

LIL DRUG STORE HEADACHE RELIEF EXTRA STRENGTH- acetaminophen, aspirin, and caffeine tablet
Lil' Drug Store Products, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Lil' Drug Store[®] Headache Relief

Extra Strength

Drug Facts

<i>Active ingredients (in each caplet)</i>	<i>Purposes</i>
Acetaminophen 250 mg	Pain reliever
Aspirin 250 mg (NSAID) *	Pain reliever
Caffeine 65 mg	Pain reliever aid

* nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - a cold
 - arthritis
 - muscular aches
 - toothache
 - premenstrual and menstrual cramps

Warnings

Reye's syndrome

Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Allergy alert

Aspirin may cause a severe allergic reaction, which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 8 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Stomach bleeding warning

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Caffeine warning

The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.

Do not use

- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are taking

- a prescription drug for diabetes, gout, or arthritis

- any other drug or are under a doctor's care for any serious condition

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better.
- ringing in the ears or loss of hearing occurs
- painful area is red or swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- any new symptoms appear

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not use more than directed**
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 caplets every 6 hours; do not take more than 8 caplets in 24 hours
- children under 12 years: do not use unless directed by a doctor

Other information

- store between 20°-25°C (68°-77°F)

Inactive ingredients

carnauba wax ¹, colloidal silicon dioxide, corn starch, hypromellose, microcrystalline cellulose, mineral oil ¹, polyethylene glycol ¹, povidone, sodium starch glycolate ¹, stearic acid, talc ¹, titanium dioxide ¹

¹ contains one or more of these ingredients

Questions or comments?

Call toll-free **1-877-507-6516 (M-F 8AM-4:30PM CST)**

Product distributed by:

Lil' Drug Store Products, Inc.
9300 Earhart Lane SW
Cedar Rapids, IA 52404

PRINCIPAL DISPLAY PANEL - 50 Caplet Bottle Carton - NDC 66715-6822

★ QUALITY
GUARANTEED ★

Compare to the Active
Ingredients in Excedrin[®]
Extra Strength †

Extra Strength
Headache
Acetaminophen,
Aspirin (NSAID) and Caffeine
Pain Reliever/Pain Reliever Aid

ACTUAL SIZE

50
Caplets

Lil'
Drug Store[®]

Extra Strength

Headache

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Aspirin (NSAID) and Caffeine
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ACTUAL SIZE

50
Caplets



Product distributed by:
Lil' Drug Store Products, Inc.
9300 Earhart Lane SW
Cedar Rapids, IA 52404

PLD-B103G
FC005259



3 66715 68224 6

Lot No:
Exp Date:

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY
SEAL UNDER CAP IS BROKEN OR MISSING.
KEEP OUTER CARTON FOR COMPLETE
WARNINGS AND PRODUCT INFORMATION.**

Drug Facts

Active ingredients (in each caplet) Purposes

Acetaminophen 250 mg.....	Pain reliever
Aspirin 250 mg (NSAID)*.....	Pain reliever
Caffeine 65 mg.....	Pain reliever aid
*nonsteroidal anti-inflammatory drug	

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - a cold
 - arthritis
 - muscular aches
 - toothache
 - premenstrual and menstrual cramps

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin redening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Allergy alert: Aspirin may cause a severe allergic reaction, which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 8 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Stomach bleeding warning: This product contains an



This product is not manufactured or distributed by GSK Consumer Healthcare distributor of Excedrin® Extra Strength.

Drug Facts (continued)

NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
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Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.

