

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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- APP 3
- APP 4
- APP 5

1023 '99 AUG 30 1999

Automatic Liquid Packaging, Inc.
 Attn: John Brda
 Regulatory Affairs Manager
 2200 Lake Shore Drive
 Woodstock, Illinois 60098-7498

AUG 23 1999

Dear Mr. Brda:

Please refer to your Applications for Exemption dated July 20, 1999, submitted under 21 CFR 201.66(e) for the following drug products:

Relief Eye Drops (tetrahydrozoline HCl and zinc sulfate) in 0.5 and 1 fl. oz. containers;
 Extra Eye Drops (tetrahydrozoline HCl and polyethylene glycol 400) in 0.5 and 1 fl. oz. containers;
 Regular Eye Drops (tetrahydrozoline HCl) in 0.5 and 1 fl. oz. containers; and
 Artificial Tears (polyvinyl alcohol and povidone) in 0.5 and 1 fluid ounce containers.

Your application requests use of type sizes, other than those required by 21 CFR 201.66 in order to accommodate all required labeling.

We have completed our review of your request and it is denied. Your Application for Exemption does not provide substantial evidence to establish that the requirements specified in 21 CFR 201.66 are inapplicable, impracticable, or contrary to public health or safety. Specifically:

1. Though not requested as exemptions, there were several deviations from the elements of the Drug Facts formed required by 21 CFR 201.66.
2. You have requested less than 6-point type for information in the Drug Facts Box, while the Drug Facts heading and other headings are larger than the minimum permitted type size. Furthermore, no attempt was made to continue the Drug Facts information on more than one panel, which may permit full compliance with 21 CFR 201.66.
3. As stated in the OTC Labeling Final Rule (64 FR 13254 at 13264-13265), the type size for required OTC drug product labeling information must be no smaller than 6-point, under the conditions set forth in the final rule, including format exceptions for small packages as identified in 21 CFR 201.66(d)(10). Furthermore, the final rule addressed the importance of type size to achieve

98N-0337

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readability, as well as the difficulty that a significant number of consumers have in reading OTC drug product labeling.

Please be advised that our comments do not address all aspects of your proposed draft labeling, and as such, do not constitute an official review of labeling.

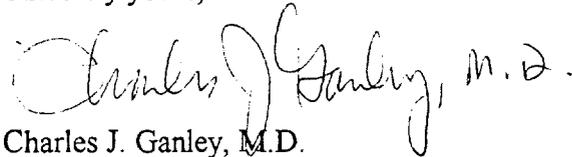
The Agency notes that the labeling on the immediate containers are difficult to read (e.g. all uppercase headings, information in paragraphs). For products that are sold with an outer package, the Agency encourages manufacturers to try to meet all of the labeling requirements in this rule on the immediate container as well.

For a copy of 21 CFR 201.66, please refer to the Dockets Management Branch website located at:

<http://www.fda.gov/cder/otc/label/label-fr-reg.htm>

Should you have any questions, please contact Elizabeth Yuan, R.Ph., Regulatory Project Manager at (301) 827-2222.

Sincerely yours,



Charles J. Ganley, M.D.
Division Director
Division of Over-the-Counter Drug Products
Center for Drug Evaluation and Research

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CC:

HFD-560 Div. File

HFD-560/Ganley/Katz/Cook/Rachanow/Rothschild/

Yuan/Merritt/Martin/Freeman/Sherman/Turner

HFD-105/DeLap/Bowen

HFD-312/R. Eshelman

HFD-610/R. West

DMB Docket #98N-0337, APP2, APP3, APP4, and APP5.

EXEMPTION DENIAL

MODE = MEMORY TRANSMISSION

START=AUG-24 15:56

END=AUG-24 15:58

FILE NO. = 007

STN NO.	COM	ABBR NO.	STATION NAME/TEL.NO.	PAGES	DURATION
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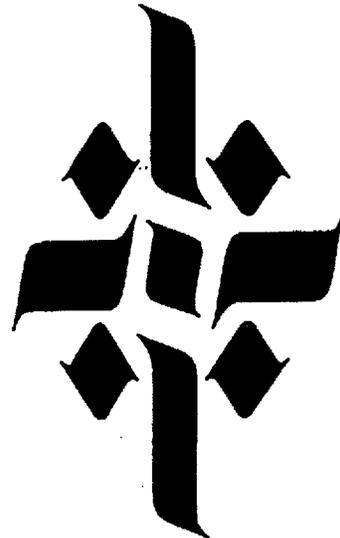
-DIV OF OTC DRUG PROD -

***** -HFD-560

- ***** -

301 827 2315- *****

**FOOD AND DRUG ADMINISTRATION
 DIVISION OF OTC DRUG PRODUCTS
 OFFICE OF DRUG EVALUATION V
 CENTER FOR DRUG EVALUATION & RESEARCH
 5600 FISHERS LANE, HFD-560
 ROCKVILLE, MD 20857-001
 301-827-2222 (phone)
 301-827-2315(fax)**



DATE 8/24/99

TO: John Brck
Regulatory Affairs Manager

PHONE: 815-338-9500

FAX: 815-338-5504

3 PGS. (FAX + COVER)

FROM: Elizabeth Yuan
Division of Over-the-Counter Drug Products

MESSAGE Attached is the Agency's response to your
Application for Exemption dated July 20, 1999, submitted
under 21 CFR 201.66(e) for Relief Eye Drops, Extra Eye
Drops, Regular Eye Drops, and Artificial Teard.

Thank you

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone (301-827-2222) and return it to us at the above address by mail. THANK YOU.

Review of Application For Exemption from 21 CFR 201.66

Report # (DMB Assigned): APP2	Sponsor: Automatic Liquid Packaging, Inc.
Drug Product: Relief Eye Drops Tetrahydrozoline HCl (vasoconstrictor) Zinc Sulfate (astringent)	Affected Label (SKU): Outer containers for 0.5 oz. and 1.0 oz. packages.
Submission Date: July 20, 1999	Review Date: August 13, 1999
Reviewer: Katharine A. Freeman	

Report # (DMB Assigned): APP3	Sponsor: Automatic Liquid Packaging, Inc.
Drug Product: Extra Eye Drops Tetrahydrozoline HCl (vasoconstrictor) Polyethylene Glycol 400 (demulcent)	Affected Label (SKU): Outer containers for 0.5 oz. and 1.0 oz. packages.
Submission Date: July 20, 1999	Review Date: August 13, 1999
Reviewer: Katharine A. Freeman	

Report # (DMB Assigned): APP4	Sponsor: Automatic Liquid Packaging, Inc.
Drug Product: Regular Eye Drops Tetrahydrozoline HCl (vasoconstrictor)	Affected Label (SKU): Outer containers for 0.5 oz. and 1.0 oz. packages.
Submission Date: July 20, 1999	Review Date: August 13, 1999
Reviewer: Katharine A. Freeman	

Report # (DMB Assigned): APP5	Sponsor: Automatic Liquid Packaging, Inc.
Drug Product: Artificial Tears Polyvinyl Alcohol (demulcent) Povidone (demulcent)	Affected Label (SKU): Outer containers for 0.5 oz. and 1.0 oz. packages.
Submission Date: July 20, 1999	Review Date: August 13, 1999
Reviewer: Katharine A. Freeman	

Request for: Content Format Deferral

Adequacy of Submission: Does the exemption and/or deferral application include the following?

Content of Submission	Yes	No
1. A cover letter that includes: the statement "application for exemption", the NDA or ANDA number for approved drug products and a description of the drug product and shelf keeping unit(s) covered by the exemption request.	X	
2. A table of contents or index		X
3. A copy of the most recent marketed product label for products marketed under a monograph or the most recent approved labeling for drugs marketed under an NDA or ANDA.		X
4. A complete listing of all the requested exemptions from 21 CFR 201.66(c) and (d).		X
5. Explain why a particular requirement is inapplicable, impracticable, or contrary to public health or safety	X	
6. Complete labeling in the Drug Facts format consistent with 21 CFR 201.66 with annotation of the parts of the label where exemptions are requested.	X	
7. A representation of the proposed labeling, including any outserts, panel extensions, or other graphical or package techniques intended to be used with the product.	X	
8. Information on formatting, text style, and text size as illustrated in 64 FR 13254 at 13293.	X	

The information provided is adequate for review: Yes No

Exemptions Requested for Format

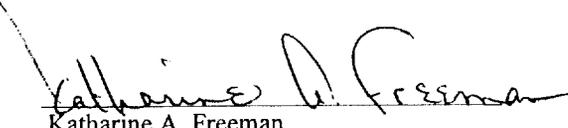
Paragraph ()	Description of Paragraph	Description of Exemption	Grant (yes / no)
(d)(2)	Drug Facts type size greater than largest type size used in Drug Facts labeling		
	Heading 8 pt or 2 point sizes greater than text point size		
X	Type size 6 pt size for information in Drug Facts	4.8 pt size (for 0.5 oz box) 5.4 pt size (for 1.0 oz box)	No
	Drug Facts (continued) type size no smaller than 8-point type		

REVIEWER COMMENTS: The sponsor has requested the same exemption for four of its ophthalmic drug products. The sponsor has asked that the exemption apply to products sold by the retail distributors they currently manufacture these products for and any future distributors. The sponsor claims there is not sufficient space for all required labeling.

