

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

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

ANIMAL ALLERGENS, FEATHER MIX- feather mix 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 - 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, 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, EPICOCUM NIGRUM- epicoccum nigrum 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, JOHNSON GRASS SORGHUM HALEPENSE- johnson grass sorghum halepense 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, BIRCH MIX- birch mix 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, ELM, AMERICAN ULMUS AMERICANA- elm, american ulmus americana injection, solution

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

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

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

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

POLLENS - TREES, PECAN CARYA CARYA ILLINOENSIS- pecan carya carya illinoensis 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, 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, GOLDENROD SOLIDAGO CANADENSIS- goldenrod solidago canadensis injection, solution

POLLENS - WEEDS AND GARDEN PLANTS, LAMB QUARTERS CHENOPODIUM ALBUM- lamb quarters chenopodium album 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, 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
Jubilant HollisterStier LLC

INSTRUCTIONS ALLERGENIC EXTRACTS FOR INTRADERMAL TESTING

WARNINGS

This product is intended for use only by licensed medical personnel experienced in administering allergenic extracts and trained to provide immediate emergency treatment in the event of a life-threatening reaction.

Allergenic extracts may potentially elicit a severe life-threatening systemic reaction, rarely resulting in death.⁷ Therefore, emergency measures and personnel trained in their use should be available immediately in the event of such a reaction. Patients should be instructed to recognize adverse reaction symptoms and cautioned to contact the physician's office if symptoms occur.

Scratch, prick or puncture test first. Test intradermally only to those antigens giving negative or questionable reactions on scratch, prick or puncture testing.

This product should never be injected intravenously.

Patients on non-selective beta blockers may be more reactive to allergens given for testing or treatment and may be unresponsive to the usual doses of epinephrine used to treat allergic reactions.⁶

Refer also to the WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS Sections below for further discussion.

DESCRIPTION

Extracts for intradermal testing are supplied in sterile multi-dose vials containing, in addition to the extract allergens and antigens, 0.5% sodium chloride, 0.275% sodium bicarbonate, up to 2% glycerin, 2.5% glycerin for APTM products, and, as preservative, 0.4% phenol. The strength of these extracts may be expressed in terms of:

1. Weight to Volume (w/v)
2. Protein Nitrogen Units/mL (PNU/mL)
3. Allergy Units/mL (AU/mL)
4. Bioequivalent Allergy Units/mL (BAU/mL)
5. Concentrate
 - **Weight to volume (w/v).** For regular extracts this describes the extraction ratio, i.e., the amount of crude allergen added to the extracting fluid. A 1:10 extract, therefore, indicates that the solution contains the extracted material from one gram of raw material added to each 10 mL of extracting fluid. The amount and composition of extracted material will vary with the kind of antigen, the extracting fluid, duration of extraction, pH, temperature, and other variables. In contrast to this, APTM (acetone precipitated) extracts, if present, are prepared by reconstituting dry allergenically active concentrates produced by a precipitation process from extracts of raw materials. For those APTM extracts labeled on a weight per volume (w/v) basis, the strength designation indicates the dry weight of finished (acetone) precipitate per volume of reconstituting fluid. For example, 1:50 (w/v) means that each gram of dry precipitate obtained from the original extract is reconstituted in 50 mL

of solution.

- **Protein Nitrogen Units per mL (PNU/mL).** One protein nitrogen unit represents 0.00001 mg phosphotungstic acid-precipitable protein nitrogen dissolved in one mL of antigen extract. The PNU content of extracts of the same antigen may vary according to the method of measuring the PNU. Thus, PNU contents of extracts from different manufacturers are not comparable unless the PNU method is known to be the same and reproducible from lot to lot. Also, the amount of protein nitrogen extracted from an antigen is influenced by the same variables as the weight to volume extract. Allergenic materials make up a variable proportion of the total protein of an extract.
- **Allergy Units per mL (AU/mL).** The potency of standardized AP™ and regular extracts labeled in Allergy Units (AU)/mL is determined by in vitro comparison to the reference standard established by the Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration.
- **Bioequivalent Allergy Units per mL (BAU/mL).** When originally licensed, the Reference Preparations for standardized extracts were arbitrarily assigned 100,000 Allergy Units (AU)/mL. Subsequently, quantitative skin testing by the ID₅₀EAL method¹⁴ was used to determine that some Reference Preparations should be assigned 10,000 AU/mL, and others 100,000 AU/mL. To avoid possible confusion about this change in the method of allergy unit assignment, the nomenclature changed for standardized extracts whose allergy units are assigned based on quantitative skin testing, and are labeled in Bioequivalent Allergy Units (BAU)/mL. References labeled 10,000 BAU/mL can be diluted one to a half million fold, and references labeled 100,000 BAU/mL can be diluted one to 5 million fold and produce a sum of erythema diameter of 50 mm when Intradermal testing highly reactive subjects.
- **Concentrate.** Concentrate label terminology applies to allergenic extract mixtures, where the individual allergens being combined vary in strength or the designation of strength.

CLINICAL PHARMACOLOGY

Allergenic extracts for intradermal testing used according to the DOSAGE AND ADMINISTRATION Section, produce erythema or erythema and wheal reactions in patients with significant IgE-mediated sensitivity to the relevant allergen. This allergic inflammatory response, although not completely understood, is thought to begin with the reaction of antigen with IgE on the surface of basophils, or mast cells, which initiates a series of biochemical events resulting in the production of histamine, slow-reacting substance of anaphylaxis and other mediators. These, in turn, produce the immediate-type wheal and flare skin reaction.

INDICATIONS AND USAGE

Certain diagnostics carry labeling which states **Allergenic Extract for Diagnostic Use Only**. Data to support the therapeutic use of products labeled with this statement have not been established.¹⁵

In addition to a carefully taken history, the use of intradermal testing extracts is an accepted method in the diagnosis of allergenic conditions.^{1, 2, 3} When scratch, prick or puncture reactions are small, or if the patient gives a history of allergic symptoms to a substance but scratch, prick or puncture tests are inconclusive, intradermal tests may be indicated. However, ANTIGENS PRODUCING LARGE 3 TO 4+ SCRATCH, PRICK OR PUNCTURE TESTS SHOULD NOT BE TESTED INTRADERMALLY.

Extracts of all allergens do not produce equivalent results in intradermal testing. The intensity of the skin reaction produced will be determined by two factors: the degree of sensitivity of the patient and the nature of the antigenic extract applied. In general, pollen extracts produce whealing reactions, whereas other inhalants produce erythematous reactions with wheals less often. Skin tests to foods seldom produce whealing reactions except for infrequent instances of severe sensitivity to fish, nuts or spices, and rarely other foods.

CONTRAINDICATIONS

There are no known absolute contraindications to allergy skin testing. Patients with cardiovascular diseases or pulmonary diseases such as symptomatic asthma, and/or who are receiving cardiovascular drugs such as beta blockers, may be at higher risk for severe adverse reactions. These patients may also be more refractory to the normal anaphylaxis treatment regime.

WARNINGS

Scratch, prick or puncture test first. Test intradermally only to those antigens giving negative or questionable reactions on scratch, prick or puncture testing. Excessively large local reactions or systemic reactions are more likely to occur if the patient is skin tested shortly after exposure to large amounts of antigen to which he or she is sensitive. Therefore, use caution when applying pollen tests to patients during their active pollen season, or after an exposure to inhalant allergens that produce symptoms. Refer to boxed WARNINGS Section.

