



AUTOMATIC LIQUID PACKAGING, INC.

2200 LAKE SHORE DRIVE WOODSTOCK, ILLINOIS 60098-7498 USA
TELEPHONE 815 338 9500 FACSIMILE 815 338 5504
<http://www.alp-bfs.com>

JUL 23 10 05

July 20, 1999

Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

RE: Application for Exemption from 21 CFR 201.66 (OTC Labeling Format)
Relief Eye Drops

To Whom it may Concern:

Automatic Liquid Packaging Inc., (ALP) is a Contract Manufacturer of OTC Ophthalmic Eye Care Products, located in Woodstock, Illinois. We contract manufacture for retail companies such as Rite Aid, Walgreen's, Sentry, etc.

For approximately 8 - 10 years we have been manufacturing and distributing a line of eye drops manufactured by our internal Personal Care division of ALP in 0.5 and 1.0 fluid Ounce Sizes. This line of products is in compliance as outlined in **21 CFR 349**. The line consists of the following:

PRODUCT NAME

ACTIVE INGREDIENT

Relief Eye Drops

Tetrahydrozoline HCL
(a vasoconstrictor)
Zinc sulfate
(an astringent)

All the active ingredients conform to USP and are in compliance to the percents of Active Ingredients allowed in **21 CFR 349**.

Automatic Liquid Packaging, Inc., is requesting an Exemption from the labeling requirements as described in Federal Register published March 17, 1999 entitled "**Over-The-Counter Human Drugs; Labeling Requirements**" for our 0.5 and 1.0 Fluid Ounce size container box. The reason for this is that when all the Agency required labeling statements are included on the back panel in the new format and Helvetica type size, there is no room for the additional FDA labeling requirements.

Please refer to the attached copies of the carton and immediate container labeling that is included in this Application. Note the Helvetica type size and arrangement of the required statements on the Principle Display Panel. In addition, note the placement of statements such as Storage requirements, Manufactured by, Bar coding, Tamper evident, and Eye Drop

98N-0337

APP 2

Page 2

Container opening instructions Statements such as this also must appear on the outside package.

As such, Automatic Liquid packaging requests an exemption from the Helvetica Labeling letter size requirements, as described in **21 CFR 201.66** (OTC Labeling Format) for the above mentioned Ophthalmic drops for our 0.5 and 1.0 fluid ounce size.

As mentioned previously in the Request for Exemption, ALP is a Contract Manufacturer of OTC Ophthalmic Eye Drops for many Retail Distributors. If the Agency will allow the requested modifications to the Principle Display Panel as attached, we also request approval for the retail distributors we manufacture the same ophthalmic product line. These distributors are detailed in the list attached to this letter. As you could imagine, from time to time, ALP will acquire a new distributor. If the Agency allows the modified text for our in-house "Your Choice" line, as well as our current list of distributors, we respectfully request that any new distributors we add be allowed these same modifications. ALP commits that the information included on the Principle Display Panel and side panels would be identical as shown in the Attachments for all present and future distributors we manufacture this eye drop line.

Please contact me at (815) 338-9500 with any questions, or if you require any additional information.

Sincerely,

AUTOMATIC LIQUID PACKAGING, INC.



John Brda
Regulatory Affairs Manager

c Al Rothchild

.5 Oz. Relief Eye Drops

Logo
Relief Eye Drops Sterile

**ASTRINGENT EYE DROPS
REDNESS RELIEVER**

• *Temporarily Relieves
Discomfort Due To Minor Eye
Irritations*

.5 fl. oz. (15 mL)

INDICATIONS: For the temporary relief of discomfort from minor eye irritations. Relieves redness of the eye due to minor eye irritations.
DIRECTIONS: instill 1 to 2 drops in the affected eye(s) up to 4 times daily

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.

Active Ingredients: Zinc Sulfate 0.25% and Tetrahydrozoline Hydrochloride 0.05%.

Inactive Ingredients: benzalkonium chloride, boric acid, EDTA, purified water, sodium chloride, and sodium citrate.

