DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-463/S-008

Pfizer Consumer Healthcare
Attention: John Jacobs
VP Global Regulatory Affairs
201 Tabor Road
Morris Plains, NJ 07950

Dear Mr. Jacobs:

Please refer to your supplemental new drug application dated December 31, 2003, received January 5, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NasalCrom® Nasal Allergy Symptom Prevention Spray (2.5 mg cromolyn sodium nasal solution).

We acknowledge receipt of your submissions dated March 12, and June 15, 2004.

Your submission of March 12, 2004 constituted a complete response to our February 12, 2004 action letter.

This supplemental application proposes an additional tradename, BenaMist® Nasal Allergy Symptom Prevention Spray.

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

The final printed labeling (FPL) must be identical to the submitted labeling (package insert, 0.44 and 0.88 fl. oz. immediate container and carton labels submitted June 15, 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 20-463/S-008." Approval of this submission by FDA is not required before the labeling is used.

If you plan to extend the tradename BenaMist® to other drug products, a consumer behavior study may be necessary to determine if consumers are able to distinguish the ingredient(s) and intended use(s) of different sub brand name(s) products with the same principle brand name.

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

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

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 Leah Cutter, Ph.D., Regulatory Project Manager, at (301) 827-2248.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
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/

Charles Ganley
7/15/04 11:57:08 AM