The sponsor has requested less than 6-point type for information in the Drug Facts box, while the Drug Facts heading and other headings are larger than the minimum permitted type size. On the box for a 0.5 ounce bottle, the Drug Facts heading is presented in 11.2 size type, and on the 1.0 ounce box that heading is presented in 12.6 size type. No attempt was made to continue the Drug Facts information on another panel, and it appears there is sufficient white space for a Drug Facts (continued) box.

The agency does not intend at this time to grant any exemption from 21 CFR 201.66 for a type size less than 6-point type.

Reviewer Recommendation: The four applications should be denied. The sponsor should revise draft labeling to conform to type sizes described in 21 CFR 201.66(d)(2), to better utilize available space, and to use Drug Facts (continued) boxes if necessary.


Katharine A. Freeman

OTC Labeling Team Concurrence: Yes No (see Labeling Team comment sheet)

cc: HFD-560: Division File
HFD-560: CGanley/LKatz
HFD-560: Freeman/Yuan



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>

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:

<u>PRODUCT NAME</u>	<u>ACTIVE INGREDIENT</u>
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

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

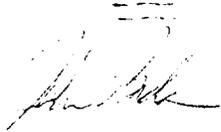
As such, Automatic Liquid packaging requests an exemption from the Helvetica Labeling letter size requirements, as described in **21 CFR 201.66** (OTC Labeling Format) for the above mentioned Ophthalmic drops for our 0.5 and 1.0 fluid ounce size.

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.

A handwritten signature in black ink, appearing to read "John Brda", is written over a horizontal line.

John Brda
Regulatory Affairs Manager

c Al Rothchild

.5 Oz. Relief Eye Drops

Logo
Relief Eye Drops Sterile

ASPIRIN 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 irritation.

DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to 4 times daily.

FOR USE IN THE EYES ONLY.

WARNING: 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:

4/95 11 0000

1 Oz. Relief Eye Drops

Logo

**Relief
Eye
Drops**

Sterile

**ASTHMA-FREE EYE DROPS
REDNESS RELIEVER**

Temporarily Relieves
Discomfort Due To
Minor Eye Irritations

1 fl. oz. (30 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.

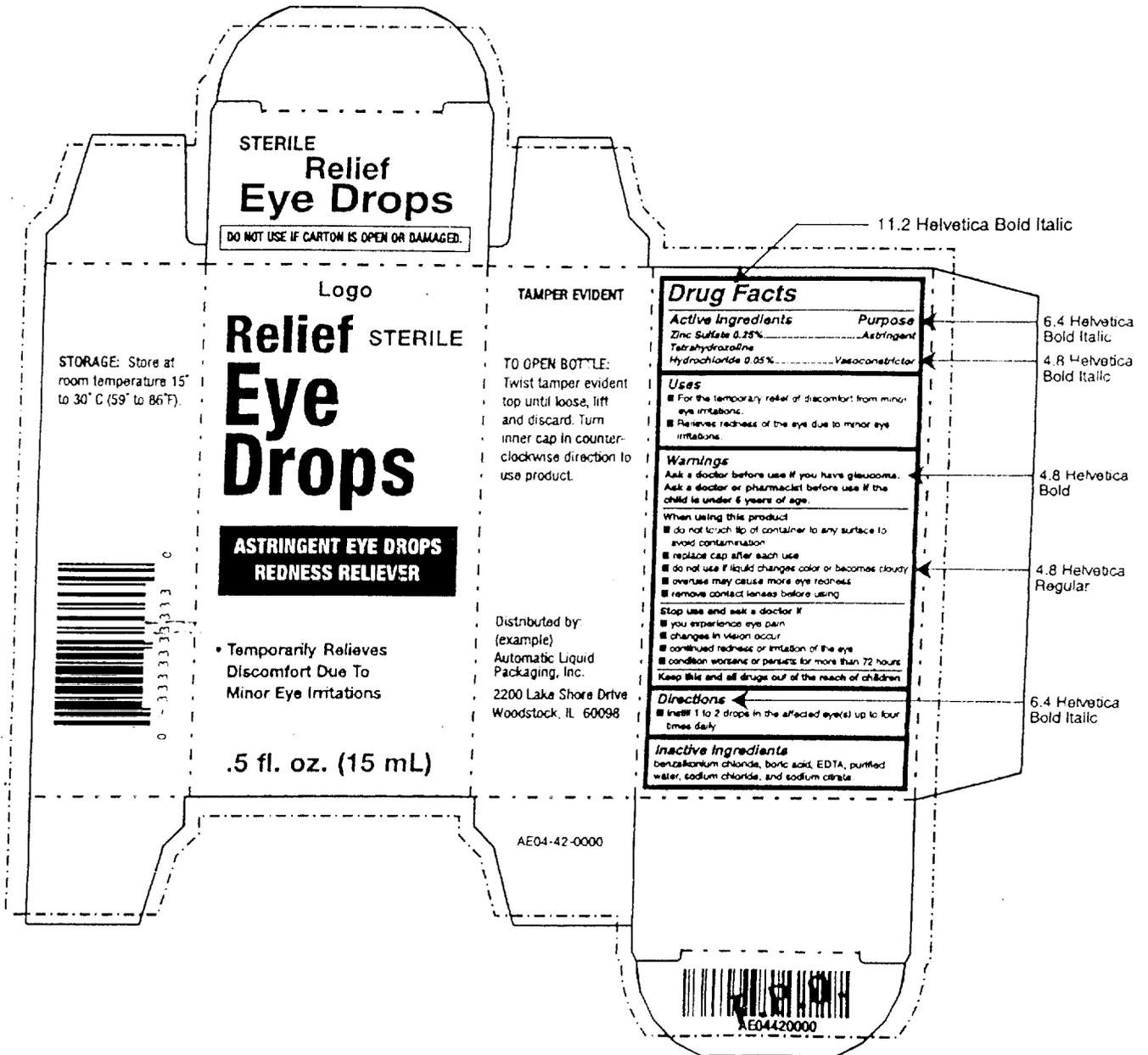
KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT. IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.

Distributed by or Manufactured by

AEOS 13-0000

.5 Oz. Relief Eye Drops



STERILE
**Relief
Eye Drops**

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

Relief STERILE
**Eye
Drops**

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



**ASTRINGENT EYE DROPS
REDNESS RELIEVER**

- Temporarily Relieves Discomfort Due To Minor Eye Irritations

.5 fl. oz. (15 mL)

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

AE04-42-0000

11.2 Helvetica Bold Italic

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.

When using this product:
 ■ do not touch tip of container to any surface to avoid contamination
 ■ 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
 Keep this and all drugs out of the reach of children

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.

6.4 Helvetica Bold Italic

4.8 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)

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

12.6 pt. Helvetica Bold

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 5 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

7.2 pt. He

5.4 pt. He

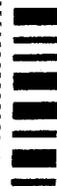
5.4 pt. He

5.4 pt. He

0.5 pt. Ha

2.5 pt. Boi

7.2 pt. He



AE04420000

.5 Oz. Relief Eye Drops

Logo
Relief Eye Drops Sterile

ASPIRIN 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.

WARNING: 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.
TAMPERS EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.

Distributed by or Manufactured by

4E05 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)

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: Manufacturer

4105-13-0000

.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 - 33333 33333 0

Relief 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

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.

When using this product

- do not touch tip of container to any surface to avoid contamination
- 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

Keep this and all drugs out of the reach of children

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.

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.

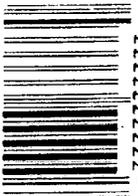
Logo

STERILE
**Relief
Eye
Drops**

**ASTRINGENT EYE DROPS
REDNESS RELIEVER**

Temporarily Relieves
Discomfort Due To
Minor Eye Irritations

1 fl. oz. (30 mL)



0 - 333333333 0

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



AE04420000

.5 Oz. Relief Eye Drops

Logo
Relief Eye Drops Sterile

ASTRINGENT EYE DROPS
ITCHNESS 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.

SEE CONTAINER TIGHTLY CLOSED
CAMPERS EVIDENT IF TAMPERS EVIDENT CAP IS REMOVED. DO NOT USE
Distributed by: Manufactured by:

4235 (3-0000)

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)

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 Tetracycline Hydrochloride 0.05%.