KEEP CONTAINER TIGHTLY CLOSED.
TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.
Distributed by or Manufactured by

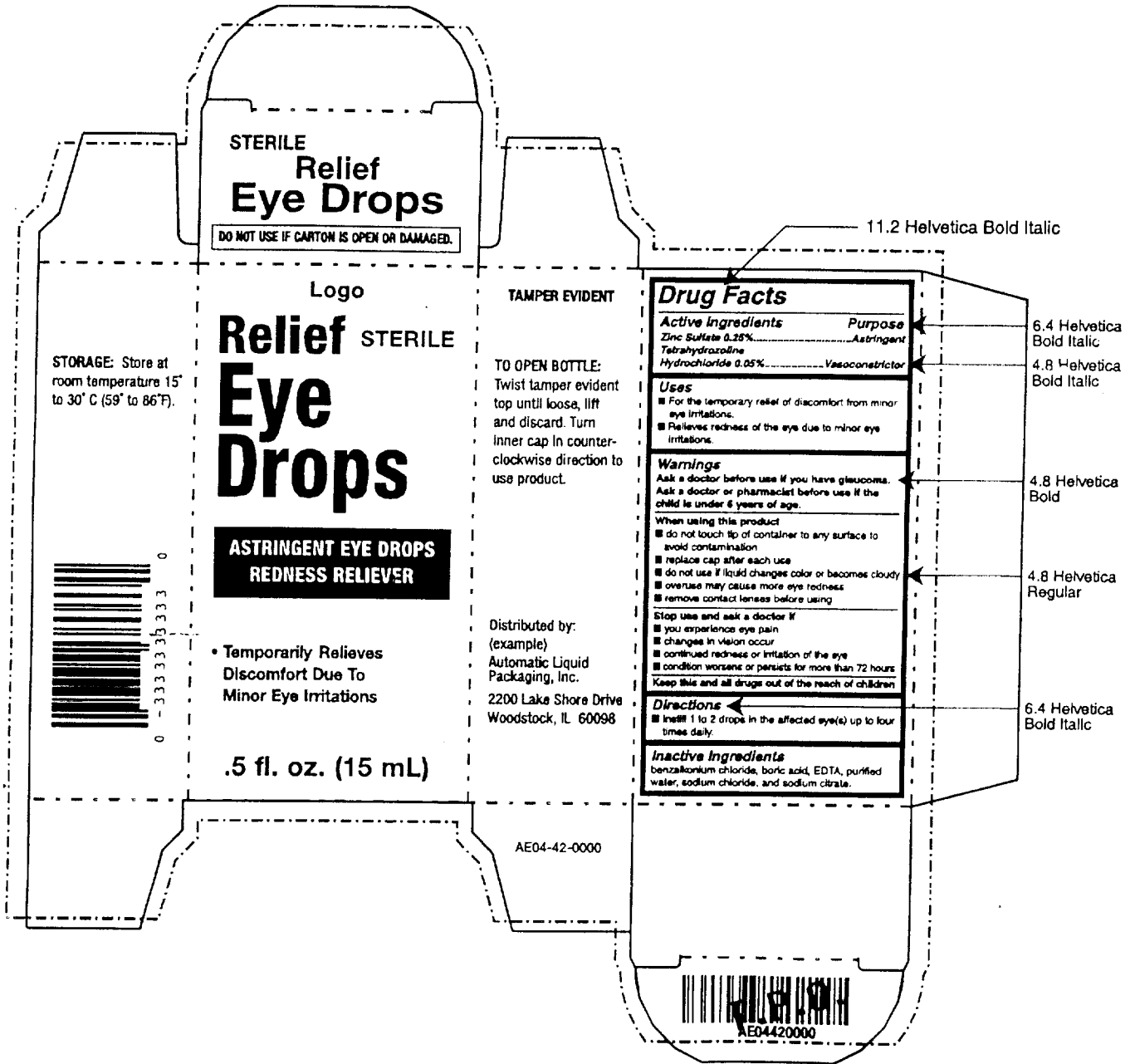
AE05-13-0000

1 Oz. Relief Eye Drops

<p>Logo</p> <p>Relief Eye Drops</p> <p>Sterile</p> <p>ASTRINGENT EYE DROPS REDNESS RELIEVER</p> <p>• <i>Temporarily Relieves Discomfort Due To Minor Eye Irritations</i></p> <p>1 fl. oz. (30 mL)</p>	<p>INDICATIONS: For the temporary relief of discomfort from minor eye irritations. Relieves redness of the eye due to minor eye irritations.</p> <p>DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to 4 times daily.</p> <p>FOR USE IN THE EYES ONLY.</p> <p>WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.</p> <p>Active Ingredients: Zinc Sulfate 0.25% and Tetrahydrozoline Hydrochloride 0.05%.</p> <p>Inactive Ingredients: benzalkonium chloride, boric acid, EDTA, purified water, sodium chloride, and sodium citrate.</p> <p>KEEP CONTAINER TIGHTLY CLOSED.</p> <p>TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.</p> <p>Distributed by or Manufactured by:</p>
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AE05-13-0000

.5 Oz. Relief Eye Drops



! Oz. Relief Eye Drops

STERILE
**Relief
Eye Drops**

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

STERILE
**Relief
Eye
Drops**

**ASTRINGENT EYE DROPS
REDNESS RELIEVER**

- Temporarily Relieves Discomfort Due To Minor Eye Irritations

1 fl. oz. (30 mL)



TO OPEN BOTTLE:
Twist tamper evident top until loose, lift and discard. Turn inner cap in counterclockwise direction to use product.

STORAGE: Store at room temperature 15° to 30°C (59° to 86°F).

AE04-42-0000

Drug Facts

Active Ingredients	Purpose
Zinc Sulfate 0.25%	Astringent
Tetrahydrozoline	
Hydrochloride 0.05%	Vasoconstrictor

Uses

- For the temporary relief of discomfort from minor eye irritations.
- Relieves redness of the eye due to minor eye irritations.

Warnings