PRECAUTIONS

1. General

It is recommended that disposable syringes and needles are used for intradermal tests to prevent the possibility of accidental transfer of serum hepatitis and other infectious agents from one person to another. Always have injectable epinephrine and a tourniquet available when tests are being made. (See ADVERSE REACTION Section.) Patients should be observed in the office for 30 to 45 minutes after each set of intradermal tests and instructed to return to the office promptly if symptoms of an allergic reaction or shock occur. In order to avoid darkening and possible precipitation, do not dilute the following extracts with solutions containing phenol: Privet pollen and food extracts of White Potato, Corn, Oat, Rye, and Wheat. Injections of such extracts discolored by reaction with phenol may produce lasting tattoo-like discoloration of the skin.

2. Information for Patients

Patients should be instructed in the recognition of adverse reactions to diagnostic testing. Patients should be made to understand the importance of a 30 to 45 minute observation period and be warned to return to the office promptly if symptoms occur after leaving.

3. Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been conducted with allergenic extracts to determine their potential for carcinogenicity, mutagenicity or impairment of fertility.

4. Pregnancy

4,5 Animal reproduction studies have not been conducted with allergenic extracts. It is also not known whether allergenic extracts can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Allergenic extracts should be given to a pregnant woman only if clearly needed.

5. Nursing Mothers

There are no current studies on secretion of the allergenic extract components in human milk or effect on the nursing infant. Because many drugs are excreted in human milk, caution should be exercised when allergenic extracts are administered to a nursing woman.

6. Drug Interactions

Patients on non-selective beta blockers may be more reactive to allergens given for testing or treatment and may be unresponsive to the usual doses of epinephrine used to treat allergic reactions.⁶ Certain medications may lessen the skin test wheal and erythema responses elicited by allergens and

histamine for varying time periods. Conventional antihistamines should be discontinued at least 5 days before skin testing. Long acting antihistamines should be discontinued for at least 3 weeks prior to skin testing.¹⁰ Topical steroids should be discontinued at the skin test site for at least 2-3 weeks before skin testing.^{10, 11} Tricyclic antidepressants such as Doxepin should be withheld for at least 7 days before skin testing.¹² Topical local anesthetics may suppress the flare responses and should be avoided in skin test sites.¹³

7. Geriatric Use

Skin test wheal size decreases with age. The decrease in allergen-induced skin test reaction parallels that to histamine; therefore, appropriate positive skin test controls should always be performed.¹

8. Pediatric Use

Wheal sizes in response to allergen skin testing can be smaller in infants than in adults. The skin response to histamine parallels that for allergens; therefore, appropriate positive control skin tests should always be performed.¹

ADVERSE REACTIONS

1. Local Reactions

Large, persistent local reactions or minor exacerbations of the patient's allergic symptoms may be treated by local cold applications and/or the use of oral antihistamines, but they should be considered a warning of possible severe systemic reactions.

2. Systemic Reactions

With careful attention to dosage and administration, such reactions occur infrequently, but it must be remembered that allergenic extracts are highly potent in sensitive individuals and OVERDOSE could result in anaphylactic symptoms. Therefore, it is imperative that physicians administering allergenic extracts understand and be prepared for the treatment of severe reactions. Adverse reaction frequency data for allergenic extract administration for testing and treatment show that risk is low.^{7, 8} It cannot be overemphasized that, under certain unpredictable combinations of circumstances, anaphylactic shock is a possibility. Other possible systemic reaction symptoms, in varying degrees of severity, are fainting, pallor, bradycardia, hypotension, angioedema, cough, wheezing, conjunctivitis, rhinitis and urticaria. **If a systemic or anaphylactic reaction does occur, apply a tourniquet above the site of injection, if tests are performed on the arms, and inject the 1:1000 epinephrine-hydrochloride intramuscularly or subcutaneously into the opposite arm. Loosen the tourniquet at least every 10 minutes. Do not obstruct arterial blood flow with the tourniquet.**

EPINEPHRINE:

ADULT DOSAGE: 0.3 to 0.5 mL should be injected. Repeat in 5 to 10 minutes if necessary.

PEDIATRIC DOSAGE: The usual initial dose is 0.01 mg (mL) per kg body weight or 0.3 mg (mL) per square meter of body surface area. Suggested dosage for infants to 2 years of age is 0.05 mL to 0.1 mL; for children 2 to 6 years, 0.15 mL; and children 6 to 12 years, 0.2 mL. Single pediatric doses should not exceed 0.3 mg (mL). Doses may be repeated as frequently as every 20 minutes, depending on the severity of the condition and the response of the patient. After administration of epinephrine, profound shock or vasomotor collapse should be treated with intravenous fluids, and possibly vasoactive drugs. Oxygen should be given by mask. Intravenous antihistamine, theophylline or adrenal corticosteroids may be used if necessary after adequate epinephrine and circulatory support have been given. Emergency resuscitation measures and personnel trained in their use should be available immediately in the event of a serious systemic or anaphylactic reaction not responsive to the above measures. [Ref. *J. Allergy Clin. Immunol.* 77 (2): 271-273, 1986]. Rarely are all of the above measures necessary; the tourniquet and epinephrine usually produce prompt responses. However, the physician should be prepared in advance for all contingencies. Promptness in beginning emergency treatment measures is of utmost importance.

3. Adverse Event Reporting

Report all adverse events to Jubilant HollisterStier LLC Customer Technical Services Department at 1 (800) 992-1120. A voluntary adverse event reporting system for health professionals is available through the FDA MEDWATCH program. Preprinted forms (FDA Form 3500) are available from the FDA by calling 1 (800) FDA-1088. Completed forms should be mailed to MEDWATCH, 5600 Fisher Lane, Rockville, MD 20852-9787 or Fax to: 1 (800) FDA-0178.

OVERDOSE SECTION

See ADVERSE REACTIONS Section.

DOSAGE AND ADMINISTRATION

1. General

Parenteral Drug Products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

2. Intradermal Testing Methods

Cleanse the rubber stopper of the vial with liquid antiseptic before withdrawing extract. A sterile tuberculin syringe with 26-gauge, short-bevel needle should be used for the injection. The anterior surface of the upper and lower arm is preferable for testing. Cleanse the skin with soap and water or wash with alcohol or other antiseptic. Introduce the needle between the superficial layers of the skin and inject 0.02 mL of the extract. Test sites should be at least 2.5 cm apart, and no more than 10 to 20 antigens should be introduced at one time. This group can be followed with additional groups of 10, providing the reactions are not numerous or strong. The same amount of extract should be injected in each site for proper comparison. It is advisable to avoid testing with more than one allergen in the same group in each series, i.e., nuts, fish, epidermals, etc. A site should be injected with 0.02 mL of the control solution. All skin tests should be validated by appropriate positive control tests (e.g., histamine) and negative control tests [e.g., Glycerin, Albumin Saline with Phenol (0.4%), or Buffered Saline with Phenol (0.4%)]. The negative control test should be the same material as is used as a diluting fluid in the tested extracts. Diluting fluid is used in the same way as an active test extract. False positive reactions are sometimes encountered in intradermal testing, and the possibility of irritation reactions should always be taken into consideration. In cases where the patient is known to be quite sensitive, screen testing by scratch, prick or puncture method is recommended, and intradermal testing should be done with caution. The intradermal strength supplied is usually safe for testing patients presenting negative scratch, prick or puncture test reactions. It is recommended that a 1:10 dilution of the stock intradermal strength be used in preliminary testing of patients not previously screened by scratch, prick or puncture tests.

