DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-300

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Attention: Carlos Langezaal, Ph.D.

Dear Dr. Langezaal,

Please refer to your new drug application (NDA) dated December 8, 2000, received December 8, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clarinex (desloratadine) Syrup 0.5 mg/mL.

We also refer to your amendments dated March 19, and June 28, 2001, June 2, 2003, and February 27 (2), June 24, July 9, 20, 29, August 10, 12, 13(2), 30 and 31 and September 1, 2004.

The February 27, 2004, submission constituted a complete response to our October 2, 2002, action letter.

This new drug application provides for the use of Clarinex for the relief of the nasal and non-nasal symptoms of seasonal and perennial allergic rhinitis, and the symptomatic relief of pruritus, reduction in the number of hives, and size of hives, in patients with chronic idiopathic urticaria in patients 2 years of age and older.

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 and with the minor editorial revisions listed below, as agreed during our telephone discussion on August 30, 2004.

1. Remove the (b)(4)---------- -------from the carton labeling.
2. Replace the ----------tainers with the approved name, Clarinex.
3. Remove the phrase, b)(4)---------- ----------from the carton and container.

The final printed labeling (FPL) must be identical to, except for including the revisions listed, the enclosed labeling (text for the package insert submitted August 30, 2004) and submitted labeling (carton and container label submitted August 30, 2004). These revisions are terms of the NDA approval. Marketing the product before making the revisions, exactly as stated, in the product's labeling 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 21-300**." 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 note that you have fulfilled the pediatric study requirement for this application in ages 2 years and above.

Please 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 the Division of Pulmonary and Allergy Drug Products 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

Submit one market package of the drug product when it is available.

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
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
9/1/04 04:07:28 PM