MOLDS - ALTERNARIA/HORMODENDRUM MIX | | | | |
|---------------------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------|--------------------|
| molds - alternaria/hormodendrum mix injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5004 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H) | | ALTERNARIA ALTERNATA | 0.1 g in 1 mL | |
| CLADOSPORIUM CLADOSPORIOIDES (UNII: 4ZWY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4ZWY20GTGO) | | CLADOSPORIUM CLADOSPORIOIDES | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-5004-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5004-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5004-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

MOLDS - MOLD MIX 10

molds - mold mix 10 injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5136 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------------|
| ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H) | ALTERNARIA ALTERNATA | 0.1 g in 1 mL |
| ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48) | ASPERGILLUS FUMIGATUS | 0.025 g in 1 mL |
| ASPERGILLUS NIDULANS (UNII: 242A53RB80) (ASPERGILLUS NIDULANS - UNII:242A53RB80) | ASPERGILLUS NIDULANS | 0.025 g in 1 mL |
| ASPERGILLUS NIGER VAR. NIGER (UNII: 9IOA40ANG6) (ASPERGILLUS NIGER VAR. NIGER - UNII:9IOA40ANG6) | ASPERGILLUS NIGER VAR. NIGER | 0.025 g in 1 mL |
| ASPERGILLUS TERREUS (UNII: QBN8K7055X) (ASPERGILLUS TERREUS - UNII:QBN8K7055X) | ASPERGILLUS TERREUS | 0.025 g in 1 mL |
| FUSARIUM OXYSPORUM VASINFECTUM (UNII: 6M98DC08TZ) (FUSARIUM OXYSPORUM VASINFECTUM - UNII:6M98DC08TZ) | FUSARIUM OXYSPORUM VASINFECTUM | 0.1 g in 1 mL |
| DENDRYPHIELLA VINOSA (UNII: 7S6NW5FH8X) (DENDRYPHIELLA VINOSA - UNII:7S6NW5FH8X) | DENDRYPHIELLA VINOSA | 0.1 g in 1 mL |
| CLADOSPORIUM CLADOSPORIOIDES (UNII: 4Z WY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4Z WY20GTGO) | CLADOSPORIUM CLADOSPORIOIDES | 0.1 g in 1 mL |
| MUCOR RACEMOSUS (UNII: 17RH99LQ7G) (MUCOR RACEMOSUS - UNII:17RH99LQ7G) | MUCOR RACEMOSUS | 0.1 g in 1 mL |
| PENICILLIUM DIGITATUM (UNII: 1SB49SV239) (PENICILLIUM DIGITATUM - UNII:1SB49SV239) | PENICILLIUM DIGITATUM | 0.02 g in 1 mL |
| PENICILLIUM EXPANSUM (UNII: 1XSC3BB35Z) (PENICILLIUM EXPANSUM - UNII:1XSC3BB35Z) | PENICILLIUM EXPANSUM | 0.02 g in 1 mL |
| PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG) | PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM | 0.02 g in 1 mL |
| CLONOSTACHYS ROSEA F. ROSEA (UNII: I5F729WZ2H) (CLONOSTACHYS ROSEA F. ROSEA - UNII:I5F729WZ2H) | CLONOSTACHYS ROSEA F. ROSEA | 0.02 g in 1 mL |
| PHOMA EXIGUA VAR. EXIGUA (UNII: 8JAG41IE4M) (PHOMA EXIGUA VAR. EXIGUA - UNII:8JAG41IE4M) | PHOMA EXIGUA VAR. EXIGUA | 0.1 g in 1 mL |
| AUREOBASIDIUM PULLULANS VAR. PULLUTANS (UNII: D1A2NG69CK) (AUREOBASIDIUM PULLULANS VAR. PULLUTANS - UNII:D1A2NG69CK) | AUREOBASIDIUM PULLULANS VAR. PULLUTANS | 0.1 g in 1 mL |
| RHIZOPUS STOLONIFER (UNII: FEE198DK4Q) (RHIZOPUS STOLONIFER - UNII:FEE198DK4Q) | RHIZOPUS STOLONIFER | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-5136-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5136-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5136-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

| MOLDS - MOLD MIX 4 | | | |
|---------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------------|----------------|
| molds - mold mix 4 injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5000 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H) | ALTERNARIA ALTERNATA | 0.1 g in 1 mL | |
| ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48) | ASPERGILLUS FUMIGATUS | 0.025 g in 1 mL | |
| ASPERGILLUS NIDULANS (UNII: 242A53RB80) (ASPERGILLUS NIDULANS - UNII:242A53RB80) | ASPERGILLUS NIDULANS | 0.025 g in 1 mL | |
| ASPERGILLUS NIGER VAR. NIGER (UNII: 9IOA40ANG6) (ASPERGILLUS NIGER VAR. NIGER - UNII:9IOA40ANG6) | ASPERGILLUS NIGER VAR. NIGER | 0.025 g in 1 mL | |
| ASPERGILLUS TERREUS (UNII: QBN8K7055X) (ASPERGILLUS TERREUS - UNII:QBN8K7055X) | ASPERGILLUS TERREUS | 0.025 g in 1 mL | |
| CLADOSPORIUM CLADOSPORIOIDES (UNII: 4ZWY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4ZWY20GTGO) | CLADOSPORIUM CLADOSPORIOIDES | 0.1 g in 1 mL | |
| PENICILLIUM DIGITATUM (UNII: 1SB49SV239) (PENICILLIUM DIGITATUM - UNII:1SB49SV239) | PENICILLIUM DIGITATUM | 0.025 g in 1 mL | |
| PENICILLIUM EXPANSUM (UNII: 1XSC3BB35Z) (PENICILLIUM EXPANSUM - UNII:1XSC3BB35Z) | PENICILLIUM EXPANSUM | 0.025 g in 1 mL | |
| PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG) | PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM | 0.025 g in 1 mL | |
| CLONOSTACHYS ROSEA F. ROSEA (UNII: I5F729WZ2H) (CLONOSTACHYS ROSEA F. ROSEA - UNII:I5F729WZ2H) | CLONOSTACHYS ROSEA F. ROSEA | 0.025 g in 1 mL | |
| Inactive Ingredients | | | |
| Ingredient Name | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-5000-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5000-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5000-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

