NDA 20-762/S-001

Schering Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey 07033

Attention: Joseph Lamendola, Ph.D.
Vice President, U.S. Regulatory Affairs

Dear Dr. Lamendola:

Please refer to your supplemental new drug application dated October 24, 1997, received November 19, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nasonex (mometasone furoate) Nasal Spray, 50 mcg.

We acknowledge receipt of your submissions dated March 30, July 24, and October 19, 1998.

This supplemental new drug application provides for revised labeling which addresses the onset of action of Nasonex Nasal Spray, 50 mcg.

We have completed the review of this supplemental application, as amended, and it is approved effective on the date of this letter with the revisions listed below.

1. The second paragraph of the CLINICAL PHARMACOLOGY, Clinical Studies subsection, should be revised to "In patients with seasonal allergic rhinitis, NASONEX Nasal Spray, 50 mcg demonstrated improvement in nasal symptoms (vs. placebo) within 11 hours after the first dose based on one single-dose, parallel group study of patients in an outdoor 'park' setting (park study) and one environmental exposure unit (EEU) study, and within 2 days in 2 randomized, double-blind, placebo-controlled, parallel group seasonal allergic rhinitis studies. Maximum benefit is usually achieved within 1 to 2 weeks after initiation of dosing."
2. The fifth and sixth sentences of the PRECAUTIONS, Information for Patients subsection should be revised to "Improvement in nasal symptoms of allergic rhinitis has been shown to occur within 11 hours after the first dose based on one single-dose, parallel group study of patients in an outdoor 'park' setting (park study) and one environmental exposure unit (EEU) study and within 2 days after the first dose in 2 randomized, double-blind, placebo-controlled, parallel group seasonal allergic rhinitis studies. Maximum benefit is usually achieved within 1 to 2 weeks after initiation of dosing."

3. A new paragraph should be added at the end of the ADVERSE REACTIONS section. It should read as follows: "In postmarketing surveillance of this product, cases of nasal burning and irritation, and rare cases of nasal septal perforation have been reported."

4. The third paragraph of the DOSAGE AND ADMINISTRATION section should be revised to "Improvement in nasal symptoms of allergic rhinitis has been shown to occur within 11 hours after the first dose based on one single-dose, parallel group study of patients in an outdoor 'park' setting (park study) and one environmental exposure unit (EEU) study and within 2 days after the first dose in 2 randomized, double-blind, placebo-controlled, parallel group seasonal allergic rhinitis studies. Maximum benefit is usually achieved within 1 to 2 weeks. Patients should use NASONEX Nasal Spray, 50 mcg only once daily at a regular interval."

5. The sentences "Based on single day studies done in a park during pollen season or in a controlled pollen exposure room, improvement in nasal symptoms of allergic rhinitis has been shown to occur within 11 hours after the first dose. In other studies that lasted up to 2 weeks, improvement in nasal symptoms of seasonal allergic rhinitis was shown to occur within 2 days after the first dose. The full benefit of NASONEX Nasal Spray, 50 mcg is usually achieved within 1 to 2 weeks." should replace the last sentence in the Caution section of the Patient's Instructions for Use.

These revisions are terms of the supplemental NDA approval. The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted October 19, 1998) with the revisions noted above.

Please submit 20 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-001." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a “Dear Health Care Practitioner” letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Dr. Denise Toyer, Project Manager, at (301) 827-5584.

Sincerely,

John K. Jenkins, M.D., F.C.C.P.
Director
Division of Pulmonary Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research