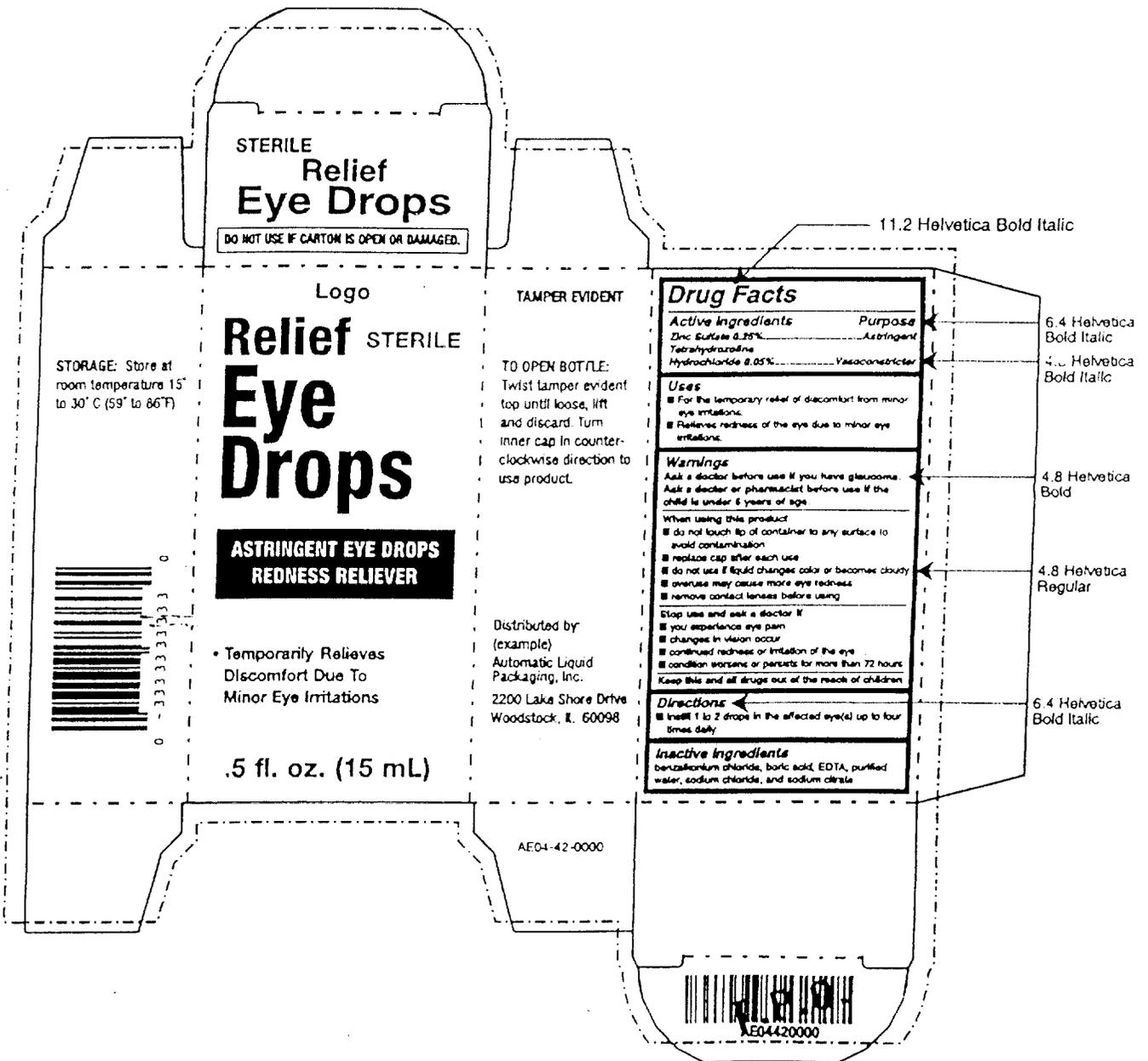
Inactive Ingredients: Benzalkonium chloride, boric acid, EDTA, purified water, sodium chloride, and sodium citrate.

KEEP CONTAINER TIGHTLY CLOSED.
TAMPER EVIDENT. IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.

Distributed by or Manufactured by

AEDS 13 0000

.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**

- Temporarily Relieves Discomfort Due To Minor Eye Irritations

.5 fl. oz. (15 mL)

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



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

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.

When using this product

- do not touch tip of container to any surface to avoid contamination
- 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

Keep this and all drugs out of the reach of children

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

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



1 Oz. Relief Eye Drops

STERILE
**Relief
Eye Drops**

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

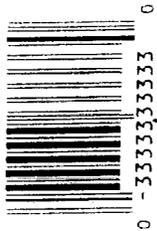
Logo

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:
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



AE04420000

SHIPPING
AUTOMATIC LIQUID PACKAGING
2200 W LAKESHORE DR
WOODSTOCK
(815) 333-9500

SHIP DATE: 22JUL99

ACTUAL WGT: 2 LBS MAN-WT

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

4565 8349 5509

Fed

4565 8349 5509

RFF: GEORGIA JENSEN

PRIORITY OVERNIGHT FR

NO: 0666924 22JUL99

Deliver by:
23JUL99

TRK: 4565 8349 5509 Form 0201

20852 MD-US

IAD
19 EDGA

1530727 SP G.T. 0399

Tori



Sm



AUTOMATIC LIQUID PACKAGING, INC.

July 20, 1999

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

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

RE: Application for Exemption from 21 CFR 201.66 (OTC Labeling Format)
Extra 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

Extra Eye Drops

Tetrahydrozoline HCL
(a vasoconstrictor)
Polyethylene Glycol 400
(a demulcent)

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

98W-0337

APP-3

Page 2

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

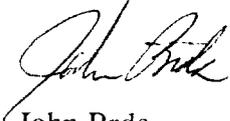
As such, Automatic Liquid packaging requests an exemption from the Helvetica Labeling letter size requirements, as described in **21 CFR 201.66** (OTC Labeling Format) for the above mentioned Ophthalmic drops for our 0.5 and 1.0 fluid ounce size.

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. Extra Eye Drops

Logo
**Eye
Drops
Extra**
Sterile

• Eye Lubricant
• Redness Reliever
Eye Drops
.5 fl. oz. (15 mL)

INDICATIONS: Relieves redness of the eye due to minor eye irritations. For use as a protectant against further irritation or to relieve dryness of the eye.
DIRECTIONS: Wash 1 to 2 drops in the affected eye(s) up to four 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: Polyethylene Glycol 400, 1.0% and Tetrahydrozoline Hydrochloride 0.05%.

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

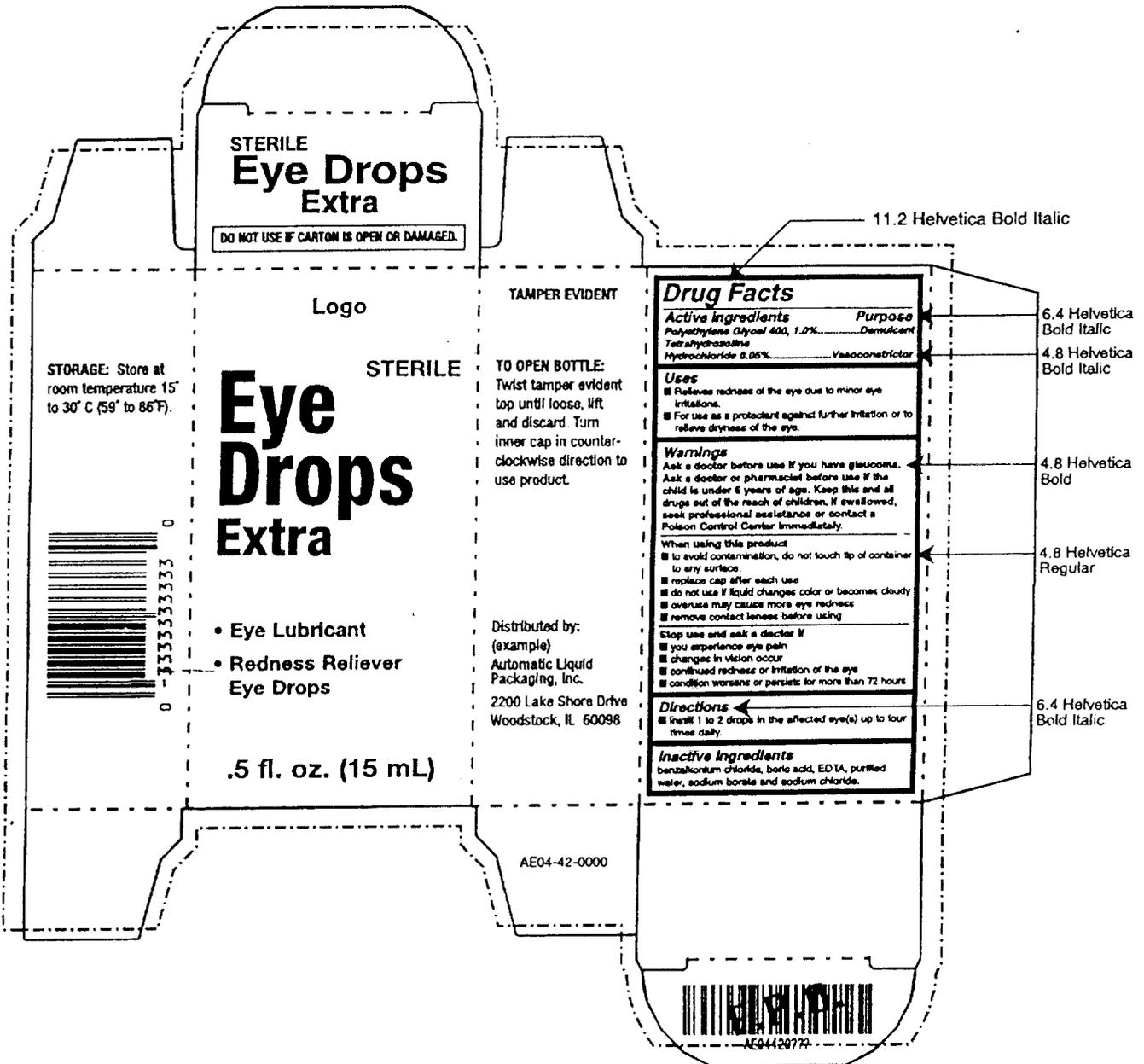
KEEP CONTAINER TIGHTLY CLOSED.
TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.
Distributed by or manufactured by