3. Use of Antigen Mixes

The use of complicated mixes of unrelated pollens for testing is not recommended since in the case of a positive reaction it does not indicate which pollen(s) are responsible, and in the case of a negative reaction, it fails to indicate whether the individual pollens at full concentration would give a positive reaction.

4. Reading Skin Test Reactions

A positive reaction consists of an urticarial wheal with surrounding erythema (resembling somewhat a mosquito bite reaction) larger than the control site. The smallest reaction considered positive is erythema with a central papule at least 5 mm in diameter. In some instances with no reaction at the control site, erythema may be considered an indication of sensitivity. In general, the size of wheal and erythema response correlates directly with the patient's sensitivity to that allergen.

Standardized Products

(a) **Mites**: The skin test concentrations of 30 AU/mL and 300 AU/mL in multiple dose vials are used for intradermal testing.

Intradermal skin test results in selected highly sensitive subjects are presented for reference purposes:

AU/mL that Elicited $\Sigma E = 50$ mm

Allergen	Number of Persons	Mean	2 Std. Dev. Range
D. farinae	12	0.0609	0.0015-2.6016
D. pteronyssinus	12	0.333	0.0003-4.0077

Intradermal extracts should be used as follows:

(1) **Patients with a negative scratch, prick or puncture test**: Patients who do not react to a valid scratch, prick or puncture test should be tested intradermally with 0.02 to 0.05 mL of a 30 AU/mL extract solution. If this test is negative, a second intradermal test may be performed using a 300 AU/mL extract solution. The negative control used with this latter dilution should contain 0.5% glycerin.

(2) **Patients tested only by the intradermal method**: Patients suspected of being highly allergic should be tested with 0.02 to 0.05 mL of a solution containing 0.03 AU/mL. A negative test should be followed by repeat tests using progressively stronger concentrations until the maximum recommended strength of 300 AU/mL is reached. The negative control used with this latter dilution should contain 0.5% glycerin.

(b) **Cat Hair and Cat Pelt**: Intradermal endpoint titration (IET) tests were completed with Cat Pelt extract using 15 subjects to determine the mean concentration required to produce a ΣE of 50 (D_{50}) mm. That concentration contained 0.042 BAU/mL (range 0.002 to 0.890 BAU/mL).

IET tests were completed with Cat Hair extract using 15 subjects to determine the mean concentration required to produce a ΣE of 50 mm (D_{50}). That concentration contained 0.049 BAU/mL (range 0.006 to 0.661 BAU/mL).

Intradermal extract should be used as follows:

Intradermal Tests should be done only on patients with a negative prick or puncture test. Patients who do not react to a valid prick or puncture test should be tested intradermally with 0.02 to 0.05 mL of a 100 BAU/mL extract solution. If this test is negative, a second intradermal test may be performed using a 1,000 BAU/mL extract solution. If the intradermal dilutions were prepared from glycerinated concentrate, the negative control used with this latter dilution should contain 5% glycerin.

Standardized Cat Hair and Cat Pelt products are not interchangeable with each other or any other cat products including those labeled AU/mL.

(c) **Ragweed pollen (Short Ragweed or Giant and Short Ragweed Mixture) Antigen E Assayed**:

The intradermal strength for Short Ragweed extract is usually 500 PNU, which by calculation contains approximately 0.7 to 3 units of Antigen E/mL. For Giant and Short Ragweed mix the suggested intradermal strength is 500 PNU, which by calculation contains 0.4 to 1.5 units of Antigen E/mL. These strengths are usually safe for testing patients previously having negative scratch, prick or puncture test reactions. A 1:10 dilution of the stock intradermal strength should be used in preliminary testing of patients not previously screened by scratch, prick, or puncture tests. A study of ragweed sensitive patients⁹ indicates that intradermal tests, using 0.05 mL of extract, produce positive reactions (1+ to 2+) at Antigen E concentrations of from 2.7×10^{-1} to 2.7×10^{-6} units per mL. The equivalent PNU range was 100 to 0.001 PNU per mL. Skin tests are graded in terms of the wheal and erythema response noted at 15 minutes. Wheal and erythema size may be recorded by actual measurement of the extent of both responses.

5. Geriatric Use

The dose is the same in patients of all age groups. Because the wheal size in response to allergen skin testing decreases with age, appropriate histamine positive control skin tests must be performed.¹

6. Pediatric Use

The dose is the same in patients of all age groups. Wheal size in response to allergen skin testing can be smaller in infants than in adults. Appropriate histamine positive control skin tests must be performed.¹

Refer to the following table to determine the skin test sensitivity grade. The corresponding ΣE (sum of the longest diameter and the mid-point orthogonal diameters of erythema) is also presented.

Grade	Erythema mm	Papule or Wheal mm	Corresponding mm ΣE
0	<5	<5	<10
±	5-10	5-10	10-20
1+	11-20	5-10	20-40
2+	21-30	5-10	40-60
3+	31-40	10-15 (a)	60-80
4+	>40	>15 (b)	> 80

^a or with pseudopods

^b or with many pseudopods

A positive skin reaction to any allergen must be interpreted in light of the patient's history of symptoms, time of year, known exposures, and eating habits.

THE SKIN TESTS ARE IN NO WAY A SUBSTITUTE FOR A CAREFUL ALLERGENIC HISTORY; RATHER, THEY SERVE AS ADDITIONAL INFORMATION TO AID IN IDENTIFYING CAUSATIVE ALLERGENS IN PATIENTS WITH ALLERGIC DISORDERS.

HOW SUPPLIED

Most allergens are available in multiple dose 5 mL vials at PNU, w/v, some mixes as Concentrate, Standardized Mite products at AU/mL (30 AU/mL and 300 AU/mL each species), or Standardized Grass products at BAU/mL [100 BAU/mL and 1,000 BAU/mL (Bermuda 100 BAU/mL only)]. Product labels state vials are for intradermal testing and list strengths.

STORAGE

The expiration date of the diagnostic extracts is listed on the container label. The extract should be stored at 2° to 8°C, and kept at this temperature range during office use.

LIMITED WARRANTY

A number of factors beyond our control could reduce the efficacy of this product or even result in an ill effect following its use. These include storage and handling of the product after it leaves our hands, diagnosis, dosage, method of administration and biological differences in individual patients. Because of these factors, it is important that this product be stored properly, and that the directions be followed carefully during use. No warranty, express or implied, including any warranty of merchantability or fitness, is made. Representatives of the Company are not authorized to vary the terms or the contents of any printed labeling, including the package insert, for this product except by printed notice from the Company's headquarters. The prescriber and user of this product must accept the terms hereof.

REFERENCES

1. Middleton, Elliott, Jr., C. E. Reed, E. F. Ellis (ed.) Allergy Principles and Practice. Vol. 1, C. V. Mosby. 1978.
2. Sheldon, J. M., R. C. Lovell, K. P. Mathews. A Manual of Clinical Allergy. W. B. Saunders, 1967.