| MOLDS - TRICHOPHYTON MIX | | | |
|------------------------------------------------------------------------------------------------|-----------------------------|-----------------------------|----------------|
| molds - trichophyton mix injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5284 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| TRICHOPHYTON TONSURANS (UNII: JY1BE33I3Y) (TRICHOPHYTON TONSURANS - UNII:JY1BE33I3Y) | | TRICHOPHYTON TONSURANS | 0.1 g in 1 mL |
| TRICHOPHYTON RUBRUM (UNII: 2ZAU32517N) (TRICHOPHYTON RUBRUM - UNII:2ZAU32517N) | | TRICHOPHYTON RUBRUM | 0.1 g in 1 mL |
| TRICHOPHYTON MENTAGROPHYTES (UNII: 199I7J3JIV) (TRICHOPHYTON MENTAGROPHYTES - UNII:199I7J3JIV) | | TRICHOPHYTON MENTAGROPHYTES | 0.1 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-5284-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5284-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5284-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|---------------------------------|-----------------|---------------|
| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
| | | | |

| Category | Citation | Date | Date |
|----------|-----------|------------|------|
| BLA | BLA103888 | 04/19/1941 | |

MOLDS, PENICILLIUM MIX

molds, penicillium mix injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5168 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|------------------|
| PENICILLIUM DIGITATUM (UNII: 1SB49SV239) (PENICILLIUM DIGITATUM - UNII:1SB49SV239) | PENICILLIUM DIGITATUM | 0.1 g in 1 mL |
| PENICILLIUM EXPANSUM (UNII: 1XSC3BB35Z) (PENICILLIUM EXPANSUM - UNII:1XSC3BB35Z) | PENICILLIUM EXPANSUM | 0.1 g in 1 mL |
| PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG) | PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM | 0.1 g in 1 mL |
| CLONOSTACHYS ROSEA F. ROSEA (UNII: I5F729WZ 2H) (CLONOSTACHYS ROSEA F. ROSEA - UNII:I5F729WZ 2H) | CLONOSTACHYS ROSEA F. ROSEA | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-5168-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5168-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5168-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

MOLDS, RUSTS AND SMUTS, ALTERNARIA TENUIS

alternaria tenuis injection, solution

Product Information

| | | | |
|---------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5008 |
|---------------------|-----------------------------|---------------------------|----------------|

| | | | | |
|----------------------------------------|----------------------------------------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H) | ALTERNARIA ALTERNATA | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | GLYCERIN (UNII: PDC6A3C0OX) | | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-5008-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5008-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5008-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| | | | |
|------------------------------------------------------|------------------------------------------------------------------------------------|---------------------------|-----------------|
| MOLDS, RUSTS AND SMUTS, ASPERGILLUS FUMIGATUS | | | |
| aspergillus fumigatus injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5020 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48) | ASPERGILLUS FUMIGATUS | 0.1 g in 1 mL |
| Inactive Ingredients | | | |
| | Ingredient Name | Strength | |
| | GLYCERIN (UNII: PDC6A3C0OX) | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-5020-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5020-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5020-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

| MOLDS, RUSTS AND SMUTS, ASPERGILLUS NIGER | | | | |
|--------------------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| aspergillus niger injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5032 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| ASPERGILLUS NIGER VAR. NIGER (UNII: 9IOA40ANG6) (ASPERGILLUS NIGER VAR. NIGER - UNII:9IOA40ANG6) | | ASPERGILLUS NIGER VAR. NIGER | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-5032-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5032-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5032-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

MOLDS, RUSTS AND SMUTS, BOTRYTIS CINEREA

botrytis cinerea injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5048 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------|-------------------|------------------|
| BOTRYTIS CINEREA (UNII: TBW53313S7) (BOTRYTIS CINEREA - UNII:TBW53313S7) | BOTRYTIS CINEREA | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-5048-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5048-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5048-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

INSECTS WHOLE BODY, ANT, FIRE SOLENOPSIS INVICTA

ant, fire solenopsis invicta injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-6513 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|------------------------------------------------------------------|-------------------|----------|
| SOLENOPTIS INVICTA (UNII: F073D4D444) (SOLENOPTIS INVICTA | | 0.1 g |

| | | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------|----------------------------------------------------|-----------------------------|
| SOLENOPSIS INVICTA (UNII: 507CR4P444) (SOLENOPSIS INVICTA - UNII:507CR4P444) | | SOLENOPSIS INVICTA | 0.1 g in 1 mL |
| Inactive Ingredients | | | |
| | | Ingredient Name | Strength |
| | | GLYCERIN (UNII: PDC6A3C00X) | |
| | | SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| | | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |
| Packaging | | | |
| # | Item Code | Package Description | Marketing Start Date |
| 1 | NDC:65044-6513-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | |
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

| | | | |
|-------------------------------------------------|-----------------------------|--------------------------------------------------------------------------|-----------------------------|
| MOLDS, RUSTS AND SMUTS, CANDIDA ALBICANS | | | |
| candida albicans injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5052 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| | | Ingredient Name | Basis of Strength |
| | | CANDIDA ALBICANS (UNII: 4D7G21HDBC) (CANDIDA ALBICANS - UNII:4D7G21HDBC) | 0.1 g in 1 mL |
| Inactive Ingredients | | | |
| | | Ingredient Name | Strength |
| | | GLYCERIN (UNII: PDC6A3C00X) | |
| | | SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| | | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |
| Packaging | | | |
| # | Item Code | Package Description | Marketing Start Date |
| 1 | NDC:65044-5052-1 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | |
| 2 | NDC:65044-5052-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | |
| 3 | NDC:65044-5052-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

MOLDS, RUSTS AND SMUTS, CANDIDA ALBICANS

candida albicans injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5055 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------|-------------------|--------------------|
| CANDIDA ALBICANS (UNII: 4D7G21HD8C) (CANDIDA ALBICANS - UNII:4D7G21HD8C) | CANDIDA ALBICANS | 0.001 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-5055-1 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5055-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5055-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