AEOS-13-0000

1 Oz. Extra Eye Drops

<p>Logo</p> <p>Eye Drops Extra</p> <p></p> <ul style="list-style-type: none">• Eye Lubricant• Redness Reliever Eye Drops <p>1 fl. oz. (30 mL)</p>	<p>Sterile</p> <p>INDICATIONS: Relieves redness of the eye due to minor eye irritations. For use as a protectant against further irritation or to relieve dryness of the eye.</p> <p>DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to four 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: Polyethylene Glycol 400, 1.0% and Tetrahydrozoline Hydrochloride 0.05%.</p> <p>Inactive Ingredients: benzalkonium chloride, boric acid, EDTA, purified water, sodium borate and sodium chloride.</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> <p>AE05-13-0000</p>
---	--

.5 Oz. Extra Eye Drops



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

1 Oz. Extra Eye Drops

STERILE
**Eye Drops
Extra**

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

STERILE

**Eye
Drops
Extra**

- Eye Lubricant
- Redness Reliever
Eye Drops

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
Polyethylene Glycol 400, 1.0%	Demulcent
Tetrahydrozoline Hydrochloride 0.05%	Vasoconstrictor

Uses

- Relieves redness of the eye due to minor eye irritations.
- For use as a protectant against further irritation or to relieve dryness of the eye.

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 seek 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 borate and sodium chloride.

12.6 pt. Helvetica Bold

7.2 pt. Helvetica Bold

5.4 pt. Helvetica Bold

5.4 pt. Helvetica Regu

5.4 pt. Helvetica Bold

0.5 pt. Hairline

2.5 pt. Border Line

7.2 pt. Helvetica Bold



0 -3333333333 0



AE04420000

.5 Oz. Extra Eye Drops

Logo
Sterile

**Eye
Drops
Extra**

- Eye Lubricant
- Redness Reliever
Eye Drops

.5 fl. oz. (15 mL)

INDICATIONS: Relieves redness of the eye due to minor eye irritations. For use as a protectant against further irritation or to relieve dryness of the eye.
DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to four 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: Polyethylene Glycol 400, 1.0% and Tetrahydrozoline Hydrochloride 0.05%.

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

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. Extra Eye Drops

<p>Logo</p> <p>Eye Drops Extra</p> 	<p>Sterile</p>	<p>INDICATIONS: Relieves redness of the eye due to minor eye irritations. For use as a protectant against further irritation or to relieve dryness of the eye.</p> <p>DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to four 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: Polyethylene Glycol 400; 1.0% and Tetrahydrozoline Hydrochloride 0.05%.</p> <p>Inactive Ingredients: benzalkonium chloride, boric acid, EDTA, purified water, sodium borate and sodium chloride.</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>
<ul style="list-style-type: none">• Eye Lubricant• Redness Reliever Eye Drops		
<p>1 fl. oz. (30 mL)</p>		<p>AEDS-13-0000</p>

.5 Oz. Extra Eye Drops

STERILE
**Eye Drops
Extra**

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

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

0 -35333333333 0

**Eye Drops
Extra**

- Eye Lubricant
- Redness Reliever Eye Drops

.5 fl. oz. (15 mL)

AE04-42-0000

AE04420772

STERILE

Logo

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

Active Ingredients	Purpose
Polychylene Glycol 400, 1.0%	Demulcent
Tetrahydrozoline	Vasoconstrictor
Hydrochloride 0.05%	

Uses

- Relieves redness of the eye due to minor eye irritations.
- For use as a protectant against further irritation or to relieve dryness of the eye.

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 borate and sodium chloride.

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

1 Oz. Extra Eye Drops

STERILE
**Eye Drops
Extra**

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

STERILE

**Eye
Drops
Extra**

- Eye Lubricant
- Redness Reliever Eye Drops

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
Polyethylene Glycol 400, 1.0%	Demulcent
Tetrahydrozoline	
Hydrochloride 0.05%	Vasoconstrictor

Uses

- Relieves redness of the eye due to minor eye irritations.
- For use as a protectant against further irritation or to relieve dryness of the eye.

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 borate and sodium chloride.

12.6 pt. Helvetica Bold

7.2 pt. Helvetica Bold I

5.4 pt. Helvetica Bold I

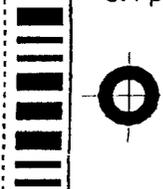
5.4 pt. Helvetica Regul

5.4 pt. Helvetica Bold

0.5 pt. Hairline

2.5 pt. Border Line

7.2 pt. Helvetica Bold I



.5 Oz. Extra Eye Drops

Logo
**Eye
Drops
Extra**
Sterile

- Eye Lubricant
- Redness Reliever
- Eye Drops

.5 fl. oz. (15 mL)

INDICATIONS: Relieves redness of the eye due to minor eye irritations. For use as a protectant against further irritation or to relieve dryness of the eye.
DIRECTIONS: Instill 1 to 2 drops in the affected eyeball up to four 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: Polyethylene Glycol 400, 1.0% and Tetrahydrozoline Hydrochloride 0.05%.

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

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

AC05-13-0000

1 Oz. Extra Eye Drops

Logo
**Eye
Drops
Extra**
Sterile

• Eye Lubricant
• Redness Reliever Eye Drops

1 fl. oz. (30 mL)

INDICATIONS: Relieves redness of the eye due to minor eye irritations. For use as a protectant against further irritation or to relieve dryness of the eye.
DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to four 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.

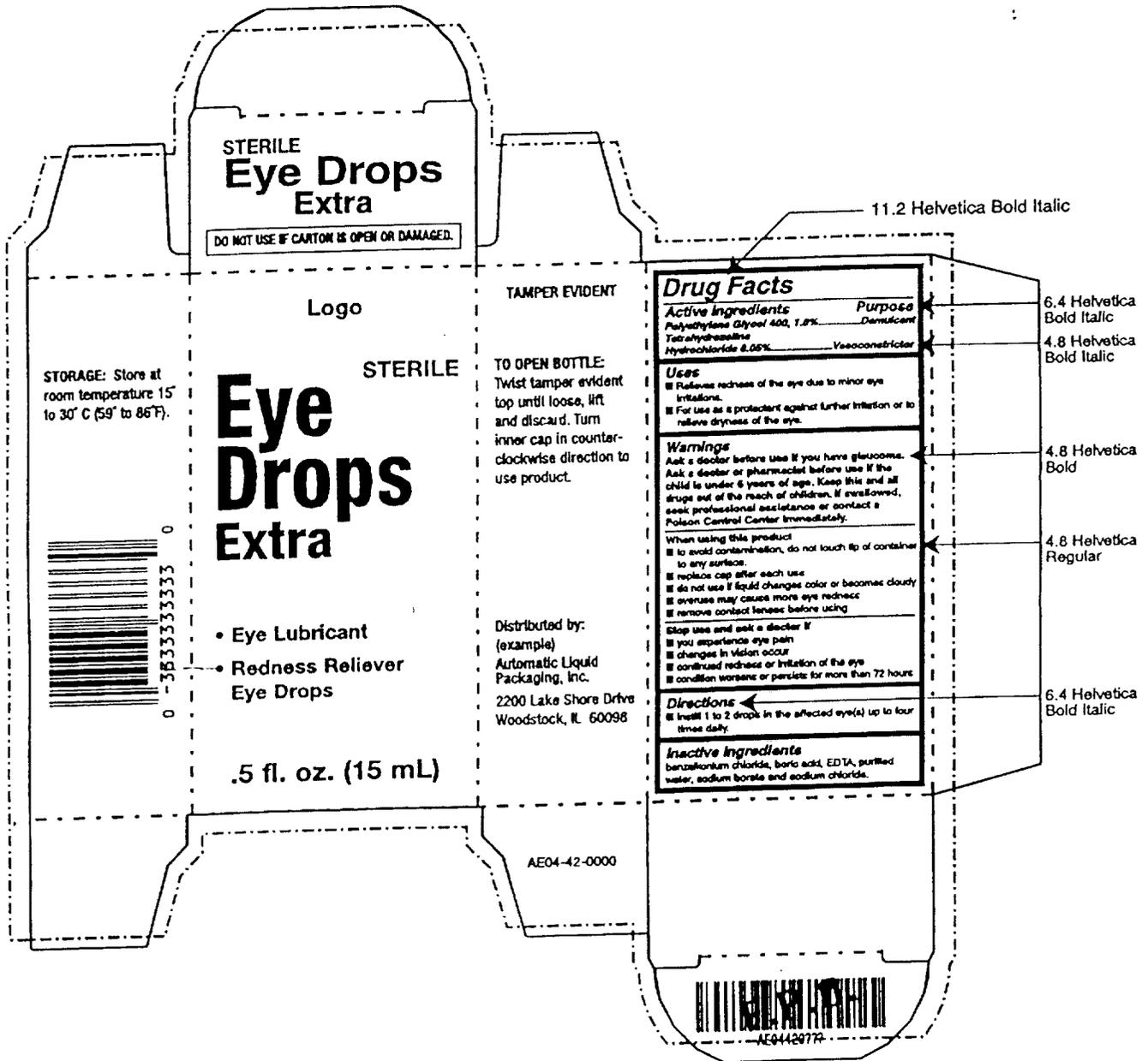
Active Ingredients: Polyethylene Glycol 400, 1.0% and Tetrachlorosine Hydrochloride 0.05%.
Inactive Ingredients: benzalkonium chloride, boric acid, EDTA, purified water, sodium borate and sodium chloride.

