DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-485/S-006

Pfizer Consumer Healthcare
Attention: Ken Warner
Director Regulatory Affairs, CMC
100 Jefferson Road,
Parsippany, New Jersey 07054

Dear Mr. Warner:

Please refer to your supplemental new drug application dated September 28, 2001, received October 1, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Visine-A® (0.3% pheniramine maleate and 0.025% naphazoline HCl) Ophthalmic Solution.

We acknowledge receipt of your submissions dated January 29 and 30, and May 15 and 22, 2003.

Your submission dated May 15, 2003, constituted a complete response to our February 1, 2002, Approvable letter.

This supplemental new drug application provided for an alternate production and testing site for Visine-A®, the use of contract facilities for stability storage, sterility testing, and particulate matter testing, changes in the size/shape of the low density polyethylene (LDPE) bottles used to package Visine-A®, the addition of a one once bottle fill, and the use of a new adhesive for the primary container label.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 28, 2001(1 oz. bottle label), and May 15, 2003 (0.5 ml, 1 ml and 4 ml carton labels, and the package insert).

We recommend that you delete the word "and" under ***Inactive ingredients*** in the **Drug** Facts panel at the time of next printing.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Laura E. Shay, Regulatory Project Manager, at (301) 827-2274.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, MD
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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