DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-485/S-007

Pfizer Consumer Healthcare
Attn: Lorna-Jane Bremer
Associate Director, Regulatory Affairs
201 Tabor Road
Morris Plains, NJ 07950

Dear Ms. Bremer:

Please refer to your supplemental new drug application dated April 14, 2004, received April 15, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Visine-A (0.3% pheniramine maleate and 0.025% naphazoline hydrochloride) Eye Drop.

This supplemental new drug application proposed an additional trade name for the product, either BenaDrops Eye Allergy Relief or (b)(4)

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for the use of BenaDrops Eye Allergy Relief as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (15ml carton, 15ml bottle, and package insert submitted on April 14, 2004) and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-485/S-007." Approval of this submission by FDA is not required before the labeling is used.

We also recommend the following labeling changes. These changes are not conditions of approval.

1) Remove “New” flag six months after introduction of the product into the marketplace.

2) Redesign the information on the container label to increase the readability. You may omit certain labeling statements, if necessary, to increase the relative prominence of the remaining statements as long as you follow the conditions required under 21 CFR 201.10(i).

3) Increase the print size of the established names within the Statement of Identity on the principal display panel.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call LCDR Keith Olin, Regulatory Project Manager, at (301) 827-2293.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Curtis Rosebraugh

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