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RESEARCH**

*APPLICATION NUMBER:*

**21-313**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-313

Schering Corporation  
2000 Galloping Hill Road  
Kenilworth, NJ 07033

Attention: Beth DiDomenico, Ph.D. M.B.A.  
Senior Manager and Liaison  
Global Regulatory Affairs

Dear Dr. DiDomenico:

Please refer to your new drug application (NDA) dated December 8, 2000, received December 27, 2000, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Clarinex-D 12 Hour (2.5 mg desloratadine and 120 mg pseudoephedrine sulfate) Extended-Release Tablets.

We also refer to your amendments dated December 27, 2000, March 16, April 2, and 27, and August 14, and 22, 2001, March 8, 2002, July 29, and October 3, 2005, and January 10, 20, and 27, and February 1, 2006.

The July 29, 2005 (received August 1, 2005) submission constituted a complete response to our October 26, 2001 action letter.

This new drug application provides for the use of Clarinex-D 12 Hour (2.5 mg desloratadine and 120 mg pseudoephedrine sulfate) Extended-Release Tablets for the relief of nasal and non-nasal symptoms of seasonal allergic rhinitis including nasal congestion, in adults and children 12 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.

The final printed labeling (FPL) must be identical to submitted labeling (package insert, submitted February 1, 2006, copy attached and immediate container and carton labels submitted January 27, 2006). 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

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submission "**FPL for approved NDA 21-313.**" 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 years 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.

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, Senior Regulatory Management Officer, at (301) 796-1318.

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  
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/s/

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Badrul Chowdhury  
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