**KEEP CONTAINER TIGHTLY CLOSED.
TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.**

Distributed by or Manufactured by

AE05-13-0000

.5 Oz. Extra Eye Drops



1 Oz. Extra Eye Drops

STERILE
**Eye Drops
Extra**

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

STERILE

**Eye
Drops
Extra**

- Eye Lubricant
- Redness Reliever
Eye Drops

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
Polyethylene Glycol 400, 1.0%	Demulcent
Tetrahydrozoline	
Hydrochloride 0.05%	Vasoconstrictor

Uses

- Relieves redness of the eye due to minor eye irritations.
- For use as a protectant against further irritation or to relieve dryness of the eye.

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 borate and sodium chloride.

12.6 pt. Helvetica Bold

7.2 pt. Helvetica Bold

5.4 pt. Helvetica Bold

5.4 pt. Helvetica Reg

5.4 pt. Helvetica Bold

0.5 pt. Hairline

2.5 pt. Border Line

7.2 pt. Helvetica Bold





AUTOMATIC LIQUID PACKAGING, INC.

July 20, 1999

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

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

RE: Application for Exemption from 21 CFR 201.66 (OTC Labeling Format)
Regular 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

Regular Eye Drops

Tetrahydrozoline HCL
(a vasoconstrictor)

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

98W-0337

APP4

Page 2

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. Tetrahydrozoline Eye Drops

Logo
Eye Drops Sterile

TETRAHYDROZOLINE HCl

- Redness Reliever Eye Drops
- Non-staining
- Clear, Colorless

.5 fl. oz. (15 mL)

INDICATIONS: Relieves redness of the eye due to minor eye irritations.

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

FOR USE IN THE EYES ONLY.

WARNINGS: Do not use 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. Read warnings on box.

Active Ingredients: Tetrahydrozoline Hydrochloride 0.05%.

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

KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED DO NOT USE.

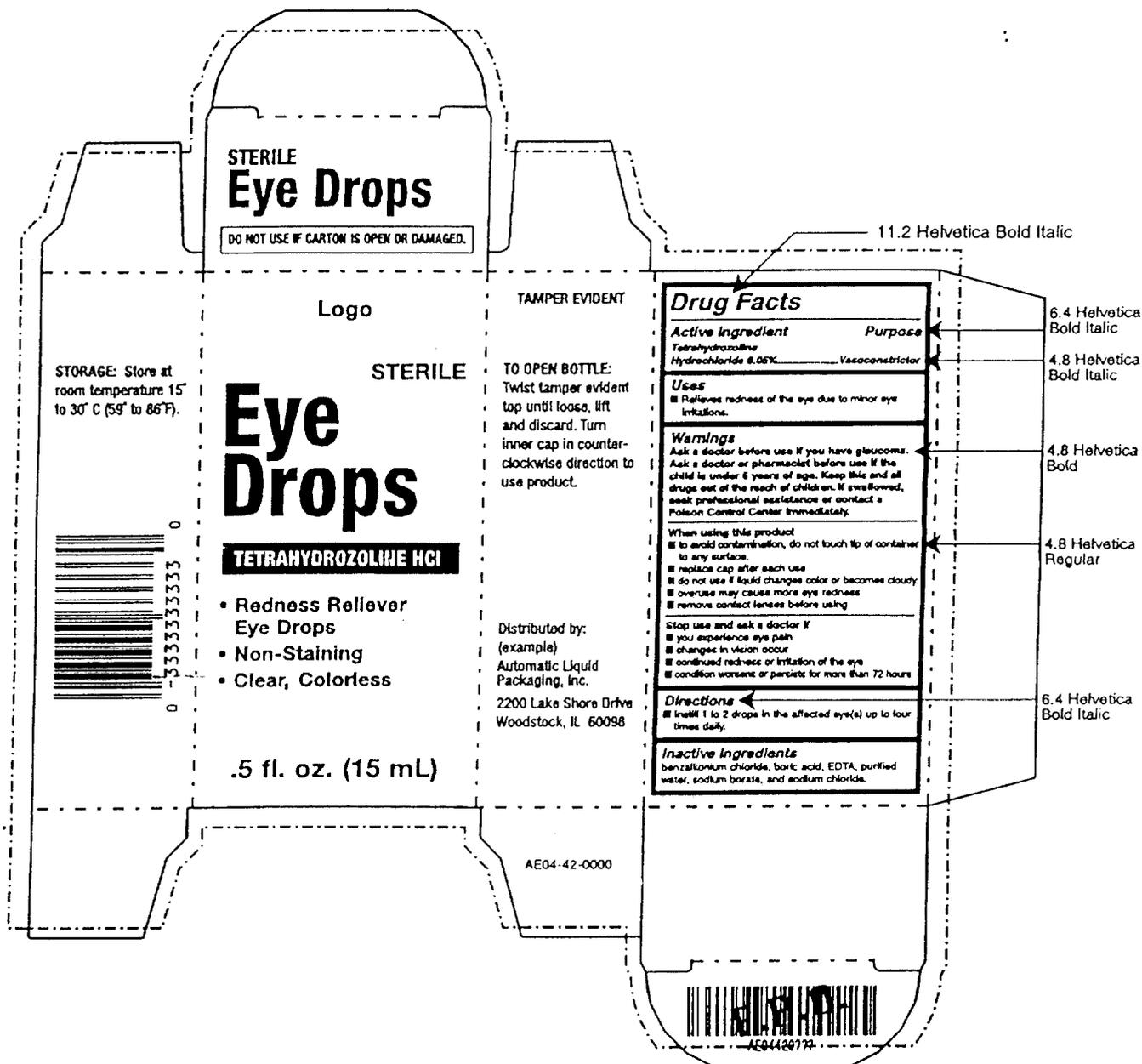
Distributed by or Manufactured by

AE05-11-0000

1 Oz. Tetrahydrozoline Eye Drops

<p>Logo</p> <p>Eye Drops</p> <p>TETRAHYDROZOLINE HCl</p> <ul style="list-style-type: none">• Redness Reliever• Eye Drops• Non-staining• Clear, Colorless <p>1 fl. oz. (30 mL)</p>	<p>Sterile</p> <p>INDICATIONS: 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 four 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 Ingredient: Tetrahydrozoline Hydrochloride 0.05%</p> <p>Inactive Ingredients: benzalkonium chloride, boric acid, EDTA, purified water, sodium borate and sodium chloride.</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> <p>AE05-13-0000</p>
--	---

.5 Oz. Tetrahydrozoline Eye Drops



1 Oz. Tetrahydrozoline Eye Drops

STERILE
Eye Drops

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

STERILE

Eye Drops

TETRAHYDROZOLINE HCl

- Redness Reliever Eye Drops
- Non-Staining
- Clear, Colorless

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
Tetrahydrozoline	•
Hydrochloride 0.05%	• Vasoconstrictor

Uses
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
- 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 borate and sodium chloride.

12.6 pt. Helvetica Bold

7.2 pt. Helv

5.4 pt. Helv

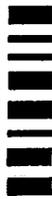
5.4 pt. Helv

5.4 pt. Helv

0.5 pt. Hair

2.5 pt. Borr

7.2 pt. Helv



AE04420000

.5 Oz. Tetrahydrozoline Eye Drops

Logo
Sterile

Eye Drops

TETRAHYDROZOLINE HCl

- Redness Reliever Eye Drops
- Non-staining
- Clear, Colorless

5 fl. oz. (15 mL)

INDICATIONS: Relieves redness of the eye due to minor eye irritations.

DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to four 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 Ingredient: Tetrahydrozoline Hydrochloride 0.05%.

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

KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED DO NOT USE.

