DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-762/S-007

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Attention: Teresa Perney, Ph.D.
Manager, Global Regulatory Affairs

Dear Dr. Perney:

Please refer to your supplemental new drug application dated July 28, 2000, received July 31, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nasonex (mometasone furoate monohydrate) Aqueous Nasal Spray, 50mcg.

We acknowledge receipt of your submissions dated October 2, November 2 and 28, 2000, January 12, and February 16, 2001, and February 10 and 24, March 10, April 19 and 23, and August 18, 2004.

Your submission of April 23, 2004, constituted a complete response to our February 2, 2001, action letter.

This supplemental new drug application provides for a new formulation of Nasonex Nasal Spray that does not include the excipient phenylethyl alcohol.

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 (text for the package insert, text for the patient package insert, and carton labels dated August 18, 2004 and immediate container labels dated April 23, 2004).

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 20-762/S-007." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Pulmonary and Allergy Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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

If you propose, at a future date,(b)(4)---------- ----------you will need to choose a unique proprietary name in order to distinguish that product from the phenylethyl free formulation of Nasonex approved in this supplement. The name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

We remind you that the term "NEW" in the descriptor "NEW Scent-Free Mist" should only be used to describe the marketing phase of the product for the first 6 months.

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 Lori Garcia, Regulatory Project Manager, at (301) 827-5580.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Drug Products, HFD-570
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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