Ask a doctor before use if you have glaucoma. Ask a doctor or pharmacist before use if the child is under 6 years of age. Keep this and all drugs out of the reach of children. If swallowed, seek professional assistance or contact a Poison Control Center immediately.

When using this product

- to avoid contamination, do not touch tip of container to any surface.
- replace cap after each use
- do not use if liquid changes color or becomes cloudy
- overuse may cause more eye redness
- remove contact lenses before using

Stop use and ask a doctor if

- you experience eye pain
- changes in vision occur
- continued redness or irritation of the eye
- condition worsens or persists for more than 72 hours

Directions

- Instill 1 to 2 drops in the affected eye(s) up to four times daily.

Inactive Ingredients
benzalkonium chloride, boric acid, EDTA, purified water, sodium chloride and sodium citrate.

12.6 pt. Helvetica Bold

7.2 pt. He

5.4 pt. He

5.4 pt. He

5.4 pt. He

0.5 pt. Ha

2.5 pt. Bo

7.2 pt. He



.5 Oz. Relief Eye Drops

Logo
Relief Eye Drops Sterile

**ASTRINGENT EYE DROPS
REDNESS RELIEVER**

Temporarily Relieves
Discomfort Due To Minor Eye
Irritations

.5 fl. oz. (15 mL)

INDICATIONS: For the temporary relief of discomfort from minor eye irritations. Relieves redness of the eye due to minor eye irritations.
DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to 4 times daily.

FOR USE IN THE EYES ONLY.

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TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.
Distributed by or Manufactured by

AE05-13-0000

1 Oz. Relief Eye Drops

Logo

**Relief
Eye
Drops**

Sterile

**ASTRINGENT EYE DROPS
REDNESS RELIEVER**

• *Temporarily Relieves
Discomfort Due To
Minor Eye Irritations*

1 fl. oz. (30 mL)

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Distributed by or Manufactured by

AE05-13-0000

.5 Oz. Relief Eye Drops

STERILE
Relief Eye Drops
DO NOT USE IF CARTON IS OPEN OR DAMAGED.