MOLDS, RUSTS AND SMUTS, CEPHALOSPORIUM ACREMONIUM

cephalosporium acremonium injection, solution

Product Information

| | | | |
|--------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5056 |
|--------------|-----------------------------|--------------------|----------------|

| | | | | |
|----------------------------------------|----------------------------------------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | SAROCLADIUM STRICTUM (UNII: 3F36V0451W) (SAROCLADIUM STRICTUM - UNII:3F36V0451W) | SAROCLADIUM STRICTUM | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | GLYCERIN (UNII: PDC6A3C00X) | | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-5056-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5056-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5056-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| | | | |
|-----------------------------------------------------|------------------------------------------------------------------------------------|---------------------------|-----------------|
| MOLDS, RUSTS AND SMUTS, CURVULARIA SPICIFERA | | | |
| curvularia spicifera injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5076 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | COCHLIOBOLUS SPICIFER (UNII: 91M9RWP3TD) (COCHLIOBOLUS SPICIFER - UNII:91M9RWP3TD) | COCHLIOBOLUS SPICIFER | 0.1 g in 1 mL |
| Inactive Ingredients | | | |
| | Ingredient Name | Strength | |
| | GLYCERIN (UNII: PDC6A3C00X) | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-5076-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5076-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5076-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

| MOLDS, RUSTS AND SMUTS, EPICOCCUM NIGRUM | | | | |
|--------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| epicoccum nigrum injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5100 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| EPICOCCUM NIGRUM (UNII: 87U156LEN7) (EPICOCCUM NIGRUM - UNII:87U156LEN7) | | EPICOCCUM NIGRUM | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-5100-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5100-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5100-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| | | | | |

| | | | |
|-----|-----------|------------|--|
| BLA | BLA103888 | 04/19/1941 | |
|-----|-----------|------------|--|

MOLDS, RUSTS AND SMUTS, EPIDERMOPHYTON FLOCCOSUM

epidermophyton floccosum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5104 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------------------------------|--------------------------|---------------|
| EPIDERMOPHYTON FLOCCOSUM (UNII: 6JR6JTN25S) (EPIDERMOPHYTON FLOCCOSUM - UNII:6JR6JTN25S) | EPIDERMOPHYTON FLOCCOSUM | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-5104-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5104-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5104-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

MOLDS, RUSTS AND SMUTS, FUSARIUM VASINFECTUM

fusarium vasinfectum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5112 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------------------------------------------|--------------------------------|---------------|
| FUSARIUM OXYSPORUM VASINFECTUM (UNII: 6M98DC08TZ) (FUSARIUM OXYSPORUM VASINFECTUM - UNII:6M98DC08TZ) | FUSARIUM OXYSPORUM VASINFECTUM | 0.1 g in 1 mL |

| Inactive Ingredients | | | | |
|---------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-5112-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5112-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5112-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| MOLDS, RUSTS AND SMUTS, HELMINTHOSPORIUM INTERSEMINATUM | | | | |
|-----------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------|--------------------|
| helminthosporium interseminatum injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5124 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| DENDRYPHIELLA VINOSA (UNII: 7S6NW5FH8X) (DENDRYPHIELLA VINOSA - UNII: 7S6NW5FH8X) | | DENDRYPHIELLA VINOSA | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-5124-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| | | | | |
|------------------------------|-------------------------------------------------|----------------------------------------------------|---------------------------|--|
| 2 | NDC:65044-5124-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5124-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

MOLDS, RUSTS AND SMUTS, HORMODENDRUM CLADOSPORIOIDES

hormodendrum cladosporioides injection, solution

| | | | | |
|----------------------------------------|--------------------------------------------------------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5128 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | CLADOSPORIUM CLADOSPORIOIDES (UNII: 4ZWY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4ZWY20GTGO) | CLADOSPORIUM CLADOSPORIOIDES | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | GLYCERIN (UNII: PDC6A3C00X) | | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-5128-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5128-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5128-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

MOLDS, RUSTS AND SMUTS, MUCOR RACEMOSUS

mucor racemosus injection, solution

| Product Information | | | | |
|------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5144 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| MUCOR RACEMOSUS (UNII: 17RH99LQ7G) (MUCOR RACEMOSUS - UNII:17RH99LQ7G) | | MUCOR RACEMOSUS | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-5144-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5144-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5144-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| MOLDS, RUSTS AND SMUTS, PENICILLIUM NOTATUM | | | |
|--------------------------------------------------------------------------------------------------------------------------|-----------------------------|------------------------------------------|------------------|
| penicillium notatum injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5208 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG) | | PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM | 0.1 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | |

| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
|----------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-5208-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5208-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5208-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| MOLDS, RUSTS AND SMUTS, PHOMA HERBARUM | | | | |
|-------------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------|--------------------|
| phoma herbarum injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5220 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| PHOMA EXIGUA VAR. EXIGUA (UNII: 8JAG41IE4M) (PHOMA EXIGUA VAR. EXIGUA - UNII:8JAG41IE4M) | PHOMA EXIGUA VAR. EXIGUA | 0.1 g in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-5220-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5220-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5220-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

MOLDS, RUSTS AND SMUTS, PULLULARIA PULLULANS

pullularia pullulans injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5235 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|------------------|
| AUREOBASIDIUM PULLULANS VAR. PULLUTANS (UNII: D1A2NG69CK) (AUREOBASIDIUM PULLULANS VAR. PULLUTANS - UNII:D1A2NG69CK) | AUREOBASIDIUM PULLULANS VAR. PULLUTANS | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-5235-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5235-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5235-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

MOLDS, RUSTS AND SMUTS, RHIZOPUS NIGRICANS

rhizopus nigricans injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5230 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|--------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| RHIZOPUS STOLONIFER (UNII: FEE198DK4Q) (RHIZOPUS STOLONIFER - UNII:FEE198DK4Q) | | RHIZOPUS STOLONIFER | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-5230-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5230-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5230-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| MOLDS, RUSTS AND SMUTS, STEMPHYLIUM BOTRYOSUM | | | | |
|-------------------------------------------------------------------------|-----------------------------|---------------------|----------------------|--------------------|
| stemphylium botryosum injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-5264 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| PLEOSPORA TARDA (UNII: TPL549N9R8) (PLEOSPORA TARDA - UNII: TPL549N9R8) | | PLEOSPORA TARDA | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |

| | | | | |
|---|------------------|----------------------------------------------------|--|--|
| 1 | NDC:65044-5264-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-5264-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-5264-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - GRASSES, BAHIA GRASS PASPALUM NOTATUM

