# CENTER FOR DRUG EVALUATION AND RESEARCH

**Approval Package for:**

**Application Number:** NDA 20762

**Trade Name:** NASONEX

**Generic Name:** MOMETASONE FUROATE

**Sponsor:** SCHERING CORP.

**Approval Date:** OCTOBER 1, 1997

# CENTER FOR DRUG EVALUATION AND RESEARCH

## APPLICATION: NDA 20762

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| Final Printed Labeling | | X | | |
| Medical Review(s) | X | | | |
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| Pharmacology Review(s) | X | | | |
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| Microbiology Review(s) | X | | | |
| Clinical Pharmacology Biopharmaceutics Review(s) | X | | | |
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# CENTER FOR DRUG EVALUATION AND RESEARCH

## APPLICATION NUMBER: NDA 20762

## APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-762

OCT 1 1997

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 new drug application dated September 30, 1996, received October 1, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nasonex (mometasone furoate) Nasal Spray.

We acknowledge receipt of your submissions dated October 4, 18, and 24, December 2, 1996, and January 31, February 3, 7, and 28, March 20 and 24, April 4, May 8, 9, 14, and 21, June 17, July 2, 11, and 21, August 6, 14, 20, and 22, and September 4, 12, 15, 16, 18, 19, 26, and 29, 1997. The user fee goal date for this application is October 1, 1997.

We have completed the review of this application including the submitted draft labeling and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for the prophylaxis and treatment of the nasal symptoms of seasonal allergic rhinitis and the treatment of the nasal symptoms of perennial allergic rhinitis, in adults and children 12 years of age and older. Accordingly, the application is approved effective on the date of this letter. The expiry for all packaging configurations is 15 months. We remind you of your decision to withdraw the from the application.

The final printed labeling (FPL) must be identical to the enclosed marked-up draft physician labeling, patient's instructions for use, and container and carton labeling. Marketing the product with FPL that is not identical to this marked-up draft labeling may render the product misbranded and an unapproved new drug.

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

Should additional information relating to the safety and effectiveness of the drug become available, revision of the labeling may be required.

We remind you of your Phase 4 commitments specified in your submission dated September 29, 1997. These commitments, along with any completion dates agreed upon, are listed below.

Protocols, data, and final reports should be submitted to this NDA. In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of each commitment. The status summary should include the expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

In addition, please submit three copies of the introductory promotional material 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 material and the package insert directly to:

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

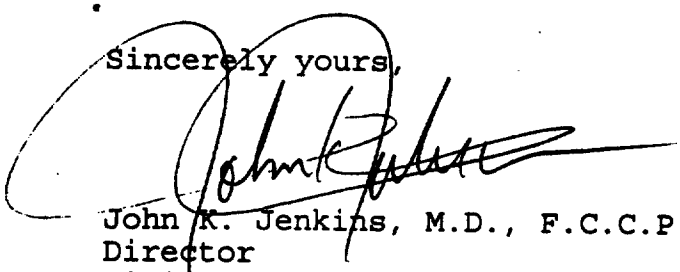
Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

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, please contact Ms. Denise Toyer, Project Manager, at (301) 827-5584.

Sincerely yours,



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

Enclosure