DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA SUPPLEMENT APPROVAL

NDA 21-067/S-007

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

Attention: Michael Belman
Director and Liaison, Global Regulatory Affairs

Dear Mr. Belman:

Please refer to your supplemental new drug application (sNDA) dated July 5, 2007, received July 6, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Asmanex Twisthaler 220mcg (mometasone furoate inhalation powder).

We acknowledge receipt of your submission dated February 8, 2008.

This supplemental new drug application provides for changes to the packaging components for Asmanex Twisthaler 220mcg (mometasone furoate inhalation powder).

We have completed our review of this application, as amended. It is approved, effective on the date of this letter.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted February 8, 2008, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 21-067/S-007**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

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 Lori Garcia, Senior Regulatory Management Officer, at (301) 796-1212.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary Allergy Products
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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