DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21605/S-006 **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 dated June 29, 2009, received June 30, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Clarinex-D® 24 HOUR (desloratadine/pseudoephedrine) Extended Release Tablets.

We acknowledge receipt of your submission dated December 15, 2009.

This Prior Approval supplemental new drug application provides for conversion of the current approved labeling to the Physician Labeling Rule format, an administrative update to the ADVERSE RECTIONS Section, amendments to the DOSAGE AND ADMINISTRATION, USE IN SPECIFIC POPULATIONS: Nursing Mothers, and the CLINICAL PHARMACOLOGY: Pharmacokinetics-Absorption Sections of the labeling text, replacement of the term hepatic “insufficiency” with hepatic “impairment”, and usage of the terms “subjects” and “patients”, where appropriate, to differentiate between enrollees and persons to whom the product will be prescribed.

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 and with the minor editorial revisions indicated in the enclosed labeling.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to, except for including the revisions indicated, the enclosed labeling (text for the package insert and patient package insert). These revisions are terms of the NDA approval. For administrative purposes, please designate this submission, “**SPL for approved NDA 21605/S-006.**

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

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

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 Project Management Officer, at (301) 796-2466.

Sincerely,

{See appended electronic signature page}

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

Enclosure:
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21605	SUPPL-6	SCHERING CORP	CLARINEX D24

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

/s/

BADRUL A CHOWDHURY
12/30/2009