3. Tuft, L., H. L. Mueller. Allergy in Children. W. B. Saunders. 1979.
4. DuBuske, L.M., C.J. Ling and A.L. Sheffer. Special problems regarding allergen immunotherapy. Immunol. Allergy. Clin. North Am. (USA). 12(1): 145-175, 1992.
5. Weinstein, A. M., D. B. Dubin, W. K. Podleski, L. L. Spector, R. S. Farr. Asthma and pregnancy. JAMA. 134(11): 1161-1165, 1979.
6. Jacobs, Robert L., Goeffrey W. Rake, Jr., et al. Potentiated anaphylaxis in patients with drug-induced beta-adrenergic blockade. J. Allergy Clin. Immunol. 68(2): 125-127, August 1981.
7. Lockey, Richard F., Linda M. Benedict, Paul C. Turkeltaub, Samuel C. Bukantz. Fatalities from immunotherapy (IT) and skin testing (ST). J. Allergy Clin. Immunol. 79(4): 660-677, 1987.
8. Turkeltaub, Paul C., Peter J. Gergen. The risk of adverse reactions from percutaneous prick-puncture allergen skin testing, venipuncture, and body measurements: Data from the second National Health and Nutrition Examination Survey 1976-80 (NHANES II). J. Allergy Clin. Immunol. 84(6): 886-890, Dec. 1989.
9. Norman, P. S., L. M. Lichtenstein, K. Ishizaka. Diagnostic tests in ragweed hay fever. J. Allergy Clin. Immunol. 52(4): 212-224, 1973.
10. Pipkorn, Ulf. Pharmacological influence of anti-allergic medication on *In Vivo* allergen testing. Allergy. 43: 81-86, 1988.
11. Andersson, M., U. Pipkorn. Inhibition of the dermal immediate allergic reaction through prolonged treatment with topical glucocorticosteroids. J. Allergy Clin. Immunol. 79(2): 345-349, February 1987.
12. Rao, Kamineni S., et al. Duration of suppressive effect of tricyclic anti-depressants on histamine induced wheal and flare reactions on human skin. J. Allergy Clin. Immunol. 82: 752-757, November 1988.
13. Pipkorn, Ulf, M. Andersson. Topical dermal anesthesia inhibits the flare but not the wheal response to allergen and histamine in the skin prick test. Clinical Allergy. 17: 307-311, 1987.
14. Turkeltaub, Paul C., C. Rastogi Suresh, Harold Baer. Office of Biologics Research and Review skin test method for evaluation of subject sensitivity to standardized allergenic extracts and for assignment of allergy units to reference preparations using the ID50EAL method (Intradermal Dilution for 50 mm Sum of Erythema Determines the Allergy Unit). Methods of the Allergenic Products Branch Office of Biologics Research and Review, FDA, Bethesda, MD 20892. Revised May 9, 1986.
15. Food and Drug Administration. Biological products; Allergenic extracts classified in Category IIIB; Final order; Revocation of licenses. Federal Register. 59(220):59228ff, November 16, 1994.
16. Griffith, I.J., Pollock, D.G. Klapper, B.L. Rogers, A.K. Nault., Sequence Polymorphism of Amb a I and Amb a II, the Major Allergens in *Ambrosia artemisiifolia* (Short Ragweed). Int. Arch. Allergy Apply. Immunol., 96: 296-304, 1991.

ALLERGENIC EXTRACT

STRENGTH

For ID Test

ANTIGEN COMMON NAME

ANTIGEN SCIENTIFIC NAME

9999XX ITEM CODE

Dose/Route: 0.02 mL Intradermally. See Package Insert. 5 mL

Lot No.: **SAMPLE**

Exp. Date: **01/01/2009**

Preservative: 0.4% Phenol

Jubilant
HollisterStier LLC
Spokane, WA 99207 USA

U.S. Lic. No. 1272
260245-A

ANIMAL ALLERGENS, AP HORSE HAIR AND DANDER

ap horse hair and dander injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:65044-4857
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EQUUS CABALLUS HAIR (UNII: 4F35XG0149) (EQUUS CABALLUS HAIR - UNII:4F35XG0149)	EQUUS CABALLUS HAIR	0.0005 g in 1 mL
EQUUS CABALLUS DANDER (UNII: J81SZ18495) (EQUUS CABALLUS DANDER - UNII:J81SZ18495)	EQUUS CABALLUS DANDER	0.0005 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-4857-5	5 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 CATTLE HAIR AND DANDER

cattle hair and dander injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:65044-4813
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BOS TAURUS HAIR (UNII: TOQ97Z8644) (BOS TAURUS HAIR - UNII:TOQ97Z8644)	BOS TAURUS HAIR	0.0005 g in 1 mL
BOS TAURUS DANDER (UNII: C8VYS726O8) (BOS TAURUS DANDER - UNII:C8VYS726O8)	BOS TAURUS DANDER	0.0005 g in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-4813-5	5 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:65044-4351

Route of Administration		INTRADERMAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
GALLUS GALLUS FEATHER (UNII: 1FCM16V0FV) (GALLUS GALLUS FEATHER - UNII:1FCM16V0FV)		GALLUS GALLUS FEATHER	200 [PNU] in 1 mL	
ANSER ANSER FEATHER (UNII: 15XI414745) (ANSER ANSER FEATHER - UNII:15XI414745)		ANSER ANSER FEATHER	200 [PNU] in 1 mL	
ANAS PLATYRHYNCHOS FEATHER (UNII: 83B65P4796) (ANAS PLATYRHYNCHOS FEATHER - UNII:83B65P4796)		ANAS PLATYRHYNCHOS FEATHER	200 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-4351-5	5 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:65044-6586
Route of Administration	INTRADERMAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
PERIPLANETA AMERICANA (UNII: 2RQ1L9N089) (PERIPLANETA AMERICANA - UNII:2RQ1L9N089)		PERIPLANETA AMERICANA	500 [PNU] in 1 mL
BLATELLA GERMANICA (UNII: G9O67I0A8Q) (BLATELLA GERMANICA - UNII:G9O67I0A8Q)		BLATELLA GERMANICA	500 [PNU] in 1 mL

Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-6586-5	5 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:65044-6516	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
SOLENOPSIS RICHTERI (UNII: 739684T11W) (SOLENOPSIS RICHTERI - UNII:739684T11W)		SOLENOPSIS RICHTERI	500 [PNU] in 1 mL	
SOLENOPSIS INVICTA (UNII: 5O7CR4P444) (SOLENOPSIS INVICTA - UNII:5O7CR4P444)		SOLENOPSIS INVICTA	500 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-6516-5	5 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:65044-5138
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H)	ALTERNARIA ALTERNATA	1000 [PNU] in 1 mL
ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48)	ASPERGILLUS FUMIGATUS	1000 [PNU] in 1 mL
ASPERGILLUS NIDULANS (UNII: 242A53RB80) (ASPERGILLUS NIDULANS - UNII:242A53RB80)	ASPERGILLUS NIDULANS	1000 [PNU] in 1 mL
ASPERGILLUS NIGER VAR. NIGER (UNII: 9IOA40ANG6) (ASPERGILLUS NIGER VAR. NIGER - UNII:9IOA40ANG6)	ASPERGILLUS NIGER VAR. NIGER	1000 [PNU] in 1 mL
ASPERGILLUS TERREUS (UNII: QBN8K7055X) (ASPERGILLUS TERREUS - UNII:QBN8K7055X)	ASPERGILLUS TERREUS	1000 [PNU] in 1 mL
FUSARIUM OXYSPORUM VASINFECTUM (UNII: 6M98DC08TZ) (FUSARIUM OXYSPORUM VASINFECTUM - UNII:6M98DC08TZ)	FUSARIUM OXYSPORUM VASINFECTUM	1000 [PNU] in 1 mL
DENDRYPHIELLA VINOSA (UNII: 7S6NW5FH8X) (DENDRYPHIELLA VINOSA - UNII:7S6NW5FH8X)	DENDRYPHIELLA VINOSA	1000 [PNU] in 1 mL
CLADOSPORIUM CLADOSPORIOIDES (UNII: 4ZWY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4ZWY20GTGO)	CLADOSPORIUM CLADOSPORIOIDES	1000 [PNU] in 1 mL
MUCOR RACEMOSUS (UNII: 17RH99LQ7G) (MUCOR RACEMOSUS - UNII:17RH99LQ7G)	MUCOR RACEMOSUS	1000 [PNU] in 1 mL
PENICILLIUM DIGITATUM (UNII: 1SB49SV239) (PENICILLIUM DIGITATUM - UNII:1SB49SV239)	PENICILLIUM DIGITATUM	1000 [PNU] in 1 mL
PENICILLIUM EXPANSUM (UNII: 1XSC3BB35Z) (PENICILLIUM EXPANSUM - UNII:1XSC3BB35Z)	PENICILLIUM EXPANSUM	1000 [PNU] in 1 mL
PENICILLIUM GLAUCUM (UNII: E3X33F517C) (PENICILLIUM GLAUCUM - UNII:E3X33F517C)	PENICILLIUM GLAUCUM	1000 [PNU] in 1 mL
PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG)	PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM	1000 [PNU] in 1 mL
CLONOSTACHYS ROSEA F. ROSEA (UNII: I5F729WZ2H) (CLONOSTACHYS ROSEA F. ROSEA - UNII:I5F729WZ2H)	CLONOSTACHYS ROSEA F. ROSEA	1000 [PNU] in 1 mL
PHOMA EXIGUA VAR. EXIGUA (UNII: 8JAG41IE4M) (PHOMA EXIGUA VAR. EXIGUA - UNII:8JAG41IE4M)	PHOMA EXIGUA VAR. EXIGUA	1000 [PNU] in 1 mL
AUREOBASIDIUM PULLULANS VAR. PULLUTANS (UNII: D1A2NG69CK) (AUREOBASIDIUM PULLULANS VAR. PULLUTANS - UNII:D1A2NG69CK)	AUREOBASIDIUM PULLULANS VAR. PULLUTANS	1000 [PNU] in 1 mL
RHIZOPUS STOLONIFER (UNII: FEE198DK4Q) (RHIZOPUS STOLONIFER - UNII:FEE198DK4Q)	RHIZOPUS STOLONIFER	1000 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5138-5	5 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:65044-5001
Route of Administration	INTRADERMAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H)		ALTERNARIA ALTERNATA	1000 [PNU] in 1 mL
ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48)		ASPERGILLUS FUMIGATUS	1000 [PNU] in 1 mL
ASPERGILLUS NIDULANS (UNII: 242A53RB80) (ASPERGILLUS NIDULANS - UNII:242A53RB80)		ASPERGILLUS NIDULANS	1000 [PNU] in 1 mL
ASPERGILLUS NIGER VAR. NIGER (UNII: 9IOA40ANG6) (ASPERGILLUS NIGER VAR. NIGER - UNII:9IOA40ANG6)		ASPERGILLUS NIGER VAR. NIGER	1000 [PNU] in 1 mL
ASPERGILLUS TERREUS (UNII: QBN8K7055X) (ASPERGILLUS TERREUS - UNII:QBN8K7055X)		ASPERGILLUS TERREUS	1000 [PNU] in 1 mL
CLADOSPORIUM CLADOSPORIOIDES (UNII: 4ZWY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4ZWY20GTGO)		CLADOSPORIUM CLADOSPORIOIDES	1000 [PNU] in 1 mL
PENICILLIUM DIGITATUM (UNII: 1SB49SV239) (PENICILLIUM DIGITATUM - UNII:1SB49SV239)		PENICILLIUM DIGITATUM	1000 [PNU] in 1 mL
PENICILLIUM EXPANSUM (UNII: 1XSC3BB35Z) (PENICILLIUM EXPANSUM - UNII:1XSC3BB35Z)		PENICILLIUM EXPANSUM	1000 [PNU] in 1 mL
PENICILLIUM GLAUCUM (UNII: E3X33F517C) (PENICILLIUM GLAUCUM - UNII:E3X33F517C)		PENICILLIUM GLAUCUM	1000 [PNU] in 1 mL
PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG)		PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM	1000 [PNU] in 1 mL
CLONOSTACHYS ROSEA F. ROSEA (UNII: I5F729WZ2H) (CLONOSTACHYS ROSEA F. ROSEA - UNII:I5F729WZ2H)		CLONOSTACHYS ROSEA F. ROSEA	1000 [PNU] in 1 mL

Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5001-5	5 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:65044-5286	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
TRICHOPHYTON TONSURANS (UNII: JY1BE33BY) (TRICHOPHYTON TONSURANS - UNII:JY1BE33BY)		TRICHOPHYTON TONSURANS	1000 [PNU] in 1 mL	
TRICHOPHYTON RUBRUM (UNII: 2ZAU32517N) (TRICHOPHYTON RUBRUM - UNII:2ZAU32517N)		TRICHOPHYTON RUBRUM	1000 [PNU] in 1 mL	
TRICHOPHYTON MENTAGROPHYTES (UNII: 199I7J3JIV) (TRICHOPHYTON MENTAGROPHYTES - UNII:199I7J3JIV)		TRICHOPHYTON MENTAGROPHYTES	1000 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:65044-5286-5	5 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, PENICILLIUM MIX

molds, penicillium mix injection, solution

Product Information				
Product Type		NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:65044-5170
Route of Administration		INTRADERMAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
PENICILLIUM DIGITATUM (UNII: 1SB49SV239) (PENICILLIUM DIGITATUM - UNII:1SB49SV239)			PENICILLIUM DIGITATUM	1000 [PNU] in 1 mL
PENICILLIUM EXPANSUM (UNII: 1XSC3BB35Z) (PENICILLIUM EXPANSUM - UNII:1XSC3BB35Z)			PENICILLIUM EXPANSUM	1000 [PNU] in 1 mL
PENICILLIUM GLAUCUM (UNII: E3X33F517C) (PENICILLIUM GLAUCUM - UNII:E3X33F517C)			PENICILLIUM GLAUCUM	1000 [PNU] in 1 mL
PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG)			PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM	1000 [PNU] in 1 mL
CLONOSTACHYS ROSEA F. ROSEA (UNII: I5F729WZ2H) (CLONOSTACHYS ROSEA F. ROSEA - UNII:I5F729WZ2H)			CLONOSTACHYS ROSEA F. ROSEA	1000 [PNU] in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5170-5	5 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:65044-50 10
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H)	ALTERNARIA ALTERNATA	1000 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-50 10-5	5 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:65044-50 22
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48)	ASPERGILLUS FUMIGATUS	1000 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5022-5	5 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:65044-5054
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CANDIDA ALBICANS (UNII: 4D7G21HDBC) (CANDIDA ALBICANS - UNII:4D7G21HDBC)		CANDIDA ALBICANS	1000 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5054-5	5 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:65044-5058	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
SAROCLADIUM STRICTUM (UNII: 3F36V0451W) (SAROCLADIUM STRICTUM - UNII:3F36V0451W)		SAROCLADIUM STRICTUM	1000 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5058-5	5 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:65044-5078
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
COCHLIOBOLUS SPICIFER (UNII: 91M9RWP3TD) (COCHLIOBOLUS SPICIFER - UNII:91M9RWP3TD)			COCHLIOBOLUS SPICIFER	1000 [PNU] in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5078-5	5 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:65044-5102
Route of Administration	INTRADERMAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
EPICOCCUM NIGRUM (UNII: 87U156LEN7) (EPICOCCUM NIGRUM - UNII:87U156LEN7)		EPICOCCUM NIGRUM	1000 [PNU] in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
PHENOL (UNII: 339NCG44TV)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
SODIUM BICARBONATE (UNII: 8MDF5V39QO)			
GLYCERIN (UNII: PDC6A3C0OX)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5102-5	5 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:65044-5114	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
FUSARIUM OXYSPORUM VASINFECTUM (UNII: 6 M98DC08TZ) (FUSARIUM OXYSPORUM VASINFECTUM - UNII:6 M98DC08TZ)		FUSARIUM OXYSPORUM VASINFECTUM	1000 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5114-5	5 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:65044-5126	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
DENDRYPHIELLA VINO SA (UNII: 7S6NW5FH8 X) (DENDRYPHIELLA VINOSA - UNII:7S6NW5FH8 X)		DENDRYPHIELLA VINOSA	1000 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8 X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5126-5	5 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:65044-5130
Route of Administration	INTRADERMAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CLADOSPORIUM CLADOSPORIOIDES (UNII: 4ZWY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4ZWY20GTGO)		CLADOSPORIUM CLADOSPORIOIDES	1000 [PNU] in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
PHENOL (UNII: 339NCG44TV)			

SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5130-5	5 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:65044-5146	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
MUCOR RACEMOSUS (UNII: 17RH99LQ7G) (MUCOR RACEMOSUS - UNII:17RH99LQ7G)		MUCOR RACEMOSUS	1000 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5146-5	5 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:65044-5210
Route of Administration	INTRADERMAL		

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	1000 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5210-5	5 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:65044-5222
Route of Administration	INTRADERMAL		

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	1000 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5222-5	5 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:65044-5234
Route of Administration	INTRADERMAL		

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	1000 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5234-5	5 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:65044-5231
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RHIZOPUS STOLONIFER (UNII: FEE198DK4Q) (RHIZOPUS STOLONIFER - UNII:FEE198DK4Q)	RHIZOPUS STOLONIFER	1000 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5231-1	5 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:65044-5266
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PLEOSPORA TARDA (UNII: TPL549N9R8) (PLEOSPORA TARDA - UNII: TPL549N9R8)	PLEOSPORA TARDA	1000 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5266-5	5 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:65044-1083
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PASPALUM NOTATUM POLLEN (UNII: V003SHB7VK) (PASPALUM NOTATUM POLLEN - UNII: V003SHB7VK)	PASPALUM NOTATUM POLLEN	500 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1083-5	5 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:65044-1746	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP)		SORGHUM HALEPENSE POLLEN	500 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1746-5	5 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:65044-1008	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ACACIA LONGIFOLIA POLLEN (UNII: 24SO2J296O) (ACACIA LONGIFOLIA POLLEN - UNII:24SO2J296O)		ACACIA LONGIFOLIA POLLEN	500 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1008-5	5 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:65044-1020
Route of Administration	INTRADERMAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ALNUS RUBRA POLLEN (UNII: Z0F2YK1B7H) (ALNUS RUBRA POLLEN - UNII:Z0F2YK1B7H)		ALNUS RUBRA POLLEN	500 [PNU] in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
PHENOL (UNII: 339NCG44TV)			

SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1020-5	5 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:65044-1062	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q)		FRAXINUS AMERICANA POLLEN	500 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1062-5	5 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:65044-1170
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BETULA PAPYRIFERA POLLEN (UNII: 3538FNV8AY) (BETULA PAPYRIFERA POLLEN - UNII:3538FNV8AY)	BETULA PAPYRIFERA POLLEN	500 [PNU] in 1 mL
BETULA PENDULA POLLEN (UNII: ZL5TV40C5Y) (BETULA PENDULA POLLEN - UNII:ZL5TV40C5Y)	BETULA PENDULA POLLEN	500 [PNU] in 1 mL
BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P)	BETULA NIGRA POLLEN	500 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1170-5	5 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:65044-1215
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety	
---------------------------------	--

Ingredient Name		Basis of Strength	Strength	
ACER NEGUNDO POLLEN (UNII: P6K070AR8V) (ACER NEGUNDO POLLEN - UNII:P6K070AR8V)		ACER NEGUNDO POLLEN	500 [PNU] in 1 mL	
ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861)		ACER SACCHARUM POLLEN	500 [PNU] in 1 mL	
ACER RUBRUM POLLEN (UNII: 700NK45C76) (ACER RUBRUM POLLEN - UNII:700NK45C76)		ACER RUBRUM POLLEN	500 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1215-5	5 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:65044-1338
Route of Administration	INTRADERMAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
JUNIPERUS ASHEI POLLEN (UNII: 544F8MEY0 Y) (JUNIPERUS ASHEI POLLEN - UNII:544F8MEY0 Y)		JUNIPERUS ASHEI POLLEN	500 [PNU] in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
PHENOL (UNII: 339NCG44TV)			
SODIUM CHLORIDE (UNII: 451W47IQ8 X)			
SODIUM BICARBONATE (UNII: 8MDF5V39QO)			
GLYCERIN (UNII: PDC6A3C0OX)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1338-5	5 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:65044-1341
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
JUNIPERUS VIRGINIANA POLLEN (UNII: PY0JA16R2G) (JUNIPERUS VIRGINIANA POLLEN - UNII:PY0JA16R2G)	JUNIPERUS VIRGINIANA POLLEN	500 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1341-5	5 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:65044-1437
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
POPULUS DELTOIDES POLLEN (UNII: 476DVV63WP) (POPULUS DELTOIDES POLLEN - UNII:476DVV63WP)	POPULUS DELTOIDES POLLEN	500 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1437-5	5 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:65044-1542
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD)	ULMUS AMERICANA POLLEN	500 [PNU] in 1 mL

Inactive Ingredients	
----------------------	--

Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1542-5	5 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:65044-1548
Route of Administration		INTRADERMAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ULMUS PARVIFOLIA POLLEN (UNII: IU0Z41653U) (ULMUS PARVIFOLIA POLLEN - UNII:IU0Z41653U)			ULMUS PARVIFOLIA POLLEN	500 [PNU] in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1548-5	5 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:65044-1665
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CELTIS OCCIDENTALIS POLLEN (UNII: 68 R9 X9 Y96 X) (CELTIS OCCIDENTALIS POLLEN - UNII:68 R9 X9 Y96 X)	CELTIS OCCIDENTALIS POLLEN	500 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1665-5	5 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:65044-1833
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety

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

ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861)	ACER SACCHARUM POLLEN	500 [PNU] in 1 mL
--	-----------------------	-------------------