bahia grass paspalum notatum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1081 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------------------------------------------------------------------|-------------------------|----------------|
| PASPALUM NOTATUM POLLEN (UNII: V003SHB7VK) (PASPALUM NOTATUM POLLEN - UNII:V003SHB7VK) | PASPALUM NOTATUM POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1081-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1081-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1081-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - GRASSES, BAHIA GRASS PASPALUM NOTATUM

bahia grass paspalum notatum injection, solution

| Product Information | | | | |
|----------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1084 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| PASPALUM NOTATUM POLLEN (UNII: V003SHB7VK) (PASPALUM NOTATUM POLLEN - UNII:V003SHB7VK) | | PASPALUM NOTATUM POLLEN | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1084-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1084-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1084-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| POLLENS - GRASSES, BROME, SMOOTH BROMUS INERMIS | | | |
|------------------------------------------------------------------------------------|-----------------------------|-----------------------|----------------|
| brome, smooth bromus inermis injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1237 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| BROMUS INERMIS POLLEN (UNII: 766QT72BK6) (BROMUS INERMIS POLLEN - UNII:766QT72BK6) | | BROMUS INERMIS POLLEN | 0.05 g in 1 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | | Strength |

| GLYCERIN (UNII: PDC6A3C00X) | | | | |
|----------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1237-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1237-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1237-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| POLLENS - GRASSES, CORN, CULTIVATED ZEA MAYS | | | | |
|-------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------|--------------------|
| corn, cultivated zea mays injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1414 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| ZEA MAYS POLLEN (UNII: 74PD8J616H) (ZEA MAYS POLLEN - UNII:74PD8J616H) | ZEA MAYS POLLEN | 0.05 g in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1414-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1414-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1414-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - GRASSES, JOHNSON GRASS SORGHUM HALEPENSE

johnson grass sorghum halepense injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1744 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | |
|------------------------------------------------------------------------------------------|--------------------------|----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP) | SORGHUM HALEPENSE POLLEN | 0.05 g in 1 mL | |

| Inactive Ingredients | |
|---------------------------------------|----------|
| Ingredient Name | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

| Packaging | | | | |
|-----------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1744-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1744-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1744-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - GRASSES, JOHNSON GRASS SORGHUM HALEPENSE

johnson grass sorghum halepense injection, solution

| Product Information | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1747 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|------------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP) | | SORGHUM HALEPENSE POLLEN | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| PHENOL (UNII: 339NCG44TV) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1747-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1747-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1747-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - GRASSES, OATS, COMMON, CULTIVATED AVENA SATIVA
oats, common, cultivated avena sativa injection, solution

| Product Information | | | | |
|--------------------------------------------------------------------------------|-----------------------------|---------------------|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2041 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| AVENA SATIVA POLLEN (UNII: A7IKY24TR7) (AVENA SATIVA POLLEN - UNII:A7IKY24TR7) | | AVENA SATIVA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |

| | | | | |
|---|------------------|----------------------------------------------------|--|--|
| 1 | NDC:65044-2041-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2041-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2041-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - GRASSES, GRASS MIX 8

grass mix 8 injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-0879 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T) | POA PRATENSIS POLLEN | 100000 [BAU] in 1 mL |
| CYNODON DACTYLON POLLEN (UNII: 175F461W10) (CYNODON DACTYLON POLLEN - UNII:175F461W10) | CYNODON DACTYLON POLLEN | 10000 [BAU] in 1 mL |
| SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP) | SORGHUM HALEPENSE POLLEN | 0.05 g in 1 mL |
| AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA) | AGROSTIS GIGANTEA POLLEN | 100000 [BAU] in 1 mL |
| PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG) | PHLEUM PRATENSE POLLEN | 100000 [BAU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-0879-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - GRASSES, SOUTHERN GRASS MIX

pollens - grasses, southern grass mix injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-0854 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------------------|------------------------------|----------------------|
| POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T) | POA PRATENSIS POLLEN | 100000 [BAU] in 1 mL |
| DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P) | DACTYLIS GLOMERATA POLLEN | 100000 [BAU] in 1 mL |
| AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA) | AGROSTIS GIGANTEA POLLEN | 100000 [BAU] in 1 mL |
| PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG) | PHLEUM PRATENSE POLLEN | 100000 [BAU] in 1 mL |
| ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y) | ANTHOXANTHUM ODORATUM POLLEN | 100000 [BAU] in 1 mL |
| SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP) | SORGHUM HALEPENSE POLLEN | 0.05 g in 1 mL |
| CYNODON DACTYLON POLLEN (UNII: 175F461W10) (CYNODON DACTYLON POLLEN - UNII:175F461W10) | CYNODON DACTYLON POLLEN | 10000 [BAU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-0854-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-0854-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-0854-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - GRASSES, SOUTHERN GRASS MIX

pollens - grasses, southern grass mix injection, solution

Product Information

| | | | | |
|----------------------------------------|---------------------------------------------------------------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-0856 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T) | POA PRATENSIS POLLEN | 10000 [BAU] in 1 mL | |
| | DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P) | DACTYLIS GLOMERATA POLLEN | 10000 [BAU] in 1 mL | |
| | AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA) | AGROSTIS GIGANTEA POLLEN | 10000 [BAU] in 1 mL | |
| | PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG) | PHLEUM PRATENSE POLLEN | 10000 [BAU] in 1 mL | |
| | ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y) | ANTHOXANTHUM ODORATUM POLLEN | 10000 [BAU] in 1 mL | |
| | SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP) | SORGHUM HALEPENSE POLLEN | 0.005 g in 1 mL | |
| | CYNODON DACTYLON POLLEN (UNII: 175F461W10) (CYNODON DACTYLON POLLEN - UNII:175F461W10) | CYNODON DACTYLON POLLEN | 1000 [BAU] in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | GLYCERIN (UNII: PDC6A3C0OX) | | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-0856-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-0856-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-0856-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - TREES, ACACIA ACACIA LONGIFOLIA

acacia longifolia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1006 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|------------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| ACACIA LONGIFOLIA POLLEN (UNII: 24SO2J296O) (ACACIA LONGIFOLIA POLLEN - UNII:24SO2J296O) | | ACACIA LONGIFOLIA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1006-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1006-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1006-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - TREES, ALDER, RED ALNUS RUBRA

