DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-605

Schering Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey 07033

Attn: David De Sousa
Senior Director, Global Regulatory Affairs

Dear Mr. De Sousa:

Please refer to your new drug application (NDA) dated April 30, 2004, received May 4, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clarinex-D® 24 Hour (desloratadine 5mg/pseudoephedrine sulfate 240mg) Extended Release Tablets.

We acknowledge receipt of your submissions dated May 27, July 30, October 1, and December 2, 2004, and February 1 and 15, and March 3, 2005.

This new drug application provides for the use of Clarinex-D® 24 Hour (desloratadine 5mg/pseudoephedrine sulfate 240mg) for the relief or nasal and non-nasal symptoms of seasonal allergic rhinitis, including nasal congestion, in patients 12 years of age and older. Clarinex-D® 24 Hour can be administered when the antihistaminic properties of desloratadine and the nasal decongestant properties of pseudoephedrine are desired.

We completed our review of this application, as amended. It 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 submitted labeling (package insert submitted, copy attached, immediate container and carton labels submitted March 3, 2005). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-605**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for patients less than 12 yeas of age for this application. We

note that you have fulfilled the pediatric study requirement for patients 12 years of age and older and in this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you of the Chemistry, Manufacturing and Controls agreements which were discussed on February 29, 2005.

If you have any questions, call Anthony M. Zeccola, Senior 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
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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