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1833-5	5 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:65044-1878
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PROSOPIS JULIFLORA POLLEN (UNII: 6EIJ3D04MR) (PROSOPIS JULIFLORA POLLEN - UNII:6EIJ3D04MR)	PROSOPIS JULIFLORA POLLEN	500 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NDC:65044-1878-5	5 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:65044-1911
Route of Administration		INTRADERMAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
MORUS ALBA POLLEN (UNII: 3I9T68187H) (MORUS ALBA POLLEN - UNII:3I9T68187H)			MORUS ALBA POLLEN	500 [PNU] in 1 mL
MORUS RUBRA POLLEN (UNII: 9LYI4RTZ52) (MORUS RUBRA POLLEN - UNII:9LYI4RTZ52)			MORUS RUBRA POLLEN	500 [PNU] in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1911-5	5 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:65044-2037	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
QUERCUS RUBRA POLLEN (UNII: SVW19ET93C) (QUERCUS RUBRA POLLEN - UNII:SVW19ET93C)		QUERCUS RUBRA POLLEN	500 [PNU] in 1 mL	
QUERCUS VIRGINIANA POLLEN (UNII: 8KDG09A4GO) (QUERCUS VIRGINIANA POLLEN - UNII:8KDG09A4GO)		QUERCUS VIRGINIANA POLLEN	500 [PNU] in 1 mL	
QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK)		QUERCUS ALBA POLLEN	500 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2037-5	5 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:65044-2016
Route of Administration	INTRADERMAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
QUERCUS RUBRA POLLEN (UNII: SVW19ET93C) (QUERCUS RUBRA POLLEN - UNII:SVW19ET93C)		QUERCUS RUBRA POLLEN	500 [PNU] in 1 mL
Inactive Ingredients			

Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2016-5	5 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:65044-2052
Route of Administration		INTRADERMAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
OLEA EUROPAEA POLLEN (UNII: 43R41XZ627) (OLEA EUROPAEA POLLEN - UNII:43R41XZ627)			OLEA EUROPAEA POLLEN	500 [PNU] in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2052-5	5 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:65044-2100
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARYA ILLINOINENSIS POLLEN (UNII: PYO4JR720 Y) (CARYA ILLINOINENSIS POLLEN - UNII:PYO4JR720 Y)	CARYA ILLINOINENSIS POLLEN	500 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8 X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2100-5	5 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:65044-2361
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ELAEAGNUS ANGUSTIFOLIA POLLEN (UNII: 68P4F4M6VD) (ELAEAGNUS ANGUSTIFOLIA POLLEN - UNII:68P4F4M6VD)		ELAEAGNUS ANGUSTIFOLIA POLLEN	500 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2361-5	5 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:65044-2565
Route of Administration	INTRADERMAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK)		PLATANUS OCCIDENTALIS POLLEN	500 [PNU] in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
PHENOL (UNII: 339NCG44TV)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
SODIUM BICARBONATE (UNII: 8MDF5V39QO)			
GLYCERIN (UNII: PDC6A3C0OX)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2565-5	5 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:65044-2621
Route of Administration	INTRADERMAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q)		FRAXINUS AMERICANA POLLEN	500 [PNU] in 1 mL
FAGUS GRANDIFOLIA POLLEN (UNII: 34X886W1H4) (FAGUS GRANDIFOLIA POLLEN - UNII:34X886W1H4)		FAGUS GRANDIFOLIA POLLEN	500 [PNU] in 1 mL
BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P)		BETULA NIGRA POLLEN	500 [PNU] in 1 mL
JUGLANS NIGRA POLLEN (UNII: 1BV28146ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28146ZR)		JUGLANS NIGRA POLLEN	500 [PNU] in 1 mL
POPULUS DELTOIDES POLLEN (UNII: 476DVV63WP) (POPULUS DELTOIDES POLLEN - UNII:476DVV63WP)		POPULUS DELTOIDES POLLEN	500 [PNU] in 1 mL
ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD)		ULMUS AMERICANA POLLEN	500 [PNU] in 1 mL
CARYA OVATA POLLEN (UNII: 54UN9R2798) (CARYA OVATA POLLEN - UNII:54UN9R2798)		CARYA OVATA POLLEN	500 [PNU] in 1 mL
ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861)		ACER SACCHARUM POLLEN	500 [PNU] in 1 mL
QUERCUS RUBRA POLLEN (UNII: SVW19ET93C) (QUERCUS RUBRA POLLEN - UNII:SVW19ET93C)		QUERCUS RUBRA POLLEN	500 [PNU] in 1 mL
PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK)		PLATANUS OCCIDENTALIS POLLEN	500 [PNU] in 1 mL
SALIX NIGRA POLLEN (UNII: 6M2JIH93ZN) (SALIX NIGRA POLLEN - UNII:6M2JIH93ZN)		SALIX NIGRA POLLEN	500 [PNU] in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
PHENOL (UNII: 339NCG44TV)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
SODIUM BICARBONATE (UNII: 8MDF5V39QO)			
GLYCERIN (UNII: PDC6A3C0OX)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2621-5	5 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:65044-2857
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CARYA ILLINOINENSIS POLLEN (UNII: PYO4JR720 Y) (CARYA ILLINOINENSIS POLLEN - UNII:PYO4JR720 Y)	CARYA ILLINOINENSIS POLLEN	500 [PNU] in 1 mL
ACER SACCHARUM POLLEN (UNII: V38QUQ786 1) (ACER SACCHARUM POLLEN - UNII:V38QUQ786 1)	ACER SACCHARUM POLLEN	500 [PNU] in 1 mL
ACER NEGUNDO POLLEN (UNII: P6K070AR8 V) (ACER NEGUNDO POLLEN - UNII:P6K070AR8 V)	ACER NEGUNDO POLLEN	500 [PNU] in 1 mL
ACER RUBRUM POLLEN (UNII: 700NK45C76) (ACER RUBRUM POLLEN - UNII:700NK45C76)	ACER RUBRUM POLLEN	500 [PNU] in 1 mL
QUERCUS RUBRA POLLEN (UNII: SVW19ET93C) (QUERCUS RUBRA POLLEN - UNII:SVW19ET93C)	QUERCUS RUBRA POLLEN	500 [PNU] in 1 mL
QUERCUS VIRGINIANA POLLEN (UNII: 8KDG09A4GO) (QUERCUS VIRGINIANA POLLEN - UNII:8KDG09A4GO)	QUERCUS VIRGINIANA POLLEN	500 [PNU] in 1 mL
QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK)	QUERCUS ALBA POLLEN	500 [PNU] in 1 mL
PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK)	PLATANUS OCCIDENTALIS POLLEN	500 [PNU] in 1 mL
SALIX NIGRA POLLEN (UNII: 6M2JIH93ZN) (SALIX NIGRA POLLEN - UNII:6M2JIH93ZN)	SALIX NIGRA POLLEN	500 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8 X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2857-5	5 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:65044-2860	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q)		FRAXINUS AMERICANA POLLEN	500 [PNU] in 1 mL	
FAGUS GRANDIFOLIA POLLEN (UNII: 34X886W1H4) (FAGUS GRANDIFOLIA POLLEN - UNII:34X886W1H4)		FAGUS GRANDIFOLIA POLLEN	500 [PNU] in 1 mL	
BETULA PAPYRIFERA POLLEN (UNII: 3538FNV8AY) (BETULA PAPYRIFERA POLLEN - UNII:3538FNV8AY)		BETULA PAPYRIFERA POLLEN	500 [PNU] in 1 mL	
BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P)		BETULA NIGRA POLLEN	500 [PNU] in 1 mL	
BETULA PENDULA POLLEN (UNII: ZL5TV40C5Y) (BETULA PENDULA POLLEN - UNII:ZL5TV40C5Y)		BETULA PENDULA POLLEN	500 [PNU] in 1 mL	
JUGLANS NIGRA POLLEN (UNII: 1BV28146ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28146ZR)		JUGLANS NIGRA POLLEN	500 [PNU] in 1 mL	
POPULUS DELTOIDES POLLEN (UNII: 476DVV63WP) (POPULUS DELTOIDES POLLEN - UNII:476DVV63WP)		POPULUS DELTOIDES POLLEN	500 [PNU] in 1 mL	
ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD)		ULMUS AMERICANA POLLEN	500 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2860-5	5 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:65044-2628	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
JUGLANS NIGRA POLLEN (UNII: 1BV28 146 ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28 146 ZR)		JUGLANS NIGRA POLLEN	500 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2628-5	5 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, WILLOW, BLACK SALIX NIGRA			
willow, black salix nigra injection, solution			
Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:65044-2679
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALIX NIGRA POLLEN (UNII: 6M2JIH93ZN) (SALIX NIGRA POLLEN - UNII:6M2JIH93ZN)	SALIX NIGRA POLLEN	500 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2679-5	5 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:65044-1407
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
XANTHIUM STRUMARIUM POLLEN (UNII: 2QOF601J1M) (XANTHIUM STRUMARIUM POLLEN - UNII:2QOF601J1M)	XANTHIUM STRUMARIUM POLLEN	500 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1407-5	5 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:65044-1632	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
SOLIDAGO CANADENSIS POLLEN (UNII: 644CZ161R5) (SOLIDAGO CANADENSIS POLLEN - UNII:644CZ161R5)		SOLIDAGO CANADENSIS POLLEN	500 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1632-5	5 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, LAMB QUARTERS
CHENOPODIUM ALBUM

