DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-658/S-026

Schering-Plough HealthCare Products
Attention: Nancy Pierro
Senior Manager, Regulatory Affairs
556 Morris Avenue
Summit, NJ 07901-1330

Dear Ms. Pierro:

Please refer to your supplemental new drug application dated September 20, 2007, received September 21, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claritin (loratadine 10 mg) tablets.

This supplemental new drug application proposes revising the principal display panel (PDP) and/or Drug Facts to include the phrase "indoor & outdoor allergies".

Two versions of the label were submitted to this supplement. Version 1 revised the PDP to include the phrase "Indoor & Outdoor Allergies".

We have completed our review of this supplemental new drug application. This supplement is approved for the revision included in Version 1 only effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Therefore, the final printed labeling (FPL) for all labels must be identical to the Version 1 submitted labeling (10-count and 30-count carton label submitted September 20, 2007), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 19-658/S-026**." Approval of this submission by FDA is not required before the labeling is used.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Elaine Abraham, Regulatory Project Manager, at (301) 796-0843.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Joel Schiffenbauer

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