

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-952

APPROVABLE LETTER



NDA 21-952

Schering-Plough HealthCare Products
Attention: Nancy Pierro
Manager, Regulatory Affairs
556 Morris Avenue
Summit, NJ 07901-1330

Dear Ms. Pierro:

Please refer to your new drug application (NDA) dated March 15, 2006, received March 16, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claritin (loratadine) Liqui-gel capsules 10 mg.

We acknowledge receipt of your submissions dated June 14, July 27, August 2 and 4, October 25, 26, and 27, November 6, and December 20, 2006.

We have completed our review of this application, as amended, and it is approvable. Before this application may be approved, however, you must submit draft labeling for the 10- and 30-count cartons revised as follows:

The bulleted statement: “**• take on an empty stomach. Taking with food may cause drowsiness.**” has not been incorporated in the *Directions* section of the “Drug Facts” labeling for both SKUs.

As the Agency stated in its faxed labeling comments of November 13, 2006 and during the teleconference call of November 30, 2006, this statement must appear as the first bulleted statement in bold type under this heading.

If additional information relating to the safety or effectiveness of this drug becomes available, further revision of the labeling may be required.

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with this division to discuss what steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call Elaine Abraham, Regulatory Project Manager, at (301) 796-0843.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

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/s/

Joel Schiffenbauer
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