STORAGE: Store at room temperature 15° to 30° C (59° to 86°F).

0 - 3333333333 0

Logo
Relief STERILE
Eye Drops
ASTRINGENT EYE DROPS
REDNESS RELIEVER

- Temporarily Relieves Discomfort Due To Minor Eye Irritations

.5 fl. oz. (15 mL)

AE04-42-0000

TAMPER EVIDENT

TO OPEN BOTTLE:
Twist tamper evident top until loose, lift and discard. Turn inner cap in counter-clockwise direction to use product.

Distributed by:
(example)
Automatic Liquid Packaging, Inc.
2200 Lake Shore Drive
Woodstock, IL 60098

Drug Facts

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Tetrahydrozoline Hydrochloride 0.05%	Vasoconstrictor

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11.2 Helvetica Bold Italic

6.4 Helvetica Bold Italic

4.8 Helvetica Bold Italic

4.8 Helvetica Bold

4.8 Helvetica Regular

6.4 Helvetica Bold Italic

AE04420000

1 Oz. Relief Eye Drops

STERILE
**Relief
Eye Drops**

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

STERILE
**Relief
Eye
Drops**

**ASTRINGENT EYE DROPS
REDNESS RELIEVER**

• Temporarily Relieves
Discomfort Due To
Minor Eye Irritations

1 fl. oz. (30 mL)



TO OPEN BOTTLE:
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Turn inner cap in
counterclockwise
direction to use
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AE04-42-0000

Drug Facts

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When using this product
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■ do not use if liquid changes color or becomes cloudy
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12.6 pt. Helvetica Bold

