DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-312/S-002

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07003

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

Dear Ms. Nehring:

Please refer to your supplemental new drug application dated August 13, 2002, received August 14, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clarinex Reditabs (desloratadine orally disintegrating tablets).

This supplemental new drug application provides for the addition of instructions for use for both the professional sample and 30 tablet unit-of use packages.

We 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 submitted labeling (patient's instructions for use and carton labels submitted August 13, 2002).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-312/S-002." Approval of this submission by FDA is not required before the labeling is used.

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 Zeccola, Regulatory Project Manager, at (301) 827-1058.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D, Ph.D.
Acting 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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