**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-891/S-004

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 April 29, 2008, received April 30, 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 June 20, 2008.

This supplemental new drug application provides for the following labeling changes:

- the addition of the descriptor "Indoor & Outdoor Allergies" to the principal display panel
- the ™ symbol on the cloud graphic has been updated to a ® symbol
- the phrase "Actual Size" that accompanied the picture of the tablet has been deleted
- 2-count Sample pouch and "Sample" bin - inclusion of "ages 2 years and older" and "Sample - Not for Sale"

Your June 20, 2008 submission notified us that the 10-count carton is intended to serve as a representative package size and any changes approved for the 10-count carton will be incorporated onto the labeling of the other carton sizes, which are identical to the 10-count cartons with the exception of count size.

We have completed our review of this application, as amended. This supplement is approved 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 submitted labeling (final printed labels for all SKUs, identical to the draft representative labels, except for the count sizes, for Children's Claritin chewable tablets 5 mg label submitted April 29, 2008 and 2-count pouch and bin draft labels for the "Sample- Not for Sale" package size submitted on June 20, 2008), and must be formatted in accordance with the applicable requirements of 21 CFR 201.66.

In addition, we have the following revision that must be made in the labels:

> Provisions for a control number and expiration date for the 2-count "Sample" pouch bin label must be included in the final printed labels.

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-004**." 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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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

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

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/s/

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Andrea Segal

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