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OCT - 6 1999

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

Re: Docket Number 98N-0337

Dear Mr. Brda:

Please refer to your Applications for Exemption dated July 20 1999, submitted under 21 CFR 201.66 (e), the letter issued by the Agency on August 23, 1999, and your telefacsimile dated August 25, 1999, 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 fl. oz. containers.

In your telefacsimile dated August 25, 1999, you requested that the Agency enumerate the deviations mentioned in its August 23, 1999 letter.

The following deviations from Drug Facts format were noted on some of your packages submitted on July 20, 1999, and August 25, 1999 (telefacsimile):

- The "Warnings" section does not appear in the proper format, and the wording of some warnings is not in the updated language. For example, warnings pursuant to 21 CFR 330.1(g) were updated to, "Keep out of reach of children," and "If swallowed, get medical help or contact a Poison Control Center right away."
- The "Ask a doctor before use if you have glaucoma" warning should be set off from other warnings and should come directly after the heading.
- Only the first word of an ingredient name, heading, or subheading should be capitalized.
- Failure to continue the Drug Facts information on other useable panels.
- Failure to use Drug Facts (continued) when using other panels.

For further guidance, Docket No. 98N-0337 contains examples of labeling for specific products in the new Drugs Facts format. We are enclosing the two example labels for ophthalmic products. Please note that the text information enclosed for both examples is in 6-point type, and one of the examples continued the required Drug Facts information on another side of the carton.

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.

98N-0337

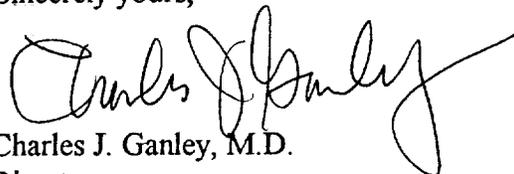
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Should you have any questions, please contact Elizabeth Yuan, R.Ph., Regulatory Project Manager at (301) 827-2222.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Charles J. Ganley". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Charles J. Ganley, M.D.

Director

Division of Over-the-Counter Drug Products  
Center for Drug Evaluation and Research

Enclosures

Opcon-A Eyedrops, 0.5 fl. oz.

Combination Product Using Standard Labeling Format\*  
[Outer Carton]

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Naphazoline HCl 0.02675%...	Redness reliever
Pheniramine maleate 0.315%...	Antihistamine
<b>Use</b> temporarily relieves itchy, red eyes caused by:	
■ pollen ■ ragweed ■ animal hair	
■ grass ■ dander	
<b>Warnings</b>	
Ask a doctor before use if you have	
■ high blood pressure	
■ heart disease	
■ narrow angle glaucoma	
■ trouble urinating due to an enlarged prostate gland	
<b>When using this product</b>	
■ do not touch tip of container to any surface to avoid contamination	
■ replace cap after each use	
■ do not use if the liquid changes color or becomes cloudy	
■ remove contact lenses before using	
■ overuse may cause more eye redness	
<b>Stop use and ask a doctor if</b>	
■ you feel eye pain	
■ changes in vision occur	
■ redness or irritation of the eyes lasts	
■ condition worsens or lasts more than 72 hours	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	

<b>Drug Facts (continued)</b>
<b>Directions</b>
■ adults and children 6 years and over: put 1 or 2 drops in affected eye(s) up to 4 times daily
■ children under 6 years: ask a doctor
<b>Other Information</b>
■ store at 20-25°C (68-77°F) ■ protect from light
<b>Inactive Ingredients</b> benzalkonium chloride, edetate disodium, hydroxypropyl methylcellulose, purified water, with a boric acid, sodium borate buffer system, and sodium chloride

- \* Note: 14 point Helvetica Condensed Bold Italic Title
- 8 point Helvetica Condensed Bold Italic Headings
- 6 point Helvetica Condensed Bold Subheadings
- 6 point Helvetica Condensed Text
- 6.5 point Leading

Clear Eyes, 0.5 oz.

Combination Product Using Standard Labeling Format\*  
[Outer Carton]

<b>Drug Facts</b>		
<b>Active Ingredients</b>	<b>Purpose</b>	
Glycerin 0.2%	Demolcent	
Naphazoline HCl 0.012%	Redness reliever	
<b>Uses</b>		
■ temporarily relieves redness due to minor eye irritation		
■ for protection against further irritation or dryness of the eye due to:		
■ smoke	■ sun glare	■ swimming
■ smog	■ contact lenses	
<b>Warnings</b>		
Ask a doctor before use if you have glaucoma		
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		
Stop use and ask a doctor if		
■ you feel eye pain	■ changes in vision occur	
■ redness or irritation of the eyes lasts		
■ condition worsens or lasts more than 72 hours		
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		
<b>Directions</b>		
■ put 1 or 2 drops in the affected eye(s) up to 4 times daily		
<b>Inactive Ingredients</b> benzalkonium chloride, boric acid, edetate disodium, purified water, sodium borate		

- \* Note: 14 point Helvetica Condensed Bold Italic Title
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- 6 point Helvetica Condensed Bold Subheadings
- 6 point Helvetica Condensed Text
- 6.5 point Leading