alder, red alnus rubra injection, solution

| Product Information | | | | |
|------------------------------------------------------------------------------|-----------------------------|---------------------|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1018 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| ALNUS RUBRA POLLEN (UNII: Z0F2YK1B7H) (ALNUS RUBRA POLLEN - UNII:Z0F2YK1B7H) | | ALNUS RUBRA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |

| | | | | |
|---|------------------|----------------------------------------------------|--|--|
| 1 | NDC:65044-1018-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1018-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1018-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, ALDER, RED ALNUS RUBRA

alder, red alnus rubra injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1021 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|------------------------------------------------------------------------------|--------------------|---------------|
| ALNUS RUBRA POLLEN (UNII: Z0F2YK1B7H) (ALNUS RUBRA POLLEN - UNII:Z0F2YK1B7H) | ALNUS RUBRA POLLEN | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1021-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1021-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1021-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, ASH, WHITE FRAXINUS AMERICANA

ash, white fraxinus americana injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1060 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------------|---------------------------|-------------------|
| FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q) | FRAXINUS AMERICANA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1060-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1060-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1060-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, BEECH, AMERICAN FAGUS GRANDIFOLIA

beech, american fagus grandifolia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1120 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------------------------------|--------------------------|-------------------|
| FAGUS GRANDIFOLIA POLLEN (UNII: 34X886W1H4) (FAGUS GRANDIFOLIA POLLEN - UNII:34X886W1H4) | FAGUS GRANDIFOLIA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

| GLYCERIN (UNII: PDC6A3C00X) | | | | |
|----------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1120-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1120-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1120-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| POLLENS - TREES, BIRCH MIX | | | | |
|-------------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------|--------------------|
| birch mix injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1168 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| BETULA PAPYRIFERA POLLEN (UNII: 3538FNV8AY) (BETULA PAPYRIFERA POLLEN - UNII:3538FNV8AY) | BETULA PAPYRIFERA POLLEN | 0.05 g in 1 mL | | |
| BETULA PENDULA POLLEN (UNII: ZL5TV40C5Y) (BETULA PENDULA POLLEN - UNII:ZL5TV40C5Y) | BETULA PENDULA POLLEN | 0.05 g in 1 mL | | |
| BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P) | BETULA NIGRA POLLEN | 0.05 g in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1168-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1168-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044- | 50 mL in 1 VIAL; Type 0: Not a Combination | | |

| 1168-4 | Product | | |
|------------------------------|------------------------------------------|----------------------|--------------------|
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, BIRCH MIX
birch mix injection, solution

| Product Information | | | |
|----------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1171 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | |
|-------------------------------------------------------------------------------------------------|--------------------------|---------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| BETULA Papyrifera Pollen (UNII: 3538FNV8AY) (BETULA Papyrifera Pollen - UNII:3538FNV8AY) | BETULA Papyrifera Pollen | 0.1 g in 1 mL | |
| BETULA Pendula Pollen (UNII: ZL5TV40C5Y) (BETULA Pendula Pollen - UNII:ZL5TV40C5Y) | BETULA Pendula Pollen | 0.1 g in 1 mL | |
| BETULA Nigra Pollen (UNII: 93963RFO1P) (BETULA Nigra Pollen - UNII:93963RFO1P) | BETULA Nigra Pollen | 0.1 g in 1 mL | |

| Inactive Ingredients | |
|----------------------------------------------|----------|
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

| Packaging | | | | |
|------------------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1171-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1171-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1171-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|------------------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, BIRCH MIX
birch mix injection, solution

| Product Information | | | | |
|-------------------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1172 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| BETULA PAPYRIFERA POLLEN (UNII: 3538FNV8AY) (BETULA PAPYRIFERA POLLEN - UNII:3538FNV8AY) | BETULA PAPYRIFERA POLLEN | 20000 [PNU] in 1 mL | | |
| BETULA PENDULA POLLEN (UNII: ZL5TV40C5Y) (BETULA PENDULA POLLEN - UNII:ZL5TV40C5Y) | BETULA PENDULA POLLEN | 40000 [PNU] in 1 mL | | |
| BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P) | BETULA NIGRA POLLEN | 40000 [PNU] in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| PHENOL (UNII: 339NCG44TV) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1172-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1172-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1172-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - TREES, BOTTLE BRUSH CALLISTEMON SPP.

bottle brush callistemon spp. injection, solution

| Product Information | | | |
|-------------------------------------------------------------------------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1207 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| MELALEUCA CITRINA POLLEN (UNII: 620II98F1T) (MELALEUCA CITRINA POLLEN - UNII:620II98F1T) | MELALEUCA CITRINA POLLEN | 0.05 g in 1 mL | |

| Inactive Ingredients | | | | |
|---------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1207-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1207-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1207-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | | 04/19/1941 | |

| POLLENS - TREES, BOXELDER/MAPLE MIX | | | | |
|------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|-----------------------|--------------------|
| boxelder/maple mix injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | | Item Code (Source) | NDC:65044-1213 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | | Basis of Strength | Strength |
| ACER NEGUNDO POLLEN (UNII: P6K070AR8V) (ACER NEGUNDO POLLEN - UNII:P6K070AR8V) | | | ACER NEGUNDO POLLEN | 0.05 g in 1 mL |
| ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861) | | | ACER SACCHARUM POLLEN | 0.05 g in 1 mL |
| ACER RUBRUM POLLEN (UNII: 700NK45C76) (ACER RUBRUM POLLEN - UNII:700NK45C76) | | | ACER RUBRUM POLLEN | 0.05 g in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1213-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| | | | | |
|------------------------------|-------------------------------------------------|----------------------------------------------------|---------------------------|--|
| 2 | NDC:65044-1213-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1213-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - TREES, BOXELDER/MAPLE MIX
boxelder/maple mix injection, solution

