DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 11-340/S-016

The Purdue Frederick Company
Attention: David Grob
Associate Director, Regulatory Affairs
One Stamford Forum
Stamford, CT 06901-3431

Dear Mr. Grob:

Please refer to your supplemental new drug application dated October 31, 2001, received November 2, 2001, submitted under the Federal Food, Drug, and Cosmetic Act for Cerumenex (triethanolamine polypeptide oleate-condensate otic solution).

We acknowledge receipt of your submission dated December 5, 2001.

This supplemental new drug application provides for the addition of a **Geriatric Use** subsection in the **PRECAUTIONS** section of the product package insert.

We have completed the review of this supplemental application, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling.

In addition, we recommend that a future labeling supplement include the following changes:
The **HOW SUPPLIED** section should be revised in order to eliminate the phrase "controlled room temperature" in accordance with the U.S. Pharmacopeia definition for the phrase.

The **HOW SUPPLIED** section should be revised in order to include the target fill volume for the container size and the color and type of plastic for the bottle, dropper, and cap.

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 11-340/S-016." Approval of this submission by FDA is not required before the labeling is used.

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

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 Michael Puglisi, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

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

/s/

Wiley Chambers

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