DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-407/S-010

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 (NDA) dated April 19, 2002, received April 22, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Visine L.R. (oxymetazoline HCl 0.025%) Eye Drops, and our approval letter dated August 23, 2002, for this supplement.

This revised letter supercedes our letter dated August 23, 2002, however, the approval date remains the same.

This "Changes Being Effected" supplemental NDA, provides for revised labeling (0.5 FL.OZ. and 1 FL.OZ.) to comply with the content and format requirements of 21 CFR 201.66.

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

The final printed labeling (FPL) must be identical to the submitted draft labeling submitted April 19, 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 19-407/S-010. Approval of this submission by FDA is not required before the labeling is used.

In addition, please consider deleting the word "and" under the inactive ingredients 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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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

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

Sincerely,
{See appended electronic signature page}

Charles Ganley, MD
Director
Division of Over the Counter Drug Products
Office of Drug Evaluation
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/

Charles Ganley
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