DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-670/S-020

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 December 22, 2008, received December 23, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claritin-D® 12 hour (5 mg loratadine /120 mg pseudoephedrine sulfate) extended-release tablets.

This supplemental new drug application provides for a new formulation for Claritin-D® 12 hour, replacing the previously approved formulation. This formulation is identical to the 5 mg loratadine/ 120 mg pseudoephedrine sulfate extended release formulation approved under ANDA 76-070 (Impax Labs). This supplemental NDA also provides for the manufacturing, packaging, and analytical testing (release and stability) operations for this formulation at the Schering-Plough facilities in Kenilworth and Union, New Jersey.

We have completed our review of this supplemental application. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labels (Claritin-D 12 Hour 10-, 20- and 30-count carton and blister foil labels submitted December 22, 2009), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 19-670/S-020**." Approval of this submission by FDA is not required before the labeling is used.

We note your request for the Agency to reinstate Claritin-D 12 Hour as the reference listed drug. It is not appropriate to request this type of change in a supplement to an approved application (see 21 CFR 314.70) Therefore, this request was not reviewed as part of this supplement. You should contact the Orange Book Staff, Mary Ann Holovac, at 240-276-8971 for further information regarding any issues concerning designation as a reference listed drug.

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 both this NDA and 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 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/

Janice Adams-King

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