DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA21-313/S-001

Schering Corporation
2000 Gallopng Hill Road
Kennilworth, NJ 07033

Attention: David De Sousa
Global Regulatroy Affairs

Dear Mr. De Sousa:

Please refer to your supplemental new drug application dated February 2, 2006, received February 3, 2006, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Clarinex-D 12 Hour Extended Release Tablet (desloratadine/pseudoephedrine).

This "Changes Being Effected" supplemental new drug application provides for revisions to the WARNINGS section of the package insert to remove renal imparment from the list of conditions for which Clarinex-D 12 Hour should be sued with caution and revisions to the Information for Patients subsection of the PRECAUTIONS section of the package insert to remove the sentence "Patients who have renal impairment should modify the dosing to one table daily." And to state that Clarinex-D 12 Hour should be generally avoided in patients with renal impairment for consistency with the Clinical Pharmacolgy section of the originally approved package insert.

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

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the submitted labeling dated February 2, 2006 (copy enclosed). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplement NDA 21-313/S-001."

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

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100

Rockville, MD 20852

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 Anthony Zeccola, Regulatory Project Manager, at (301) 796-1318.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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
7/19/2007 12:10:37 PM