DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21165/S-014
NDA 21300/S-011
NDA 21312/S-011
NDA 21563/S-001

SUPPLEMENT APPROVAL

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

Attention: David De Sousa, Senior Director
Global Regulatory Affairs

Dear Mr. De Sousa:

Please refer to your Supplemental New Drug Application (sNDA) dated June 28, 2010, received June 29, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Clarinex® RediTabs, Oral Solution, and Tablets.

We acknowledge receipt of your amendments dated October 5 and December 7, 2010.

These Prior Approval supplemental new drug applications provide for conversion of the current approved labeling to the Physician Labeling Rule format, labeling revisions that are consistent with Clarinex® 12-HOUR and 24-HOUR, administrative updates to the copyright and manufacturer information based on the merger between Merck and Schering-Plough, and includes the addition of a patient information sheet (PPI) for Clarinex® RediTabs, Oral Solution, and Tablets.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the following revisions and/or comments:

- Include the copyright year at the end of the package insert and patient package insert.
- The revision date at the end of the package insert and the patient package insert should be deleted, since it located in the highlights section of the label.

As soon as possible, but no later than 14 days from the date of this letter, submit, using 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, except with the comment indicated, the enclosed labeling (text for the package insert, text for the patient package insert) and include the labeling changes proposed in any

pending "Changes Being Effected" (CBE) supplements and any annual reportable changes not included in the enclosed labeling.
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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes with the comment indicated above approved in these supplemental applications.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to these NDAs to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 Montgomery Bowen, Regulatory Project Manager, at (301) 796-2466.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
Content of Labeling

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
12/22/2010
Deputy Division Director