

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-952

OTHER REVIEW(S)



OTC Drug Labeling Review Resubmission

Office of Nonprescription Drug Products
Center for Drug Evaluation and Research • Food and Drug Administration

SUBMISSION DATE 12/19/07 **REVIEW DATE** 4/28/08
4/14/08

NDA 21-952

SUBMISSION TYPE 000

SPONSOR/CONTACT Nancy Pierro
Senior Manager, Regulatory Affairs
Schering-Plough HealthCare Products
556 Morris Avenue
Summit, NJ 07901-1330

DRUG PRODUCT (BRAND NAME) Claritin Liqui-Gels Capsules
(loratadine 10 mg liquid filled capsules)

ACTIVE INGREDIENT(S) [ESTABLISHED NAME(S)] Loratadine

PHARMACOLOGICAL CATEGORY Antihistamine

LABELING SUBMITTED (SKU) 10- and 30-counts carton labels
10-counts blister card

PROJECT MANAGER Elaine Abraham

REVIEWER'S NAME Marina Chang, R. Ph.

BACKGROUND

In response to our approvable letter dated 1/12/07, the sponsor is re-submitting the 10- and 30- counts carton labels and 10 counts blister foil card for our review and comment.

REVIEWER'S COMMENT**I. Carton label (10- and 30- counts)****A. "Drug Facts"**

In this submission, the sponsor did not incorporate the bulleted statement:

"• take on an empty stomach. Taking with food may cause drowsiness."

in the *Directions* as requested in the approvable letter dated 1/12/07.

Based on the data submitted to this submission, the Clinical Pharmacology reviewer (see Clinical Pharmacology review dated 4/24/08) has concluded that that no additional directions (such as "take on an empty stomach. Taking with food may cause drowsiness") are required to advise consumers of the safe and effective use of this product when taking with food.

B. Annotated "Drug Facts" specifications:

The annotated "Drug Facts" specifications are acceptable.

II. 10-counts blister card: The blister foil card is acceptable**RECOMMENDATIONS**

1. This application can be approved. Request the sponsor to submit final printed labels identical to the draft 10- and 30-counts carton labels submitted on 12/19/07 and 10-counts blister foil card submitted on 04/14/08, when available.
2. Inform the sponsor the flag "New" needs to be deleted from the labels six months after marketing.

Marina Chang, R. Ph.
Reviewer's name

Matthew Holman
Team Leader concurrence

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/s/

Marina Chang
4/28/2008 07:53:19 AM
INTERDISCIPLINARY

Matthew Holman
4/28/2008 09:16:28 AM
INTERDISCIPLINARY



Food and Drug Administration
Center for Drug Evaluation and Research
Office of Nonprescription Products
Division of Nonprescription Clinical Evaluation

FACSIMILE TRANSMITTAL SHEET

DATE: November 13, 2006

To: Nancy Pierro	From: Elaine Abraham Project Manager
Company: Schering-Plough HealthCare Products	Division of Nonprescription Clinical Evaluation Office of Nonprescription Products
Fax number: (908) 473-1741	Fax number: (301) 796-9899
Phone number: (908) 473-1784	Phone number: (301) 796-0843
Subject: NDA 21-952 labeling comments	

Total no. of pages including cover: 2

Comments:

Document to be mailed:	YES	☒ NO
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Please refer to your new drug application NDA 21-952 dated March 15, 2006 for Claritin liquid-gel capsules 10 mg and your amendment dated October 26, 2006.

We have reviewed your labeling and have the following comments:

Revise the labeling for the 10- and 30-count cartons as follows:

1. Delete the phrase _____ wherever it appears in the labeling of this product, unless there are data to support this claim. The data must be reviewed by the agency before the claim can be made in the labeling.
2. Revise the Directions section of the "Drug Facts" labeling to include the following bulleted statement: **"• take on an empty stomach. Taking with food may cause drowsiness."** This statement must appear as the first bulleted statement in bold type under this heading. Based on the food effect study that you submitted, this drug product showed greater bioavailability when taken with food. As the data indicated in the application, the administration of Claritin Liqui-Gels Capsules (loratadine 10 mg) with food increased the loratadine C_{max} (53.06%), AUC_{0-t} (121.13%), and AUC_{0-∞} (118.03%). Consequently, drowsiness may occur if this product is taken with food. Consumers should be alerted to this possible effect.

b(4)

In order to ensure a timely action for your supplements, we request that you respond to the issues listed above as soon as possible by sending revised draft labeling by email or fax, in addition to sending a copy to your NDA.

APPEARS THIS WAY ON ORIGINAL

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/s/

Elaine Abraham
11/13/2006 01:15:48 PM
CSO

OTC Drug Labeling Review
Division of Over-The-Counter Drug Products (HFD-560)
Center for Drug Evaluation and Research • Food and Drug Administration

NDA Labeling Amendment Review

NDA # 21-952

Submission Date: 10/26/06

Review Date: 11/09/06

Applicant: Schering-Plough HealthCare Products
556 Morris Avenue
Summit, New Jersey 07901-1330
(908) 473-1741

Applicant's Representative: Nancy Pierro
Regulatory Affairs Manager

Drug: Claritin Liqui-Gels Capsules
Loratadine, 10 mg

Pharmacologic Category: Antihistamine

Submitted: Revised draft labeling provided for:

- 10- and 30-count carton
- Annotated Drug Facts specifications

Background:

