DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-485/S-005

Pfizer, Inc.
Attention: Rita Wittich
Vice President, Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms. Wittich:

Please refer to your supplemental new drug application dated July 10, 2001, received July 11, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Visine-A (0.025% naphazoline hydrochloride and 0.3% pheniramine maleate ophthalmic solution).

We acknowledge receipt of your submissions dated August 24, 2001, and June 5, 2002.

This Changes Being Effected supplemental new drug application provides for labeling changes to comply with the content and format requirements of 21 CFR § 201.66, the amendment to the final monograph for OTC ophthalmic products published in the Federal Register, June 21, 2000 (65 FR 38426), and the requirements set forth in the August 28, 2000, letter from FDA, addressed to Taylor Pharmaceuticals, for an additional warning statement.

We have completed the review of this supplemental application, as amended, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (immediate container label submitted on August 24, 2001, and carton label and Consumer Labeling leaflet submitted June 5, 2002) and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten 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-005. Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit one copy of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to:

Center for Drug Evaluation and Research
Division of Over-the-Counter Drug Products, HFD-560
Attention: Division Document Room
9201 Corporate Blvd.
Rockville, Maryland 20850-3202

If a letter communicating important information about this drug product (i.e., a Dear Health Care Professional letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 Elaine Abraham, Project Manager, at (301) 827-2293.

Sincerely,

{See appended electronic signature page}

Linda M. Katz, 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/

Linda Katz

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