DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-762/S-021

Schering Corporation
2000 Galloping Hill Rd.
Kenilworth NJ 07033

Attention: Mary Jane Nehring
Senior Director
Marketed Products Support and Training

Dear Ms. Nehring:

Please refer to your supplemental new drug application dated June 10, 2003, received June 11, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nasonex (mometasone furoate monohydrate) Aqueous Nasal Spray.

This supplemental new drug application provides for the addition of the sentence "Disturbance of taste and smell have been reported very rarely" to the ADVERSE REACTIONS section of the package insert and minor editorial revisions to the package insert and Patient's Instructions for Use and the Applicator Cleaning Instructions.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 10, 2003 (copy enclosed).

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 Akilah Green, Regulatory Project Manager, at (301) 827-5585.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Division Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
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/

Badrul Chowdhury

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