lamb quarters chenopodium album injection, solution

Product Information				
Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:65044-1788	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
CHENOPODIUM ALBUM POLLEN (UNII: 098LKK5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKK5NCN)		CHENOPODIUM ALBUM POLLEN	500 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1788-5	5 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:65044-2127
Route of Administration	INTRADERMAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS		AMARANTHUS	500 [PNU]

RETROFLEXUS POLLEN - UNII:73B14PX5FW)		RETROFLEXUS POLLEN	in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2127-5	5 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:65044-2214	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
PLANTAGO LANCEOLATA POLLEN (UNII: DO87T1U2CI) (PLANTAGO LANCEOLATA POLLEN - UNII:DO87T1U2CI)		PLANTAGO LANCEOLATA POLLEN	500 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:65044-2214-5	5 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:65044-2295	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
AMBROSIA TRIFIDA POLLEN (UNII: KU1V1898XX) (AMBROSIA TRIFIDA POLLEN - UNII:KU1V1898XX)		AMBROSIA TRIFIDA POLLEN	500 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2295-5	5 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:65044-2310	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
AMBROSIA PSILOSTACHYA POLLEN (UNII: RX18M46K8L) (AMBROSIA PSILOSTACHYA POLLEN - UNII:RX18M46K8L)		AMBROSIA PSILOSTACHYA POLLEN	500 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2310-5	5 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:65044-2364
Route of Administration	INTRADERMAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
SALSOLA KALI POLLEN (UNII: 2MH135KC6G) (SALSOLA KALI POLLEN - UNII:2MH135KC6G)		SALSOLA KALI POLLEN	500 [PNU] in 1 mL
Inactive Ingredients			
Ingredient Name			Strength

PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2364-5	5 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:65044-2415
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARTEMISIA VULGARIS POLLEN (UNII: ANT994T71D) (ARTEMISIA VULGARIS POLLEN - UNII:ANT994T71D)	ARTEMISIA VULGARIS POLLEN	500 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2415-5	5 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:65044-2484
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATRIPLEX CANESCENS POLLEN (UNII: 26U0BU8G83) (ATRIPLEX CANESCENS POLLEN - UNII:26U0BU8G83)	ATRIPLEX CANESCENS POLLEN	500 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2484-1	5 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:65044-1302
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
AMARANTHUS PALMERI POLLEN (UNII: 1GH3WV23KH) (AMARANTHUS PALMERI POLLEN - UNII:1GH3WV23KH)			AMARANTHUS PALMERI POLLEN	500 [PNU] in 1 mL
AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW)			AMARANTHUS RETROFLEXUS POLLEN	500 [PNU] in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1302-5	5 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:65044-1518
Route of Administration	INTRADERMAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
RUMEX CRISPUS POLLEN (UNII: V825XJG64G) (RUMEX CRISPUS POLLEN - UNII:V825XJG64G)		RUMEX CRISPUS POLLEN	500 [PNU] in 1 mL
RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW)		RUMEX ACETOSELLA POLLEN	500 [PNU] in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
PHENOL (UNII: 339NCG44TV)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
SODIUM BICARBONATE (UNII: 8MDF5V39QO)			

GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1518-5	5 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:65044-2319	
Route of Administration	INTRADERMAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
AMBROSIA TRIFIDA POLLEN (UNII: KU1V1898XX) (AMBROSIA TRIFIDA POLLEN - UNII:KU1V1898XX)		AMBROSIA TRIFIDA POLLEN	500 [PNU] in 1 mL	
AMBROSIA ARTEMISIIFOLIA POLLEN (UNII: K20Y81ACO3) (AMBROSIA ARTEMISIIFOLIA POLLEN - UNII:K20Y81ACO3)		AMBROSIA ARTEMISIIFOLIA POLLEN	500 [PNU] in 1 mL	
AMBROSIA PSILOSTACHYA POLLEN (UNII: RX18M46K8L) (AMBROSIA PSILOSTACHYA POLLEN - UNII:RX18M46K8L)		AMBROSIA PSILOSTACHYA POLLEN	500 [PNU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PHENOL (UNII: 339NCG44TV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2319-5	5 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:65044-1782
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BASSIA SCOPARIA POLLEN (UNII: 07A108ZKW5) (BASSIA SCOPARIA POLLEN - UNII:07A108ZKW5)	BASSIA SCOPARIA POLLEN	500 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1782-5	5 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:65044-1860
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

IVA AXILLARIS POLLEN (UNII: 13KFG30UBR) (IVA AXILLARIS POLLEN - UNII:13KFG30UBR)	IVA AXILLARIS POLLEN	500 [PNU] in 1 mL
IVA ANNUA POLLEN (UNII: Y2U5S5PF22) (IVA ANNUA POLLEN - UNII:Y2U5S5PF22)	IVA ANNUA POLLEN	500 [PNU] in 1 mL
CYCLACHAENA XANTHIFOLIA POLLEN (UNII: V80TPZ0T6J) (CYCLACHAENA XANTHIFOLIA POLLEN - UNII:V80TPZ0T6J)	CYCLACHAENA XANTHIFOLIA POLLEN	500 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1860-5	5 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:65044-2631
Route of Administration	INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
XANTHIUM STRUMARIUM POLLEN (UNII: 2QOF601J1M) (XANTHIUM STRUMARIUM POLLEN - UNII:2QOF601J1M)	XANTHIUM STRUMARIUM POLLEN	500 [PNU] in 1 mL
CHENOPODIUM ALBUM POLLEN (UNII: 098LKX5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKX5NCN)	CHENOPODIUM ALBUM POLLEN	500 [PNU] in 1 mL
AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW)	AMARANTHUS RETROFLEXUS POLLEN	500 [PNU] in 1 mL
RUMEX CRISPUS POLLEN (UNII: V825XJG64G) (RUMEX CRISPUS POLLEN - UNII:V825XJG64G)	RUMEX CRISPUS POLLEN	500 [PNU] in 1 mL
RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW)	RUMEX ACETOSELLA POLLEN	500 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2631-5	5 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	

Labeler - Jubilant HollisterStier LLC (069263643)

Registrant - Jubilant HollisterStier LLC (069263643)