DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-891/S-005

Schering-Plough HealthCare Products, Inc.
Attention: Nancy Pierro
Senior Manager, Regulatory Affairs
56 Livingston Avenue
Roseland, NJ 07068

Dear Ms. Pierro:

Please refer to your supplemental new drug application dated June 12, 2008, received June 13, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Claritin (loratadine 5 mg) chewable tablets.

We acknowledge receipt of your submission dated October 3, 2008.

This supplemental new drug application provides for the removal of the reference to the existing USP monograph, Loratadine Tablet Monograph.

Two versions of the label were submitted to this supplement. Version 1 revised the statement of identity to reflect the change in established name from "loratadine tablets" to "loratadine" to indicate the title of the applicable USP monograph for loratadine. Version 2 made the same change as Version 1 but also added the descriptor "Indoor & Outdoor Allergies" to the principal display panel.

We have completed our review of this application. This supplement is approved for the revisions included in Version 2, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the Version 2 submitted label (10-count carton label submitted June 12, 2008), and must be formatted in accordance with the applicable 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 21-891/S-005**." 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
WO22, 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}

Andrea Leonard-Segal, M.D.
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/

Andrea Segal

10/8/2008 07:45:33 AM