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1216 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| | | |
|-------------------------------------------------------------------------------------------|--------------------------|-----------------|
| Active Ingredient/Active Moiety | | |
| Ingredient Name | Basis of Strength | Strength |
| ACER NEGUNDO POLLEN (UNII: P6K070AR8V) (ACER NEGUNDO POLLEN - UNII:P6K070AR8V) | ACER NEGUNDO POLLEN | 0.1 g in 1 mL |
| ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861) | ACER SACCHARUM POLLEN | 0.1 g in 1 mL |
| ACER RUBRUM POLLEN (UNII: 700NK45C76) (ACER RUBRUM POLLEN - UNII:700NK45C76) | ACER RUBRUM POLLEN | 0.1 g in 1 mL |

| | |
|----------------------------------------------|-----------------|
| Inactive Ingredients | |
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

| | | | | |
|------------------|------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1216-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1216-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1216-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| | | | |
|------------------------------|-------------------------------------------------|-----------------------------|---------------------------|
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, BOXELDER/MAPLE MIX

boxelder/maple mix injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1217 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------------------------|-----------------------|---------------------|
| ACER NEGUNDO POLLEN (UNII: P6K070AR8V) (ACER NEGUNDO POLLEN - UNII:P6K070AR8V) | ACER NEGUNDO POLLEN | 40000 [PNU] in 1 mL |
| ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861) | ACER SACCHARUM POLLEN | 40000 [PNU] in 1 mL |
| ACER RUBRUM POLLEN (UNII: 700NK45C76) (ACER RUBRUM POLLEN - UNII:700NK45C76) | ACER RUBRUM POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1217-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1217-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1217-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, CEDAR, MOUNTAIN JUNIPERUS ASHEI

cedar, mountain juniperus ashei injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1336 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | | | |
|---------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| JUNIPERUS ASHEI POLLEN (UNII: 544F8MEY0Y) (JUNIPERUS ASHEI POLLEN - UNII:544F8MEY0Y) | | JUNIPERUS ASHEI POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| | | Ingredient Name | Strength | |
| | | GLYCERIN (UNII: PDC6A3C00X) | | |
| | | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | |
| | | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1336-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1336-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1336-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| | | | | |
|---------------------------------------------------------|-----------------------------|--------------------------------------------------------------------------------------|-----------------------------|---------------------------|
| POLLENS - TREES, CEDAR, MOUNTAIN JUNIPERUS ASHEI | | | | |
| cedar, mountain juniperus ashei injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1339 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | | Ingredient Name | Basis of Strength | Strength |
| | | JUNIPERUS ASHEI POLLEN (UNII: 544F8MEY0Y) (JUNIPERUS ASHEI POLLEN - UNII:544F8MEY0Y) | JUNIPERUS ASHEI POLLEN | 0.1 g in 1 mL |
| Inactive Ingredients | | | | |
| | | Ingredient Name | Strength | |
| | | PHENOL (UNII: 339NCG44TV) | | |
| | | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | |
| | | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044- | 10 mL in 1 VIAL; Type 0: Not a Combination | | |

| | | | | |
|---|------------------|----------------------------------------------------|--|--|
| 1 | 1339-2 | Product | | |
| 2 | NDC:65044-1339-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1339-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, CEDAR, RED JUNIPERUS VIRGINIANA

cedar, red juniperus virginiana injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1343 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------------------------------------|-----------------------------|----------------|
| JUNIPERUS VIRGINIANA POLLEN (UNII: PY0JA16R2G) (JUNIPERUS VIRGINIANA POLLEN - UNII:PY0JA16R2G) | JUNIPERUS VIRGINIANA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1343-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1343-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1343-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, CEDAR, RED JUNIPERUS VIRGINIANA

cedar, red juniperus virginiana injection, solution

| Product Information | | | | |
|------------------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1342 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| JUNIPERUS VIRGINIANA POLLEN (UNII: PY0JA16R2G) (JUNIPERUS VIRGINIANA POLLEN - UNII:PY0JA16R2G) | | JUNIPERUS VIRGINIANA POLLEN | 0.1 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| PHENOL (UNII: 339NCG44TV) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1342-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1342-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1342-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| POLLENS - TREES, COTTONWOOD, COMMON POPULUS DELTOIDES | | | | |
|------------------------------------------------------------------------------------------|-----------------------------|---------------------------|----------------|--|
| cottonwood, common populus deltoides injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1435 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| POPULUS DELTOIDES POLLEN (UNII: 476DVV63WP) (POPULUS DELTOIDES POLLEN - UNII:476DVV63WP) | | POPULUS DELTOIDES POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |

SODIUM BICARBONATE (UNII: 8MDF5V39QO)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1435-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1435-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1435-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, COTTONWOOD, COMMON POPULUS DELTOIDES

cottonwood, common populus deltoides injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1438 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------------------------------|--------------------------|---------------------|
| POPULUS DELTOIDES POLLEN (UNII: 476DVV63WP) (POPULUS DELTOIDES POLLEN - UNII:476DVV63WP) | POPULUS DELTOIDES POLLEN | 20000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1438-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1438-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1438-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, CYPRESS, ARIZONA CUPRESSUS ARIZONICA

cypress, arizona cupressus arizonica injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1450 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------------------------------------------------------------------------|----------------------------|----------------|
| CUPRESSUS ARIZONICA POLLEN (UNII: 232DMH0XVF) (CUPRESSUS ARIZONICA POLLEN - UNII:232DMH0XVF) | CUPRESSUS ARIZONICA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1450-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1450-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1450-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, CYPRESS, BALD TAXODIUM DISTICHUM

cypress, bald taxodium distichum injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1453 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|--------------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| TAXODIUM DISTICHUM POLLEN (UNII: O12H03B41R) (TAXODIUM DISTICHUM POLLEN - UNII:O12H03B41R) | | TAXODIUM DISTICHUM POLLEN | 0.02 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1453-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1453-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1453-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

