DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-165/S-006 and 21-312/S-004

Schering Corporation
2000 Galloping Hill Rd.
Kenilworth NJ 07033

Attention: Mary Jane Nehring
Senior Director, Marketed Products Support and Training

Dear Ms. Nehring:

Please refer to your supplemental new drug applicationsdated July 28, 2003, received July 29, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clarinex (desloratadine) Tablets and Clarinex Reditabs (desloratadine rapidly disintegrating) Tablets.

These "Changes Being Effected" supplemental new drug applications provide for the addition of palpitations to the ADVERSE REACTIONS Section of the package insert and revision of the legal name of the manufacturer of Clarinex Reditabs.

We completed our review of these supplemental new drug applications and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 28, 2003.

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HFD-410
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 Anthony Zeccola, Regulatory Health Project Manager, at (301) 827-1058.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Division Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
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/

Badrul Chowdhury
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