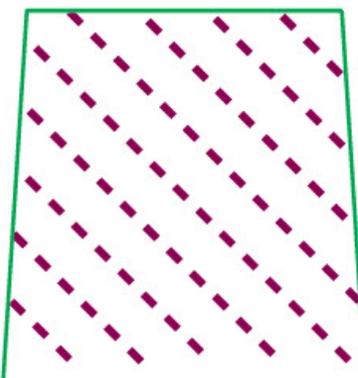
Do not use

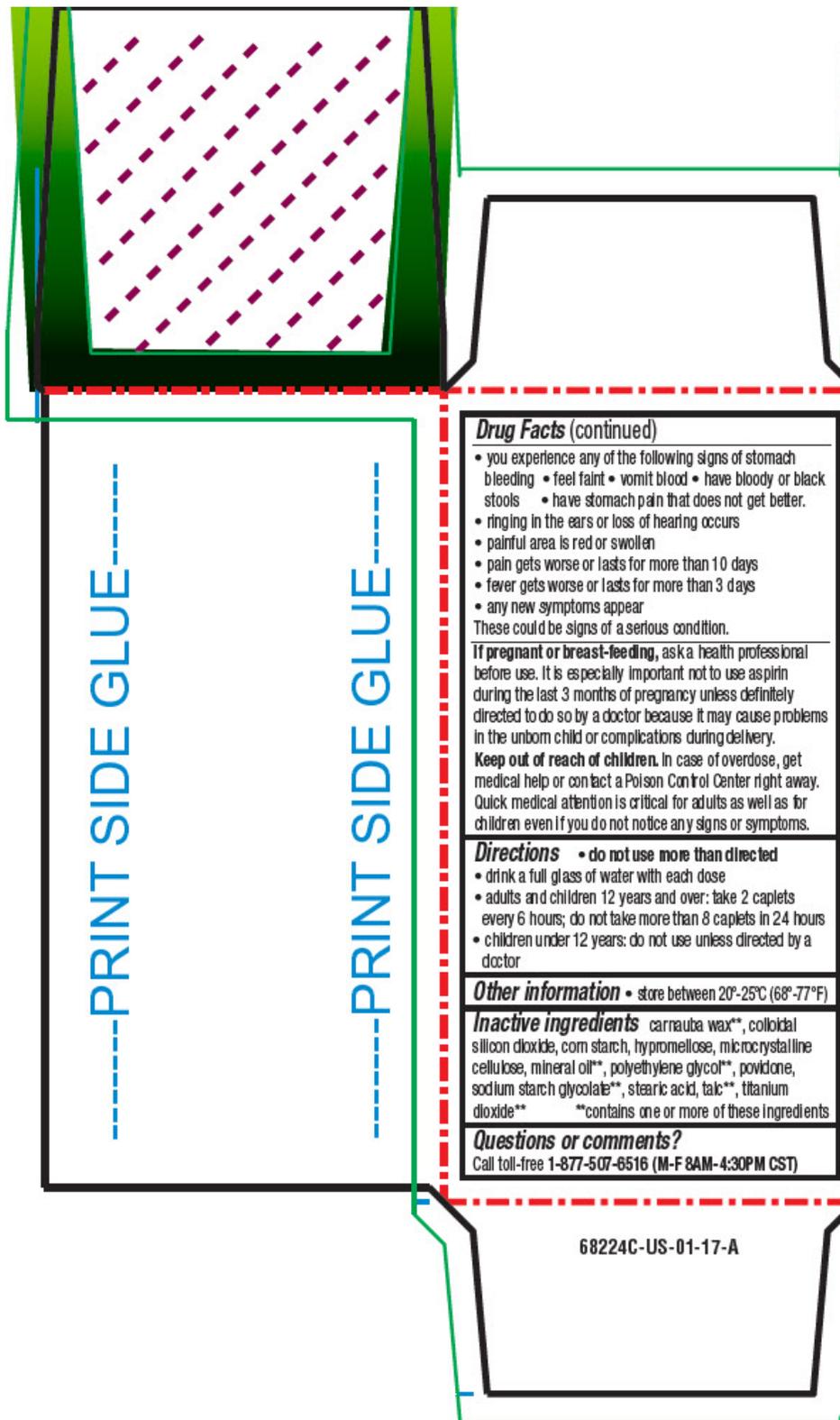
- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- Ask a doctor before use if**
- you have liver disease
 - stomach bleeding warning applies to you
 - you have a history of stomach problems, such as heartburn
 - you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
 - you are taking a diuretic
 - you have asthma

- Ask a doctor or pharmacist before use if you are taking**
- a prescription drug for diabetes, gout, or arthritis
 - any other drug or are under a doctor's care for any serious condition

Stop use and ask a doctor if an allergic reaction occurs. Seek medical help right away.





PRINCIPAL DISPLAY PANEL - 50 Caplet Bottle Carton - NDC 66715-5822

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GUARANTEED ★

Compare to the Active
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Extra Strength[†]

Extra Strength
Headache
Acetaminophen,
Aspirin (NSAID) and Caffeine
Pain Reliever/Pain Reliever Aid

ACTUAL SIZE

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Lil'
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Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin redening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Allergy alert: Aspirin may cause a severe allergic reaction, which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

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Drug Facts (continued)