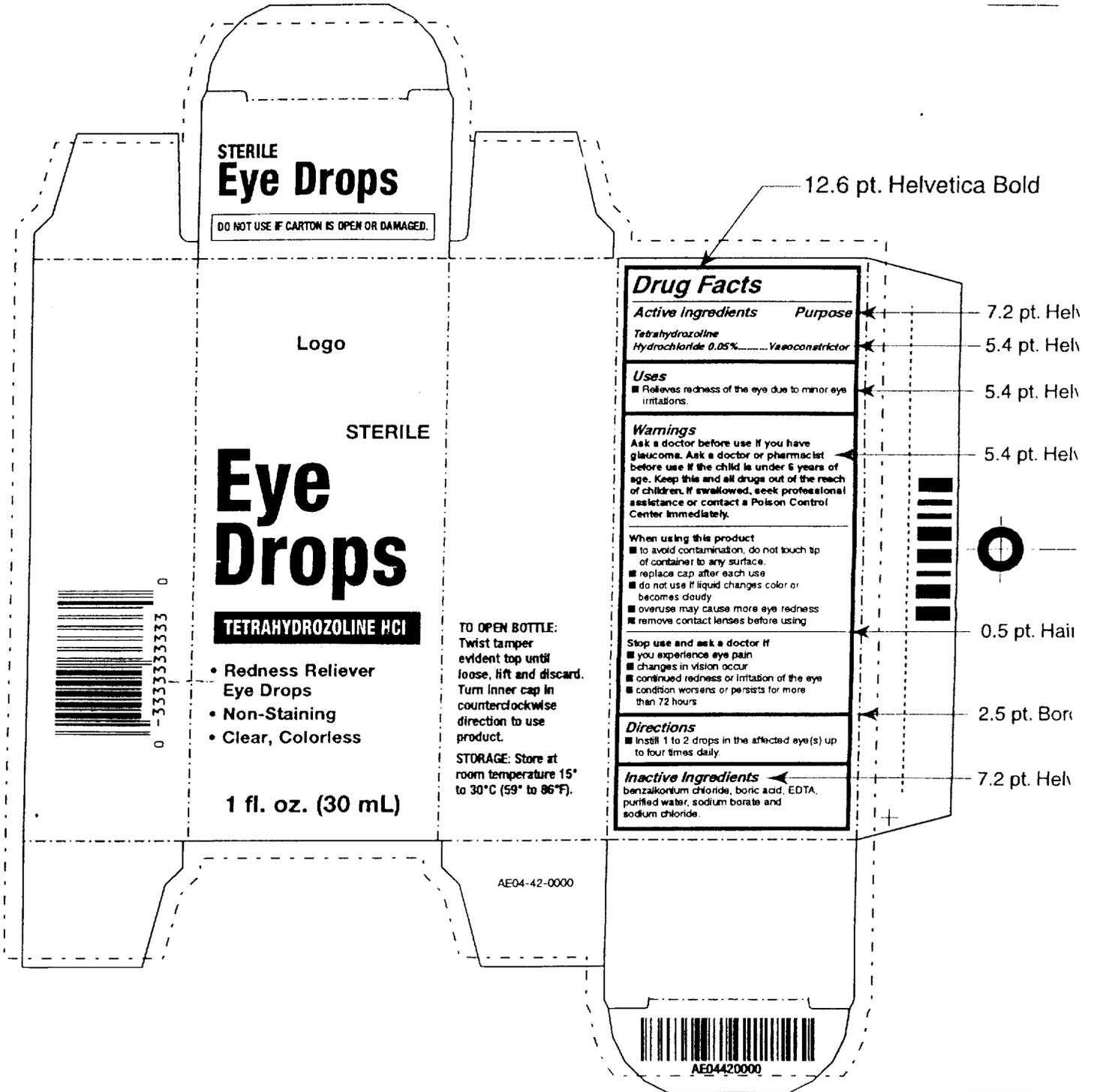
Distributed by or Manufactured by

AL 05 11 0000

1 Oz. Tetrahydrozoline Eye Drops

<p>Logo</p> <p>Eye Drops</p> <p>Sterile</p> <p>TETRAHYDROZOLINE HCl</p> <ul style="list-style-type: none">• Redness Reliever Eye Drops• Non-staining• Clear, Colorless <p>1 fl. oz. (30 mL)</p>	<p>INDICATIONS: 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 four 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 Ingredient: Tetrahydrozoline Hydrochloride 0.05%</p> <p>Inactive Ingredients: Benzalkonium chloride, boric acid, EDTA, purified water, sodium borate and sodium chloride.</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> <p>AE05-13-0000</p>
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1 Oz. Tetrahydrozoline Eye Drops



STERILE
Eye Drops

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

STERILE

Eye Drops

TETRAHYDROZOLINE HCl

- Redness Reliever Eye Drops
- Non-Staining
- Clear, Colorless

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

12.6 pt. Helvetica Bold

Drug Facts

Active Ingredients Purpose

Tetrahydrozoline Hydrochloride 0.05% Vasoconstrictor

Uses

- 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 borate and sodium chloride.

7.2 pt. Helv

5.4 pt. Helv

5.4 pt. Helv

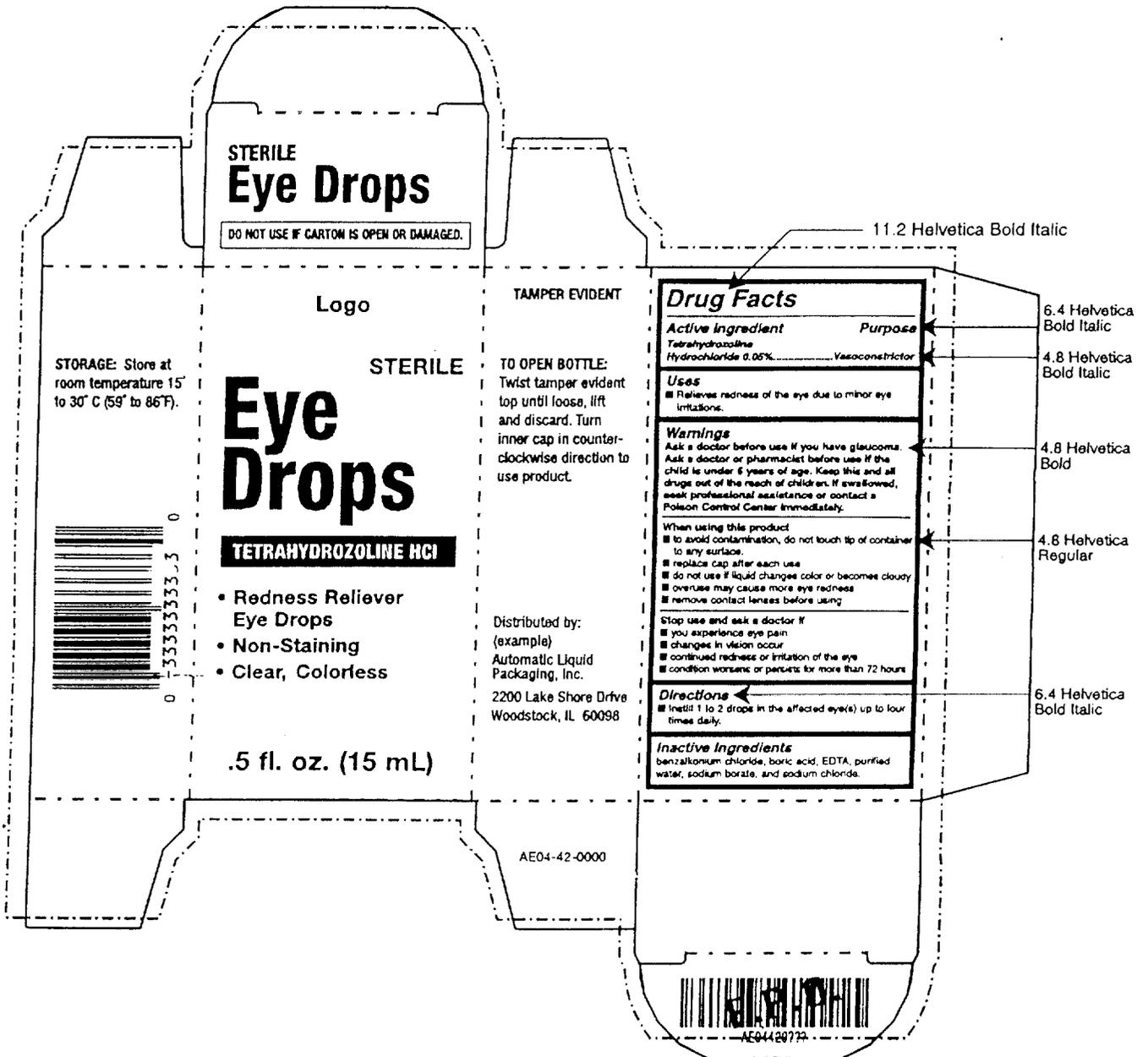
5.4 pt. Helv

0.5 pt. Hair

2.5 pt. Borv

7.2 pt. Helv

.5 Oz. Tetrahydrozoline Eye Drops



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

.5 Oz. Tetrahydrozoline Eye Drops

Logo

Eye Drops Sterile

TETRAHYDROZOLINE HCl

- Redness Reliever Eye Drops
- Non-staining
- Clear, Colorless

.5 fl. oz. (15 mL)

INDICATIONS: Relieves redness of the eye due to minor eye irritations.

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

FOR USE IN THE EYES ONLY.

WARNINGS: Do not use 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 Ingredient: Tetrahydrozoline Hydrochloride, 0.05%.

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

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. Tetrahydrozoline Eye Drops

Logo

Eye Drops Sterile

TETRAHYDROZOLINE HCl

- Redness Reliever Eye Drops
- Non-staining
- Clear, Colorless

1 fl. oz. (30 mL)

INDICATIONS: Relieves redness of the eye due to minor eye irritations.
DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to four times daily.

FOR USE IN THE EYES ONLY.

