DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-762/S-023

Schering Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey 07033

Attention: Ronald J. Garutti, M.D.
Group Vice President
Global Regulatory Affairs

Dear Dr. Garutti:

Please refer to your supplemental new drug application dated February 26, 2004, received February 26, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nasonex (mometasone furoate monohydrate) Aqueous Nasal Spray, 50 mcg.

We acknowledge receipt of your submissions dated April 6 and 26, June 25, November 12, 19 and 30, and December 7 and 9, 2004.

This supplemental new drug application provides clinical support for the use of Nasonex (mometasone furoate monohydrate) Aqueous Nasal Spray, 50 mcg, for the treatment of nasal polyps in patients 18 years of age and older.

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 and with the minor editorial revisions indicated in the enclosed labeling.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted labeling (immediate container and carton labels submitted November 19, 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/these submission(s) should be designated "FPL for approved supplement NDA 20-762/S-023." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies for ages 6 to 17 years until December 15, 2007.

We remind you that a waiver for pediatric studies for this application was granted for patients less than 6 years old, but denied for patients 6 to 17 years old, in our letter dated October 8, 2004.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered a required post-marketing study commitment. The status of these post-marketing studies shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric studies under PREA for the treatment of nasal polyps in pediatric patients ages 6 to 17.

   Final Report Submission: December 15, 2007

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric post-marketing study commitment must be clearly designated "**Required Pediatric Study Commitments**".

Submit clinical protocols to your IND for this product. Submit non-clinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these post-marketing study commitments must be prominently labeled "**Post-marketing Study Protocol**", "**Post-marketing Study Final Report**", or "**Post-marketing Study Correspondence**."

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(s) 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

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 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
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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