DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19-670/S-022 (Claritin-D® 12 Hour)
NDA 20-470/S-034 (Claritin-D® 24 Hour) **SUPPLEMENT APPROVAL**

Schering-Plough
Attention: Nancy Pierro
Associate Director, Regulatory Affairs
56 Livingston Avenue
Roseland, NJ 07068

Dear Ms. Pierro:

Please refer to your supplemental new drug applications (NDAs) dated July 24, 2009, received July 27, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Claritin-D® 12 Hour (loratadine 5 mg, pseudoephedrine sulfate 120 mg) extended release tablets and Claritin-D® 24 Hour (loratadine 10 mg, pseudoephedrine sulfate 240 mg) extended release tablets.

We acknowledge receipt of your submission dated December 16, 2009.

These "Prior Approval" supplemental new drug applications provide for the addition of the descriptor "Indoor & Outdoor Allergies" to the principal display panel of the cartons.

Your July 24, 2009 submissions notified us that the 10-count carton, for both supplemental new drug applications, is intended to serve as a representative package size. Any changes approved for the 10-count carton will be incorporated onto the carton label of the other package sizes, which are identical to the 10-count carton with the exception of the count size.

We have completed our review of these applications, as amended. They are 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 labels and Claritin-D® 24 Hour 5-, 10- and 15-count cartons labels submitted on December 16, 2009), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Even though no revisions were made to the immediate container (blister card) label for the Claritin-D® 12 Hour 10-, 20- and 30-count package sizes and the Claritin-D® 24 Hour 5-, 10- and 15-count package sizes, we request that you submit immediate container (blister card) labels for both the Claritin-D® 12 Hour and Claritin-D® 24 Hour drug product as part of the FPL for

these supplements to maintain a record of the complete labeling for these count sizes and packaging configurations.

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 these submissions "**Final Printed Labeling for approved NDA 19-670/S-022 and NDA 20-470/S-034."** Approval of these submissions by FDA is not required before the labeling is used.

We remind you to make provisions for the expiration date and lot number in the final printed labeling.

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA for these drug products, not to these supplemental NDAs. In the future, do not make submissions to these supplemental NDAs, except for the final printed labeling requested above.

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20470	SUPPL-34	SCHERING PLOUGH HEALTHCARE PRODUCTS INC	CLARITIN-D 24 HOUR
NDA-19670	SUPPL-22	SCHERING PLOUGH HEALTHCARE PRODUCTS INC	CLARITIN-D

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
01/25/2010