

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-952**

**APPROVAL LETTER**



NDA 21-952

**NDA APPROVAL**

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 Liqui-Gels (loratadine 10 mg) capsules.

We acknowledge the receipt of your submissions dated December 19, 2007, and February 1, April 8, 10, and 14, 2008.

The December 19, 2007 submission constituted a complete response to our January 12, 2007 action letter.

This new drug application provides for the use of Claritin Liqui-Gels (loratadine 10 mg) capsules for the temporary relief of symptoms due to hay fever or other upper respiratory allergies: runny nose, sneezing, itchy, watery eyes, and itching of the nose or throat in adults and children 6 years of age and older.

We have 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.

### **LABELING**

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the submitted labeling (10- and 30-count carton labels submitted December 19, 2007, and 10-count blister card submitted April 14, 2008), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission

**“Final Printed Labeling for approved NDA 21-952.”** Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the flag “New” from the principal display panel six months after introduction into the marketplace.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

### **PEDIATRIC RESEARCH EQUITY ACT (PREA)**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to less than 2 years for the following reason: (seasonal) allergic rhinitis does not exist in the 0 to 2 years age group.

This product does not offer any additional therapeutic benefit over existing therapies for the pediatric population ages 2 to <6 years of age because there are other age appropriate loratadine formulations, and it is appropriately labeled for use in children ages 6 to 17 years for allergic rhinitis. Therefore, no additional pediatric studies are needed.

### **LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

### **REPORTING REQUIREMENTS**

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 Elaine Abraham, Regulatory Project Manager, at (301) 796-0843.

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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

Enclosure

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

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Joel Schiffenbauer  
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