DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-470/S-019

Schering Corporation
Attention: Mary Jane Nehring
Senior Director, Marketed Products Support and Training
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Ms. Nehring:

Please refer to your supplemental new drug application dated February 10, 2003, received February 11, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claritin-D 24 Hour (10 mg loratadine and 240 mg pseudoephedrine sulfate) Extended Release Tablet.

This "Changes Being Effected" supplemental new drug application provides for a change in the labeled storage conditions.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 10, 2003.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Elaine Abraham, R.Ph., Regulatory Project Manager, at (301) 827-2301.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
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/

Marina Chang

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