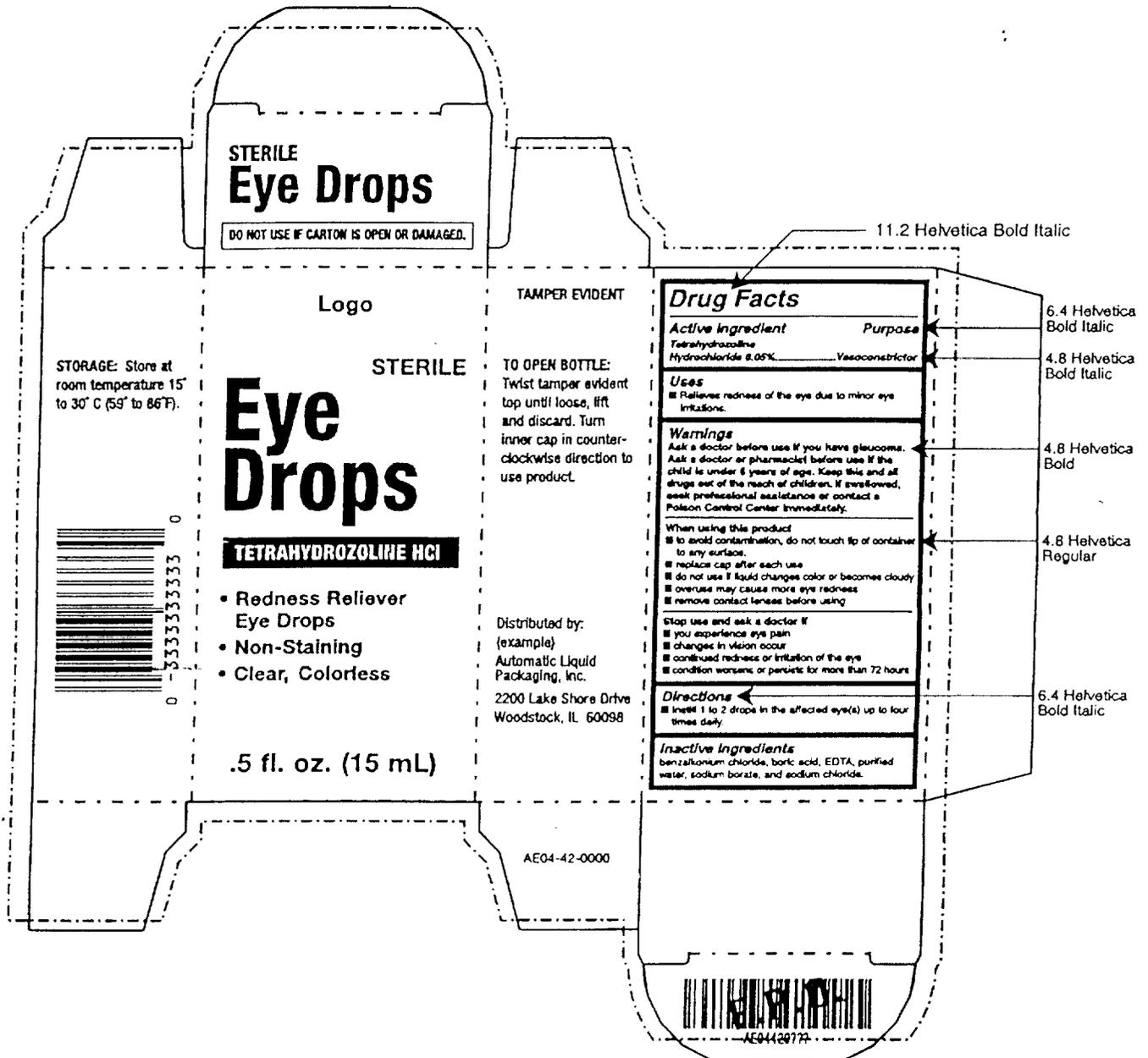
WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.

Active Ingredient: Tetrahydrozoline Hydrochloride 0.05%
Inactive Ingredients: benzalkonium chloride, boric acid, EDTA, purified water, sodium borate and sodium chloride.

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

AE05-13-0000

.5 Oz. Tetrahydrozoline Eye Drops



STERILE
Eye Drops

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

STERILE

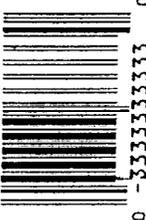
Eye Drops

TETRAHYDROZOLINE HCl

- Redness Reliever Eye Drops
- Non-Staining
- Clear, Colorless

.5 fl. oz. (15 mL)

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



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

AE04-42-0000

Drug Facts

Active Ingredient	Purpose
Tetrahydrozoline Hydrochloride 0.05%	Vasoconstrictor

Uses
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 surfaces.
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 borate, and sodium chloride.

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



1 Oz. Tetrahydrozoline Eye Drops

STERILE
Eye Drops

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

STERILE

Eye Drops

TETRAHYDROZOLINE HCl

- Redness Reliever Eye Drops
- Non-Staining
- Clear, Colorless

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
Tetrahydrozoline Hydrochloride 0.05%	Vasoconstrictor

Uses
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 5 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

- 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 borate and sodium chloride.

12.6 pt. Helvetica Bold

7.2 pt. Helv

5.4 pt. Helv

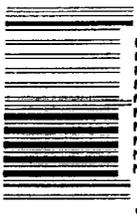
5.4 pt. Helv

5.4 pt. Helv

0.5 pt. Hair

2.5 pt. Bor

7.2 pt. Helv





AUTOMATIC LIQUID PACKAGING, INC.

July 20, 1999

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

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

RE: Application for Exemption from 21 CFR 201.66 (OTC Labeling Format)
Artificial Tears

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

Artificial Tears

Polyvinyl Alcohol
(a demulcent)
Povidone
(a demulcent)

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.

9810-0337

APP 5

Page 2

In addition, note the placement of statements such as Storage requirements, Manufactured by, Bar coding, Tamper evident, and Eye Drop 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. Artificial Tear Eye Drops

Logo
Sterile

**Artificial
Tears**

• Lubricant Eye Drops
.5 fl. oz. (15 mL)

INDICATIONS: For the temporary relief of burning and irritation due to dryness of the eye.
DIRECTIONS: Instill 1 or 2 drops in the affected eye(s) as needed.
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: Polyvinyl Alcohol, 1.4% and Povidone 0.6%
Inactive Ingredients: benzalkonium chloride, EDTA, purified water, sodium chloride, sodium phosphate monobasic, and dibasic.

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. Artificial Tears Eye Drops

Logo

**Artificial
Tears**

• *Lubricant Eye Drops*

1 fl. oz. (30 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) as needed.
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: Polyvinyl Alcohol, 1.4% and Povidone 0.6%

Inactive Ingredients: benzalkonium chloride, EDTA, purified water, sodium chloride, sodium phosphate monobasic and dibasic.

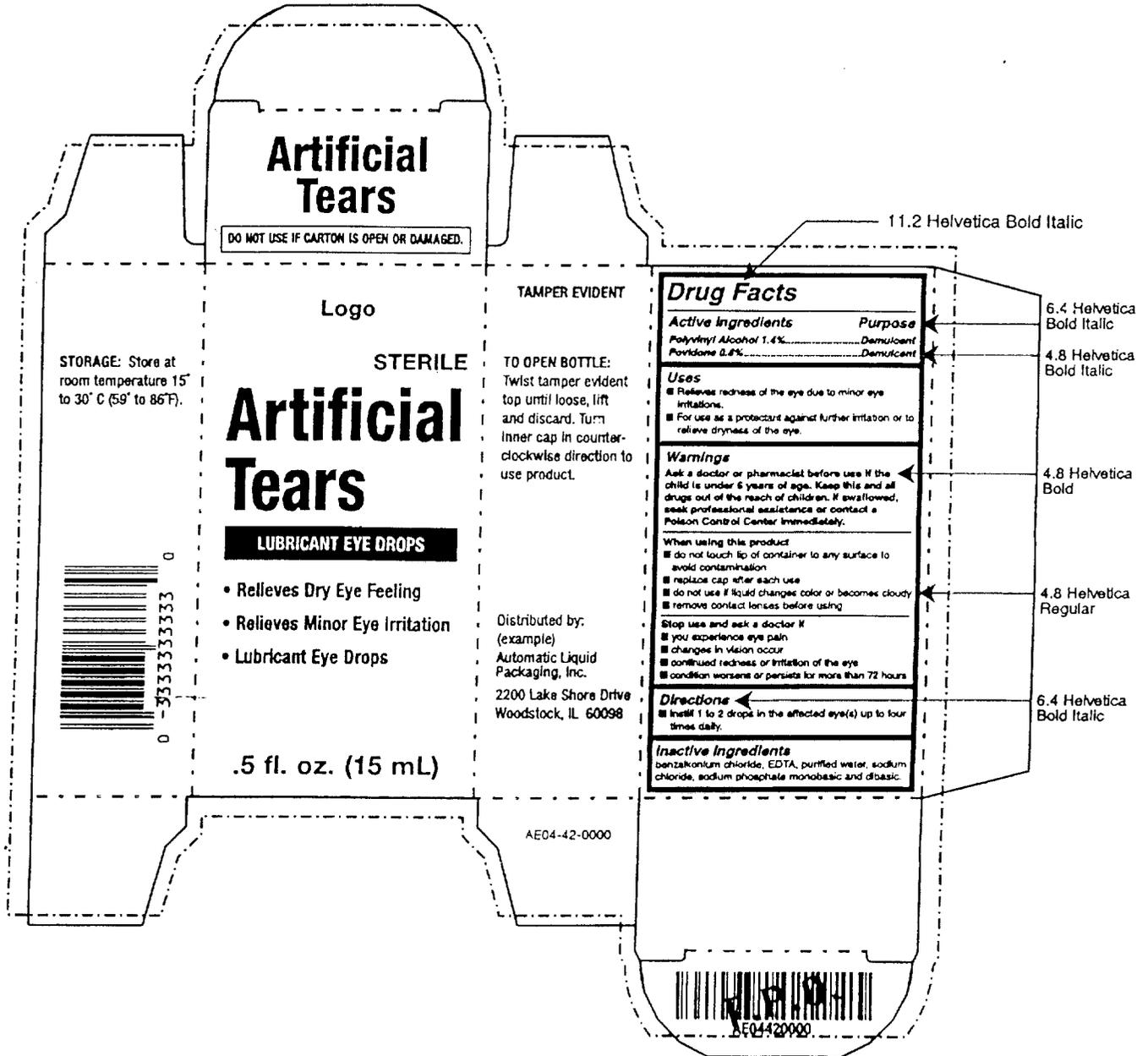
KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.