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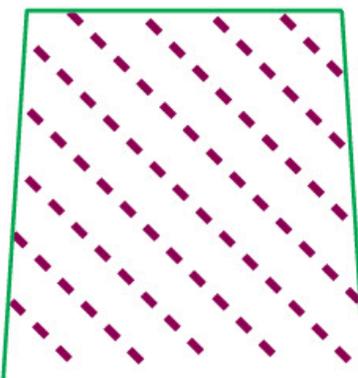
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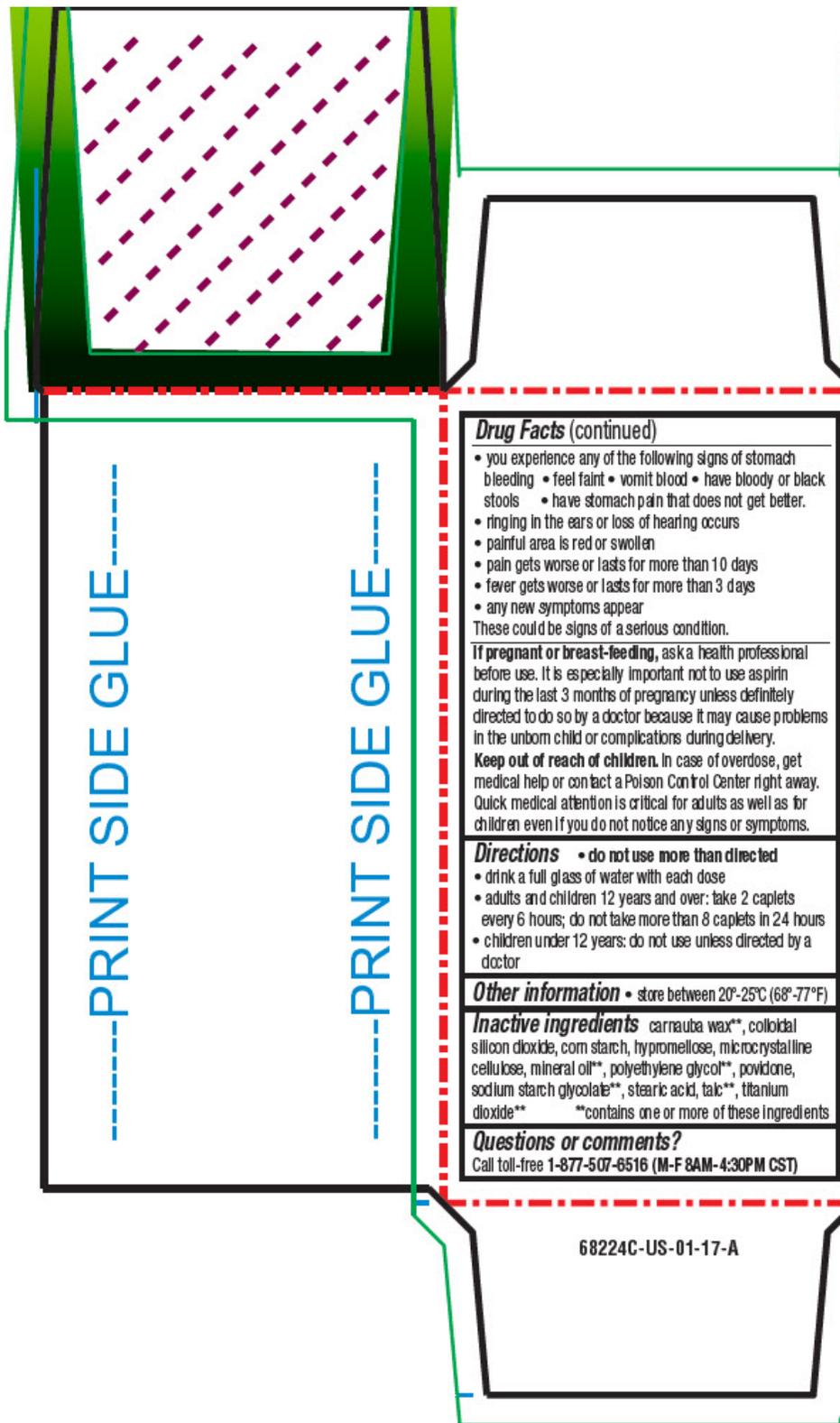
- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- Ask a doctor before use if**
- you have liver disease
 - stomach bleeding warning applies to you
 - you have a history of stomach problems, such as heartburn
 - you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
 - you are taking a diuretic
 - you have asthma

- Ask a doctor or pharmacist before use if you are taking**
- a prescription drug for diabetes, gout, or arthritis
 - any other drug or are under a doctor's care for any serious condition

Stop use and ask a doctor if an allergic reaction occurs. Seek medical help right away.





LIL DRUG STORE HEADACHE RELIEF EXTRA STRENGTH

acetaminophen, aspirin, and caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-6822
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	TCL370
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715-6822-4	1 in 1 CARTON	02/27/2019	09/24/2024
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	11/27/2017	09/24/2024

LIL DRUG STORE HEADACHE RELIEF EXTRA STRENGTH

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MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	2793
Contains			

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Labeler - Lil' Drug Store Products, Inc. (093103646)

Revised: 11/2021

Lil' Drug Store Products, Inc.