POLLENS - TREES, ELM, AMERICAN ULMUS AMERICANA

elm, american ulmus americana injection, solution

| Product Information | | | | |
|--------------------------------------------------------------------------------------|-----------------------------|------------------------|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1540 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | | ULMUS AMERICANA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |

| | | | | |
|---|------------------|----------------------------------------------------|--|--|
| 1 | NDC:65044-1540-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1540-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1540-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, ELM, AMERICAN ULMUS AMERICANA

elm, american ulmus americana injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1543 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------|------------------------|---------------|
| ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | ULMUS AMERICANA POLLEN | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1543-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1543-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1543-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, ELM, AMERICAN ULMUS AMERICANA

elm, american ulmus americana injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1544 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------|------------------------|---------------------|
| ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD) | ULMUS AMERICANA POLLEN | 40000 [PNU] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1544-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1544-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1544-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, ELM, CHINESE ULMUS PARVIFOLIA

elm, chinese ulmus parvifolia injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1546 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------------------------------------------------------------------------------|-------------------------|----------------|
| ULMUS PARVIFOLIA POLLEN (UNII: IU0Z41653U) (ULMUS PARVIFOLIA POLLEN - UNII:IU0Z41653U) | ULMUS PARVIFOLIA POLLEN | 0.05 g in 1 mL |

| Inactive Ingredients | | | | |
|---------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1546-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1546-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1546-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | | 04/19/1941 | |

| POLLENS - TREES, EUCALYPTUS, EUCALYPTUS GLOBULUS | | | | |
|-----------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------|--------------------|
| eucalyptus, eucalyptus globulus injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1564 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| EUCALYPTUS GLOBULUS POLLEN (UNII: 7XW7TB10X9) (EUCALYPTUS GLOBULUS POLLEN - UNII: 7XW7TB10X9) | | EUCALYPTUS GLOBULUS POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1564-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1564-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1564-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, GUM, SWEET LIQUIDAMBAR STYRACIFLUA

gum, sweet liquidambar styraciflua injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1660 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|------------------------------------------------------------------------------------------------------|--------------------------------|----------------|
| LIQUIDAMBAR STYRACIFLUA POLLEN (UNII: 5Q246DS5BS) (LIQUIDAMBAR STYRACIFLUA POLLEN - UNII:5Q246DS5BS) | LIQUIDAMBAR STYRACIFLUA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1660-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1660-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1660-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, GUM, SWEET LIQUIDAMBAR STYRACIFLUA

gum, sweet liquidambar styraciflua injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1662 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|------------------------------------------------------------------------------------------------------|--------------------------------|---------------|
| LIQUIDAMBAR STYRACIFLUA POLLEN (UNII: 5Q246DS5BS) (LIQUIDAMBAR STYRACIFLUA POLLEN - UNII:5Q246DS5BS) | LIQUIDAMBAR STYRACIFLUA POLLEN | 0.1 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1662-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1662-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1662-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, HACKBERRY CELTIS OCCIDENTALIS

hackberry celtis occidentalis injection, solution

Product Information

| | | | |
|-------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1663 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------------------------------------------------------------------------|----------------------------|----------------|
| CELTIS OCCIDENTALIS POLLEN (UNII: 68R9X9Y96X) (CELTIS OCCIDENTALIS POLLEN - UNII:68R9X9Y96X) | CELTIS OCCIDENTALIS POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1663-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1663-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1663-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, HICKORY, SHAGBARK CARYA OVATA

hickory, shagbark carya ovata injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1702 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------------------|--------------------|-------------------|
| CARYA OVATA POLLEN (UNII: 54UN9R2798) (CARYA OVATA POLLEN - UNII:54UN9R2798) | CARYA OVATA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1702-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1702-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1702-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, LINDEN BASSWOOD TILIA AMERICANA

linden basswood tilia americana injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1801 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------------|------------------------|-------------------|
| TILIA AMERICANA POLLEN (UNII: E2B4Q4BXJG) (TILIA AMERICANA POLLEN - UNII:E2B4Q4BXJG) | TILIA AMERICANA POLLEN | 0.05 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:65044-1801-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1801-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1801-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, MAPLE, HARD ACER SACCHARUM

maple, hard acer saccharum injection, solution

Product Information

| | | | |
|--------------------------------|-----------------------------|---------------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1831 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-------------------------------------------------------------------------------------------|-----------------------|-------------------|
| ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861) | ACER SACCHARUM POLLEN | 0.05 g in 1 mL |

| Inactive Ingredients | | | | |
|---------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1831-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1831-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1831-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | | 04/19/1941 | |

| POLLENS - TREES, MELALEUCA PUNK TREE MELALEUCA QUINQUENERVIA | | | | |
|-------------------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------|--------------------|
| melaleuca punk tree melaleuca quinquenervia injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1873 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| MELALEUCA QUINQUENERVIA POLLEN (UNII: NX974IRT8E) (MELALEUCA QUINQUENERVIA POLLEN - UNII: NX974IRT8E) | | MELALEUCA QUINQUENERVIA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1873-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1873-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| | | | | |
|------------------------------|-------------------------------------------------|----------------------------------------------------|---------------------------|--|
| 3 | NDC:65044-1873-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| | | | | |
|------------------------------------------------------|--------------------------------------------------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| POLLENS - TREES, MESQUITE, PROSOPIS JULIFLORA | | | | |
| mesquite, prosopis juliflora injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1876 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | PROSOPIS JULIFLORA POLLEN (UNII: 6EIJ3D04MR) (PROSOPIS JULIFLORA POLLEN - UNII:6EIJ3D04MR) | PROSOPIS JULIFLORA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | GLYCERIN (UNII: PDC6A3C00X) | | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1876-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1876-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1876-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| | | | | |
|--------------------------------------|-----------------------------|---------------------------|----------------|--|
| POLLENS - TREES, MULBERRY MIX | | | | |
| mulberry mix injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1909 | |

| | | | | |
|----------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------|-----------------------------|---------------------------|
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | MORUS ALBA POLLEN (UNII: 3I9T68187H) (MORUS ALBA POLLEN - UNII:3I9T68187H) | MORUS ALBA POLLEN | 0.05 g in 1 mL | |
| | MORUS RUBRA POLLEN (UNII: 9LYI4RTZ52) (MORUS RUBRA POLLEN - UNII:9LYI4RTZ52) | MORUS RUBRA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | GLYCERIN (UNII: PDC6A3C00X) | | | |
| | SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| | SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1909-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1909-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1909-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| | | | |
|----------------------------------------|-------------------------------------------------------------------------------------|---------------------------|-----------------|
| POLLENS - TREES, MULBERRY MIX | | | |
| mulberry mix injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-1912 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | MORUS ALBA POLLEN (UNII: 3I9T68187H) (MORUS ALBA POLLEN - UNII:3I9T68187H) | MORUS ALBA POLLEN | 0.1 g in 1 mL |
| | MORUS RUBRA POLLEN (UNII: 9LYI4RTZ52) (MORUS RUBRA POLLEN - UNII:9LYI4RTZ52) | MORUS RUBRA POLLEN | 0.1 g in 1 mL |
| Inactive Ingredients | | | |
| | Ingredient Name | Strength | |

