DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-993

Schering-Plough HealthCare Products
Attention: Nancy Pierro
Manager, Regulatory Affairs
556 Morris Avenue
Summit, New Jersey 07901

Dear Ms. Pierro:

Please refer to your new drug application (NDA) dated February 10, 2006, received February 13, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claritin RediTabs 12 Hour (5 mg loratadine) orally disintegrating tablets.

We acknowledge receipt of your submissions dated March 15, April 11, May 10, June 9, 16, 19, 20, and 27, August 25, September 8, and 22, October 2, 3, 4, 6, and 13, 2006.

This new drug application provides for the use of Claritin RediTabs 12 Hour (5 mg loratadine) orally disintegrating tablets for the temporary relief of symptoms due to hay fever or other upper respiratory allergies: runny nose, sneezing, itchy, watery eyes, and itching of the nose or throat.

We have completed our review of this application, as amended. It 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 enclosed labeling (5- and 10-count blister cards submitted September 8, 2006, 5-, 10-, 30-, 40-count carton, and 10-count alternate graphics carton labels submitted October 4, 2006), and must be in the "Drug Facts" format (21 CFR 201.66). Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL for all stock keeping units 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 NDA 21-993**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We reference our June 27, 2006 letter granting a partial waiver and noting that you have otherwise fulfilled the pediatric study requirement for this application.

We remind you of the following agreements stated in your October 2 and 6, 2006 submissions:

1. The 5- and 10- count blister card labels submitted on February 10, 2006 will be discontinued no later than 6 months post approval.

2. The 5- and 10- count blister card labels submitted on September 8, 2006 will be implemented no later than 6 months post approval.

3. A prior approval supplement to add a disintegration test and acceptance limits for both release and shelf-life drug product testing will be submitted to the NDA.

We request the following revision at the time of next printing or 180 days, whichever occurs first:

Revise the carton label for all stock keeping units to include the descriptor "12 Hour" in close proximity to wherever the phrase "Claritin Reditabs" appears to help avoid possible consumer confusion with the "24 Hour" Claritin Reditabs product.

We remind you to remove the flag "New 12 Hour!" from the principal display panel six months after introduction into the marketplace.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 Neel Patel, Regulatory Project Manager, at (301) 796-0970.

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

Enclosure

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
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