DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-762/S-014

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Attention: Mary Jane Nehring
Sr. Director, Marketed Products Support, Worldwide Regulatory Affairs

Dear Ms. Nehring:

Please refer to your supplemental new drug application dated September 25, 2002, received September 26, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nasonex (mometasone furoate monohydrate) Aqueous Nasal Spray.

We acknowledge receipt of your submission dated October 1, 2002.

This supplemental new drug application provides for the addition of repriming instructions, subsequent to cleaning of the nasal actuator tip, to the package insert.

We have 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 and with the minor editorial revisions listed below.

In the PRECAUTIONS section, the 'Pregnancy: Teratogenic Effects: Pregnancy Category C' subsection, the third paragraph, the first sentence should read as follows (The word "hernia" was missing in the proposed package insert.):

> In rats, mometasone furoate produced umbilical hernia at topical dermal doses of 600 mcg/kg and above (approximately 25 times the maximum recommended daily intranasal dose in adults on a mcg/m^2 basis).

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert submitted September 25, 2002). These revisions are terms of the approval of this application.

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 ten 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-014." Approval of this submission by FDA is not required before the labeling is used.

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

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 Christine Yu, R.Ph., LCDR, U.S. PHS, Regulatory Management Officer, at (301) 827-1051.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Acting Director
Division of Pulmonary and Allergy Drug Products, HFD-570
Office of Drug Evaluation II
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/

Badrul Chowdhury
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