



NDA20762/S-038

SUPPLEMENT APPROVAL

Schering-Plough
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

Attention: Katie Picone, PharmD
Manager, Global Regulatory Affairs

Dear Dr. Picone:

Please refer to your July 30, 2009, Supplemental New Drug Application (sNDA), received July 31, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nasonex® (mometasone furoate) Nasal Spray, 50 mcg.

We acknowledge receipt of your submissions dated November 11, 2009, and May 3, 19, and 21, 2010.

This Prior Approval supplemental new drug application provides for the relief of nasal congestion associated with seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling text for the package insert submitted on May 21, 2010 and text for the patient package insert submitted on May 3, 2010. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your July 30, 2009, submission containing final printed carton and container labels.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to 2 years because necessary studies are impossible or highly impracticable. This is because seasonal allergic rhinitis does not exist in children < 2 years of age because two seasonal exposures to allergens are needed to induce the symptoms of seasonal allergic rhinitis. Therefore, a partial waiver of pediatric studies in subjects aged 0 to <2 years of age is justified for Nasonex® Nasal Spray for the treatment of nasal congestion associated with seasonal allergic rhinitis.

We note that you have fulfilled the pediatric study requirement for ages 2 to 18 years for this application.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Philantha Bowen, Senior Regulatory Management Officer, Regulatory Project Manager, at (301) 796-2466.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary, Allergy, and Rheumatology
Products
Office of Drug Evaluation II
Office of New Drugs
Center for Drug Evaluation and Research

Enclosures: Content of Labeling/May 3, 2010 (PPI) and May 21, 2010 (PI)

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20762	SUPPL-38	SCHERING PLOUGH HEALTHCARE PRODUCTS INC	NASONEX NASAL SPRAY (MOMETASONE FUROATE)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LYDIA I GILBERT MCCLAIN
05/26/2010
Deputy Director