



NDA 19-658/S-021

Schering Corporation
Attention: Mary Jane Nehring
Senior Director, Marketed Products Support and Training
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Ms. Nehring:

Please refer to your supplemental new drug application dated January 14, 2003, received January 15, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claritin (10 mg loratadine) Tablet.

We acknowledge receipt of your submissions dated March 5, April 23, May 29 and 30, and June 6, 2003. We also acknowledge receipt of your letter of commitment dated June 13, 2003.

This supplemental new drug application provides for 1-count samples to be distributed by healthcare professionals and 2-count packaging for direct-to-consumer distribution.

We have completed our review of this supplemental application, as amended, and it is approved effective on the date of this letter.

We agree with your proposed conditions of use of the tri-fold card for distribution directly to consumers, as provided in the submissions dated June 6 and 13, 2003.

The final printed labeling (FPL) must be identical to the submitted draft labeling (labeling components and configuration submitted June 6, 2003, with revisions as stated in the June 13, 2003 correspondence, and carton label for professional dispensing submitted on April 23, 2003) and must be formatted in accordance with the requirements of 21 CFR 201.66.

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 19-658/S-021." 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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Elaine Abraham, R.Ph., Regulatory Project Manager, at (301) 827-2301.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Curtis Rosebraugh
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