7.2 pt. Hel

5.4 pt. Hel

5.4 pt. Hel

5.4 pt. Hel

0.5 pt. Hai

2.5 pt. Boi

7.2 pt. Hel



.5 Oz. Relief Eye Drops

Logo
Relief Eye Drops Sterile

ASTRINGENT EYE DROPS
REDNESS RELIEVER

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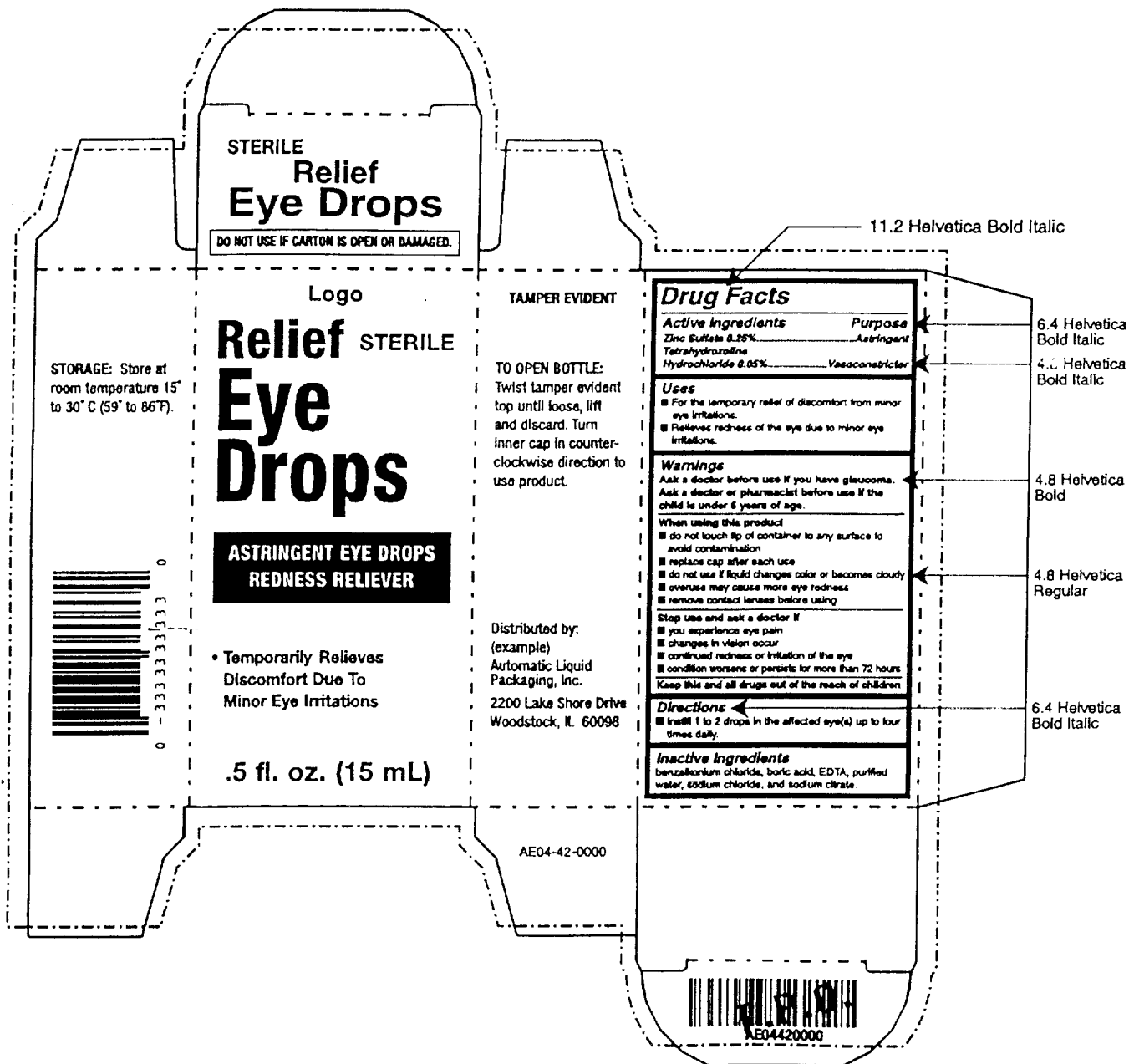
Distributed by or Manufactured by

AE05-13-0000

1 Oz. Relief Eye Drops

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.5 Oz. Relief Eye Drops



STERILE
**Relief
Eye Drops**

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

Relief **STERILE**
**Eye
Drops**

**ASTRINGENT EYE DROPS
REDNESS RELIEVER**

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(example)
Automatic Liquid Packaging, Inc.
2200 Lake Shore Drive
Woodstock, IL 60098

AE04-42-0000

11.2 Helvetica Bold Italic

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6.4 Helvetica Bold Italic
4.0 Helvetica Bold Italic

4.8 Helvetica Bold

4.8 Helvetica Regular

6.4 Helvetica Bold Italic



1 Oz. Relief Eye Drops

STERILE
**Relief
Eye Drops**

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

STERILE
**Relief
Eye
Drops**

**ASTRINGENT EYE DROPS
REDNESS RELIEVER**

• Temporarily Relieves
Discomfort Due To
Minor Eye Irritations

1 fl. oz. (30 mL)



0 - 3333333333 0

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AE04-42-0000

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12.6 pt. Helvetica Bold

7.2 pt. Hel

5.4 pt. Hel

5.4 pt. Hel

5.4 pt. Hel

0.5 pt. Hai

2.5 pt. Bot

7.2 pt. Hel



AE04420000

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SHIP DATE: 22JUL99

SHIPPING
AUTOMATIC LIQUID PACKAGING
2200 W LAKESHORE DR
WOODSTOCK IL 60098
(815)338-9500

ACTUAL WGT: 2 LBS MAN-HT

TO:
FOOD & DRUG ADMINISTRATION
5630 FISHERS LANE
ROOM 1061
ROCKVILLE MD 20852

4565 8349 5509

FedEx

4565 8349 5509

REF: GEORGIA JENSM

PRIORITY OVERNIGHT

FR

AD# 0666924 22JUL99

Deliver by:
23JUL99

TRK# 4565 8349 5509 Form 0201

20852 -MD-US

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Tori



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