DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-641/S-024

Schering-Plough HealthCare Products
Attention: Charles Lanese
Manager, Regulatory Affairs
56 Livingston Avenue
Roseland, NJ 07068

Dear Mr. Lanese:

Please refer to your supplemental new drug application dated March 24, 2008, received March 25, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claritin Oral Solution (loratadine 5 mg/5 mL syrup).

This supplement provides for replacing the current glass bottle approved for Claritin® Oral Solution, Fruit Flavor with the plastic bottle container/closure system currently approved for Claritin® Oral Solution, Grape Flavor. The [redacted] glass bottle sizes are being removed from the NDA.

We have completed our review of this supplemental new drug application. This supplement is approved, effective on the date of this letter.

The labeling submitted with this application has been superseded by the labeling submitted in Supplement 025. Refer to our letter of July 25, 2008 for the labeling.

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 set forth under 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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