DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-952/S-003

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 application dated January 19, 2009, received January 21, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claritin® Liqui-Gels® (loratadine 10 mg) capsules.

This supplemental new drug application proposes to add the descriptor "Indoor & Outdoor Allergies" to the principal display panel of the 10-count and 30-count carton labels. The supplement contained a 10-count carton label that is representative of the 10- and 30-count package size carton labels.

We have completed our review of this application. 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 enclosed label (10-count carton label, representative of the 10- and 30-count package size carton labels, submitted on January 19, 2009) and must be formatted in accordance with the requirements of 21 CFR 201.66. The FPL submission should include both the 10- and 30-count carton 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 21-952/S-003**." Approval of this submission by FDA is not required before the label 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

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, email or call Michelle Poindexter, Regulatory Project Manager, at michelle.poindexter@fda.hhs.gov or (301) 796-4795.

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

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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