| PHENOL (UNII: 339NCG44TV) | | | | |
|----------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-1912-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-1912-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-1912-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| POLLENS - TREES, OAK MIX | | | | |
|---------------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------|--------------------|
| oak mix injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2035 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| QUERCUS RUBRA POLLEN (UNII: SVW19ET93C) (QUERCUS RUBRA POLLEN - UNII:SVW19ET93C) | | QUERCUS RUBRA POLLEN | 0.05 g in 1 mL | |
| QUERCUS VIRGINIANA POLLEN (UNII: 8KDG09A4GO) (QUERCUS VIRGINIANA POLLEN - UNII:8KDG09A4GO) | | QUERCUS VIRGINIANA POLLEN | 0.05 g in 1 mL | |
| QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK) | | QUERCUS ALBA POLLEN | 0.05 g in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2035-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2035-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044- | 50 mL in 1 VIAL; Type 0: Not a Combination | | |

| 2035-4 | Product | | |
|------------------------------|------------------------------------------|----------------------|--------------------|
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, OAK MIX
oak mix injection, solution

| Product Information | | | |
|----------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2038 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | |
|----------------------------------------|---------------------------------------------------------------------------------------------------|---------------------------|---------------|
| | Ingredient Name | Basis of Strength | Strength |
| | QUERCUS RUBRA POLLEN (UNII: SVW19ET93C) (QUERCUS RUBRA POLLEN - UNII:SVW19ET93C) | QUERCUS RUBRA POLLEN | 0.1 g in 1 mL |
| | QUERCUS VIRGINIANA POLLEN (UNII: 8KDG09A4GO) (QUERCUS VIRGINIANA POLLEN - UNII:8KDG09A4GO) | QUERCUS VIRGINIANA POLLEN | 0.1 g in 1 mL |
| | QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK) | QUERCUS ALBA POLLEN | 0.1 g in 1 mL |

| Inactive Ingredients | |
|----------------------------------------------|----------|
| Ingredient Name | Strength |
| PHENOL (UNII: 339NCG44TV) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |

| Packaging | | | | |
|------------------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2038-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2038-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2038-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|------------------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

POLLENS - TREES, OAK MIX
oak mix injection, solution

| Product Information | | | | |
|---------------------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2039 | |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| QUERCUS RUBRA POLLEN (UNII: SVW19ET93C) (QUERCUS RUBRA POLLEN - UNII:SVW19ET93C) | QUERCUS RUBRA POLLEN | 20000 [PNU] in 1 mL | | |
| QUERCUS VIRGINIANA POLLEN (UNII: 8KDG09A4GO) (QUERCUS VIRGINIANA POLLEN - UNII:8KDG09A4GO) | QUERCUS VIRGINIANA POLLEN | 20000 [PNU] in 1 mL | | |
| QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK) | QUERCUS ALBA POLLEN | 20000 [PNU] in 1 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| PHENOL (UNII: 339NCG44TV) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2039-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2039-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2039-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| BLA | BLA103888 | 04/19/1941 | | |

| POLLENS - TREES, OAK, RED QUERCUS RUBRA | | | |
|-----------------------------------------------------------------------------------------|-----------------------------|---------------------------|----------------|
| oak, red quercus rubra injection, solution | | | |
| Product Information | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-2014 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| QUERCUS RUBRA POLLEN (UNII: SVW19ET93C) (QUERCUS RUBRA POLLEN - UNII:SVW19ET93C) | QUERCUS RUBRA POLLEN | 0.05 g in 1 mL | |

| Inactive Ingredients | | | | |
|---------------------------------------|------------------------------------------|----------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2014-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2014-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044-2014-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | | 04/19/1941 | |

| POLLENS - TREES, OLIVE OLEA EUROPAEA | | | | |
|------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------|--------------------|
| olive olea europaea injection, solution | | | | |
| Product Information | | | | |
| Product Type | NON-STANDARDIZED ALLERGENIC | | Item Code (Source) | NDC:65044-2050 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | | Basis of Strength | Strength |
| OLEA EUROPAEA POLLEN (UNII: 43R41XZ 627) (OLEA EUROPAEA POLLEN - UNII:43R41XZ 627) | | | OLEA EUROPAEA POLLEN | 0.05 g in 1 mL |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| GLYCERIN (UNII: PDC6A3C00X) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-2050-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-2050-3 | 30 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 3 | NDC:65044- | 50 mL in 1 VIAL; Type 0: Not a Combination | | |

| 2050-4 | Product | | |
|------------------------------|------------------------------------------|----------------------|--------------------|
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 04/19/1941 | |

ANIMAL ALLERGENS, UF DOG HAIR-DANDER CANIS SPP
 animal allergens, dog dander canis spp injection, solution

| Product Information | | | |
|----------------------------|-----------------------------|--------------------|----------------|
| Product Type | NON-STANDARDIZED ALLERGENIC | Item Code (Source) | NDC:65044-4850 |
| Route of Administration | PERCUTANEOUS, SUBCUTANEOUS | | |

| Active Ingredient/Active Moiety | | | |
|-----------------------------------------------------------------------------------------------------------|-------------------------------|------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| CANIS LUPUS FAMILIARIS HAIR (UNII: 05S7L91ZTR) (CANIS LUPUS FAMILIARIS HAIR - UNII:05S7L91ZTR) | CANIS LUPUS FAMILIARIS HAIR | 0.0008 g in 1 mL | |
| CANIS LUPUS FAMILIARIS DANDER (UNII: 11JCK302I4) (CANIS LUPUS FAMILIARIS DANDER - UNII:11JCK302I4) | CANIS LUPUS FAMILIARIS DANDER | 0.0008 g in 1 mL | |

| Inactive Ingredients | | | |
|----------------------------------------------|----------|--|--|
| Ingredient Name | Strength | | |
| GLYCERIN (UNII: PDC6A3C00X) | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | |

| Packaging | | | | |
|------------------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65044-4850-2 | 10 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| 2 | NDC:65044-4850-4 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|------------------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| BLA | BLA103888 | 07/01/2022 | |

Labeler - Jubilant HollisterStier LLC (069263643)

Registrant - Jubilant HollisterStier LLC (069263643)