DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-704/S-021

Schering-Plough HealthCare Products
ATTN: Sangeeta Patel
Manager, Regulatory Affairs
56 Livingston Avenue
Roseland, NJ 07068-1733

Dear Ms. Patel:

Please refer to your supplemental new drug application dated September 30, 2008, received October 1, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claritin® RediTabs (loratadine) orally disintegrating tablet, 10 mg.

We acknowledge receipt of your supplement amendment submission dated October 30, 2008.

This supplemental new drug application provides for:

1. An additional release testing and manufacturing site for the commercial 10-count blister pack, **(b) (4)**
2. Update of microbiology specifications and testing methods in accordance with USP Harmonized Microbiology Test Methods and Specifications which will become effective in May 2009.
3. Deletion of "Made in the United Kingdom" on carton label, based on the 10-count carton labels submitted on October 30, 2008 as representative labels for other count sizes for Claritin RediTabs 10 mg and Claritin RediTabs 10 mg Alternate Graphic label (includes flag "ages 6 years and older)."

We completed our review of this application, as amended. This application 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 the draft representative labels, except for the count sizes, for Claritin RediTabs 10 mg and Claritin RediTabs 10mg Alternate Graphic label [includes flag "ages 6 years and older"] submitted October 30, 2008). In addition, you must submit final printed labels identical to the draft 10-count labels submitted on October 30, 2008. The final printed labeling must be formatted in accordance with the requirements of 21 CFR 201.66. These revisions are terms of the approval of this application.

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 20-704/S-021**." 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Janice Adams-King, Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Products
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

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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