DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-312/S-007

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Attention: Satish Joshi
Senior Manager, CMC Global Regulatory Affairs

Dear Mr. Joshi,

Please refer to your supplemental new drug application dated March 14, 2005, received March 17, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clarinex® (desloratadine) RediTabs® 2.5 mg and 5 mg Orally Disintegrating Tablet.

We acknowledge receipt of your submissions dated March 15, April 14, May 25, and June 15, 2005.

This supplemental new drug application provides for changes to the formulation and the addition of a 2.5 mg strength.

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

The final printed labeling (FPL) must be identical to the submitted labeling, copy enclosed (package insert submitted March 14, 2005, immediate container and carton labels submitted June 15, 2005).

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 21-312/S-007**." Approval of this submission by FDA is not required before the labeling 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, HFD-410
FDA
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 Anthony M. Zeccola, Regulatory Management Officer, at (301) 827-1058.

Sincerely,

{See appended electronic signature page}

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

Badrul Chowdhury
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