In this Minor Labeling Amendment (submitted 10/25/06 as S-007), Schering Corporation is amending its NDA 21-952 application to include electronic labeling. However, the sponsor has further revised the draft 10- and 30-count carton labeling by adding:

1. The liquid-gel icon and the phrase "Liqui-Gels Capsules" _____ wherever the word "Claritin" appears on the side panels
2. The phrase "Claritin Liqui-Gels Capsules." _____ to the back panel of both SKUs.

b(4)

Reviewer Comment:

Carton 10- and 30-count SKUs:

A. PDP, side-panels, and back panel:

"Liqui-Gels capsules. _____"

Reviewer comment: The addition of the phrase "Liqui-Gels Capsules" on the side panels and the phrase "Claritin Liqui-Gels Capsules" on the back panel are acceptable. However, the accompanied phrase _____ must be deleted wherever it appears in the labeling, unless there are data to support this claim.

b(4)

B. Drug Facts panel: "**Directions**" section

• **take on an empty stomach. Taking with food may cause drowsiness.**

Reviewer comment: The statement "**take on an empty stomach. Taking with food may cause drowsiness**" [in bold type] should be added as the first bulleted statement in the "**Directions**" section. Based on the food

effect study submitted by the sponsor, this drug product showed greater bioavailability when taken with food. As the data indicated in the application, the administration of Claritin Liqui-Gels Capsules (loratadine 10 mg) with food increased the loratadine C_{max} (53.06%), AUC_{0-4} (121.13%), and $AUC_{0-\infty}$ (118.03%). Consequently, drowsiness may occur if this product is taken with food. Consumers should be alerted to this possible effect.

- C. The annotated specifications for the **Drug Facts** format are acceptable for the 10- and 30-count carton SKUs.

Recommendations:

The draft labeling for the 10- and 30-count cartons are not acceptable. Inform the sponsor to revise and resubmit draft carton labeling for these two SKUs before the action due date as follows:

1. Delete the phrase ~~_____~~ ' wherever it appears in the labeling of this product, unless there are data to support this claim. The data must be reviewed by the agency before the claim can be made in the labeling.
2. Revised the Directions section of the "Drug Facts" labeling to include the following bulleted statement: "**• take on an empty stomach. Taking with food may cause drowsiness.**" This statement must appear as the first bulleted statement in bold type under this heading. Based on the food effect study submitted by the sponsor, this drug product showed greater bioavailability when taken with food. As the data indicated in the application, the administration of Claritin Liqui-Gels Capsules (loratadine 10 mg) with food increased the loratadine C_{max} (53.06%), AUC_{0-4} (121.13%), and $AUC_{0-\infty}$ (118.03%). Consequently, drowsiness may occur if this product is taken with food. Consumers should be alerted to this possible effect.

b(4)

Cazemiro R. Martin
Reg. Review Chemist/IDS

Concur: Marina Chang, R.Ph.
Team Leader

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/s/

Cazemiro Martin
11/9/2006 09:30:37 AM
INTERDISCIPLINARY

Marina Chang
11/9/2006 09:51:06 AM
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OTC Drug Labeling Review

Division of Over-The-Counter Drug Products (HFD-560)

Center for Drug Evaluation and Research • Food and Drug Administration

NDA Labeling Review

NDA # 21-952

Submission Date: 3/15/06 and 6/14/06

Review Date: 8/16/06

Applicant: Schering-Plough HealthCare Products
556 Morris Avenue
Summit, New Jersey 07901-1330
(908) 473-1741

Applicant's Representative: Doreen Frank, Director
Regulatory Affairs

Drug: Claritin Liqui-Gels Capsules
Loratadine, 10 mg

Pharmacologic Category: Antihistamine

Submitted: Draft labeling provided for:

- 10- and 30-count carton
- 10-count blister card
- Annotated Drug Facts specifications

Background:

In this submission, Schering Corporation is seeking approval to market Claritin Liqui-Gels Capsules, an immediate release liquid-gels capsule dosage form, containing 10 mg of loratadine for allergic rhinitis. According to the sponsor, the liquid-gels capsules will be package in 10-count aluminum based laminated blister cards and placed in fully labeled cartons. According to the sponsor, the proposed labeling for this product is based on the currently approved labeling for the OTC antihistamine loratadine.

Reviewer Comment:

1. Carton labeling (10- and 30-count SKUs)

A. New!

[Reviewer comment: The flag "New!" must be deleted from the PDP six months after introduction into the market place.]

B. Other comments:

[Reviewer comment: The labeling is tentatively acceptable. Note: During an internal NDA team meeting, clinical and bioequivalence discussions focused on possible food effect on bioavailability. If it is determined that there is a food effect, additional labeling may be required pending the completion of the clinical and bioequivalence reviews.]

2. Blister card labeling: (10-count)

[Reviewer comment: Labeling is acceptable]

3. The annotated specifications for the **Drug Facts** format (March 15, 2006 submission) are acceptable for the 10- and 30-count carton SKUs.

Recommendations:

1. The labeling included in this submission is tentatively acceptable. However, further labeling revision may be required pending the completion of the clinical and bioequivalence reviews regarding possible food effect. The project manager will need to check with this OTC labeling reviewer before notifying the sponsor of the acceptability of the draft labeling included in this submission.
2. Inform the sponsor that the flag "New!" must be deleted from the PDP six months after introduction into the market place.

Cazemiro R. Martin
Reg. Review Chemist/IDS

Concur: Marina Chang, R.Ph.
Team Leader

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/s/

Cazemiro Martin
8/16/2006 08:06:29 AM
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Marina Chang
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