Distributed by or Manufactured by

AE05 13-0000

.5 Oz. Artificial Tears



1 Oz. Artificial Tears

Artificial Tears

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

STERILE

Artificial Tears

LUBRICANT EYE DROPS

- Relieves Dry Eye Feeling
- Relieves Minor Eye Irritation
- Lubricant Eye Drops



0 3333 33333

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
Polyvinyl Alcohol 1.4%	Demulcent
Povidone 0.6%	Demulcent

Uses

- Relieves redness of the eye due to minor eye irritations.
- For use as a protectant against further irritation or to relieve dryness of the eye.

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, EDTA, purified water, sodium chloride, sodium phosphate monobasic and dibasic.

12.6 pt. Helvetica Bold

7.2 pt. Helv

5.4 pt. Helv

5.4 pt. Helv

5.4 pt. Helv

0.5 pt. Hair

2.5 pt. Bor

7.2 pt. Helv



AE04420000

.5 Oz. Artificial Tear Eye Drops

Logo
Sterile
**Artificial
Tears**

• Lubricant Eye Drops
.5 fl. oz. (15 mL)

INDICATIONS: For the temporary relief of burning and irritation due to dryness of the eye.
DIRECTIONS: Instill 1 or 2 drops in the affected eye(s) as needed.
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: Polyvinyl Alcohol, 1.4% and Povidone 0.6%
Inactive Ingredients: benzalkonium chloride, EDTA, purified water, sodium chloride, sodium phosphate monobasic and dibasic

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

AEOS 13 0000

1 Oz. Artificial Tears Eye Drops

Logo

Artificial Tears

• Lubricant Eye Drops

1 fl. oz. (30 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) as needed.

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: Polyvinyl Alcohol 1.4% and Povidone 0.6%

Inactive Ingredients: Benzalkonium chloride, EDTA, purified water, sodium chloride, sodium phosphate monobasic and dibasic.

KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.

Distributed by or Manufactured by

AE05-13-0000

Artificial Tears

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

STERILE

Artificial Tears

LUBRICANT EYE DROPS

- Relieves Dry Eye Feeling
- Relieves Minor Eye Irritation
- Lubricant Eye Drops

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
Polyvinyl Alcohol 1.4%	Demulcent
Povidone 0.6%	Demulcent

Uses

- Relieves redness of the eye due to minor eye irritations.
- For use as a protectant against further irritation or to relieve dryness of the eye.

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, EDTA, purified water, sodium chloride, sodium phosphate monobasic and dibasic.

12.6 pt. Helvetica Bold

7.2 pt. Helv

5.4 pt. Helv

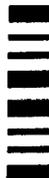
5.4 pt. Helv

5.4 pt. Helv

0.5 pt. Hair

2.5 pt. Bor

7.2 pt. Helv



.5 Oz. Artificial Tear Eye Drops

Logo
Sterile
**Artificial
Tears**

• Lubricant Eye Drops
.5 fl. oz. (15 mL)

INDICATIONS. For the temporary relief of burning and irritation due to dryness of the eye.
DIRECTIONS. Instill 1 or 2 drops in the affected eye(s) as needed.
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. Polyvinyl Alcohol, 1.4% and Povidone 0.6%
Inactive Ingredients. benzalkonium chloride, EDTA, purified water, sodium chloride, sodium phosphate monobasic, and dibasic.

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

AEDS 13 0000

1 Oz. Artificial Tears Eye Drops

Logo

**Artificial
Tears**

Lubricant Eye Drops

1 fl. oz. (30 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) as needed.

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: Polystyryl Alcohol, 1.4% and Povidone 0.6%.

Inactive Ingredients: benzalkonium chloride, EDTA, purified water, sodium chloride, sodium phosphate monobasic and dibasic.

KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.

Distributed by or Manufactured by

AE05-13-0000

.5 Oz. Artificial Tears

Artificial Tears

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

Artificial Tears

LUBRICANT EYE DROPS

- Relieves Dry Eye Feeling
- Relieves Minor Eye Irritation
- Lubricant Eye Drops

.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

Active Ingredients	Purpose
Polyvinyl Alcohol 1.4%	Demulcent
Purified Water 0.6%	Demulcent

Uses

- Relieves redness of the eye due to minor eye irritation.
- For use as a protectant against further irritation or to relieve dryness of the eye.

Warnings

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

- Do not touch tip of container to any surface to avoid contamination.
- Replace cap after each use.
- Do not use if liquid changes color or becomes cloudy.
- Remove contact lenses before using.

Stop use and ask a doctor if

- you experience eye pain
- changes in vision occur
- 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, EDTA, purified water, sodium chloride, sodium phosphate monobasic and dibasic.

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. Artificial Tears

Artificial Tears

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

STERILE

Artificial Tears

LUBRICANT EYE DROPS

- Relieves Dry Eye Feeling
- Relieves Minor Eye Irritation
- Lubricant Eye Drops

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
Polyvinyl Alcohol 1.4%	Demulcent
Povidone 0.6%	Demulcent

Uses

- Relieves redness of the eye due to minor eye irritations.
- For use as a protectant against further irritation or to relieve dryness of the eye.

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, EDTA, purified water, sodium chloride, sodium phosphate monobasic and dibasic

12.6 pt. Helvetica Bold

7.2 pt. Helv

5.4 pt. Helv

5.4 pt. Helv

5.4 pt. Helv

0.5 pt. Hair

2.5 pt. Borr

7.2 pt. Helv



AE04420000

EYEDROPS .5 OZ. AND 1 OZ.

FIRST AID/SAFETY MARKET

.5 oz. Tetra

MIAMI MARKET-EXPORT

.5 oz. Tetra Eyedrops

.5 oz. Extra Eyedrops

.5 oz. Relief Eyedrops

.5 oz. Artificial Tears

AARP Retired Persons Pharmacy

1 oz. F-455 PVA Lubricant Eyedrops

1 oz. F-707 PVA Povidone Eyedrops

1 oz. R-450 Eyedrops

1 oz. Extra Eyedrops

1 oz. Relief Eyedrops

ALBERTSONS

.5 oz. Tetra Eyedrops

.5 oz. Extra Eyedrops

ALPINE DISTRIBUTORS

.5 oz. Tetra Eyedrops

AMERICAN DRUG

.5 oz. Extra Eyedrops

.5 oz. Relief Eyedrops

AMES

.5 oz. Tetra Eyedrops

.5 oz. Extra Eyedrops

.5 oz. Relief Eyedrops

.5 oz. Artificial Tears

BRUNOS

.5 oz. Tetra Eyedrops

.5 oz. Extra Eyedrops

.5 oz. Relief Eyedrops

CERTIFIED GROCERS

.5 oz. Tetra Eyedrops

DEMOULAS

.5 oz. Tetra Eyedrops
.5 Extra Eyedrops

DUANE READE

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears

FEDERATED FOODS

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears

GENOVESE

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears

GRANDALL

.5 oz. Tetra Eyedrops

GRANDPAS

.5 oz. Tetra Eyedrops

GRAND UNION

.5 oz. Tetra Eyedrops

HARMON DISCOUNT

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears

HARRIS TEETER

1 oz. Tetra Eyedrops
1 oz. Relief Eyedrops

KROGER/PEYTON

1 oz. Tetra Eyedrops
1 oz. Extra Eyedrops
1 oz. Relief Eyedrops

LONGS

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears
1 oz. Tetra Eyedrops
1 oz. Extra Eyedrops
1 oz. Relief Eyedrops

MARSH

.5 oz. Tetra Eyedrops

MCCLANE/CVP

.5 oz. Tetra Eyedrops

NASH FINCH

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Artificial Tears

PAHTMARK

.5 oz. Tetra Eyedrops
.5 oz. Extra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears

PUBLIX

.5 oz. Tetra Eyedrops
.5 oz. Relief Eyedrops
.5 oz. Artificial Tears

REPUBLIC DRUGS

.5 oz. Tetra Eyedrops

RITE AID

1 oz. Tetra Eyedrops
1 oz. Extra Eyedrops
1 oz. Relief Eyedrops

SAFEWAY/VONS

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Tetra Eyedrops

SHOPKO

- .5 oz. Tetra Eyedrops
- .5 oz. Artificial Tears

SUPERMARKET SERVICES

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Relief Eyedrops
- .5 oz. Artificial Tears

VALUE STAR

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Relief Eyedrops
- .5 oz. Artificial Tears

WALGREENS

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Relief Eyedrops
- .5 oz. Artificial Tears

WINN DIXIE

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Relief Eyedrops
- .5 oz. Artificial Tears