

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-952

PROPRIETARY NAME REVIEW(S)

**Division of Medication Errors and Technical Support (DMETS)
Office of Surveillance and Epidemiology
WO 22, MAIL STOP 4447
Center for Drug Evaluation and Research**

PROPRIETARY NAME, LABEL, AND LABELING REVIEW

DATE OF REVIEW: May 3, 2006

NDA #: 21-952

NAME OF DRUG: **Claritin®**
(Loratadine Capsules)
10 mg

NDA SPONSOR: Schering-Plough HealthCare Products, Inc.

I. INTRODUCTION

This consult was written in response to a request from the Division of Nonprescription Clinical Development (HFD-560), for an assessment of the descriptor Liqui-Gels™ used in conjunction with the proprietary name, Claritin®, with regard to potential name confusion with other proprietary or established drug names. Container label (blister foils) and carton labeling were provided for review and comment from a medication error perspective.

PRODUCT INFORMATION

Claritin® Liqui-gels™ (loratadine) contains 10 mg of loratadine for the relief of sneezing, runny nose, itchy/watery eyes, itchy throat or itchy nose. The recommended dosing is one capsule daily with no more than one in twenty-four hours in patients over the age of six years. The sponsor currently markets additional Claritin drug products: Claritin Reditabs (Claritin Hives Relief Reditabs, Claritin Pediatric Reditabs), Claritin 24-hour (Claritin Hives Relief), Claritin syrup, and Claritin-D (12 and 24 hour formulations). All the products include 10 mg of loratadine excluding Claritin syrup (5 mg per teaspoonful) and Claritin-D 12 hour (5 mg loratadine/120 mg pseudoephedrine, currently listed as discontinued but still available in the marketplace).

APPEARS THIS WAY ON ORIGINAL

II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of several standard published drug product reference texts^{i,iii} as well as several FDA databases^{iii,iv} for existing drug names which sound-alike or look-alike to Claritin Liqui-Gels to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted^v. The SAEGIS^{vi} Pharma-In-Use database was searched for drug names with potential for confusion. An expert panel discussion was conducted to review all findings from the searches. In addition, DMETS conducted three prescription analysis studies consisting of two written prescription studies (inpatient and outpatient) and one verbal prescription study, involving health care practitioners within FDA. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name.

A. EXPERT PANEL DISCUSSION

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the addition of the descriptor "Liqui-Gels" in conjunction with the proprietary name, Claritin. Potential concerns regarding drug marketing and promotion related to the proposed name were also discussed. This group is composed of DMETS Medication Errors Prevention Staff with representation from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The group relies on their clinical and other professional experiences and a number of standard references when making a decision on the acceptability of a proprietary name.

1. DDMAC does not provide comments on the promotional aspects of over-the-counter products. The Federal Trade Commission (FTC) regulates the promotional aspects of these products.
2. The Expert Panel identified the currently marketed Claritin drug product line as having the potential for confusion with Claritin® Liqui-Gels™. These products are listed in Table 1 (see page 4), along with the dosage forms available and usual dosage.

APPEARS THIS WAY ON ORIGINAL

ⁱ MICROMEDEX Integrated Index, 2006, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.

ⁱⁱ Facts and Comparisons, online version, Facts and Comparisons, St. Louis, Missouri.

ⁱⁱⁱ AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-06, and the electronic online version of the FDA Orange Book.

^{iv} Phonetic and Orthographic Computer Analysis (POCA)

^v www location <http://www.uspto.gov/tmdb/index.html>.

^{vi} Data provided by Thomson & Thomson's SAEGIS™ Online service, available at www.thomson-thomson.com

Table 1: Potential Look-Alike Names Identified for Claritin Liqui-Gels			
Product Name	Established name, Dosage form(s)	Usual adult dose*	Other**
Claritin Liqui-Gels	Loratadine Capsules, 10 mg	One Capsule Daily	N/A
Children's Claritin (Fruit Flavored and Grape Syrup)	Loratadine Syrup 5 mg/mL	One to two teaspoonsful daily.	LA/SA
Claritin 24 hour Allergy	Loratadine 10 mg Tablets	One tablet daily.	LA/SA
Claritin Hives Relief	Loratadine 10 mg Tablets	One tablet daily.	LA/SA
Claritin RediTabs, (Pediatric and Hives Relief)	Loratadine 10 mg Tablets	One tablet daily.	LA/SA
Claritin-D (12 hour and 24 hour)	Loratadine/Pseudoephedrine Sulfate 5 mg/120 mg (12 hour, discontinued) 10 mg/240 mg (24 hour)	(24 hour), one tablet daily. (12 hour listed as discontinued in the orange book), one tablet every 12 hours.	LA/SA

*Frequently used, not all-inclusive.
**LA (look-alike)/SA (sound-alike).

B. PRESCRIPTION ANALYSIS STUDIES

Prescription studies were conducted on other Claritin products such as Claritin Reditabs 12 Hour and Children's Claritin Chewables. These studies did not reveal significant problems with the names. Therefore, DMETS did not conduct prescription studies.

C. SAFETY EVALUATOR RISK ASSESSMENT INCLUDING RESULTS OF THE FDA DATABASE SEARCHES

In reviewing the addition of the descriptor "Liqui-Gels" used in conjunction with the proprietary name of Claritin, the primary concerns relating to look-alike confusion with other marketed Claritin drug products and their tradename extensions.

As there are multiple Claritin drug products currently marketed, DMETS searched the FDA Adverse Event Reporting System (AERS) database for post-marketing safety reports with the Claritin product line. DMETS used the tradename and verbatim letter string of "Clari%" and the High Level Group Term (HLGT) of "medication errors." In addition, the Drug Quality Reporting System (DQRS) database was also searched for similar reports with "Claritin." These searches revealed one complaint (2006) of potential confusion with the "Children's Claritin" packaging; implicating that the "up to 24 days of relief Children's Claritin 24 hours" was misleading to how long the medication would last. However, with the introduction of the Liqui-gel capsule to the product line, a potential source of confusion may be if the consumer is unaware that there are several formulations of Claritin with different ingredients (potentially containing pseudoephedrine) and dosing frequencies. There were no errors involving confusion with the nomenclature, labels, or labeling of the current non-prescription Claritin product line.

With regards to the descriptor "Liqui-gels", there are currently six drug products marketed as "Liqui-gels™" and one "liquigel" (without the hyphen). The latter "liquigel" relates to Refresh Liquigel, which is a viscous eye drop. The "Liqui-gels™" terminology is also associated with such OTC products as Advil and Benadryl. The descriptor Liqui-gels means liquid filled capsules for these products as it does for this proposed name. As there are multiple products currently marketed using this terminology for the same dosage form, DMETS suspects the introduction of Claritin Liqui-gels

to the Claritin product line should not lead to confusion. Thus, DMETS has no objections to the use of descriptor "Liqui-Gels" in conjunction with the proprietary name of Claritin.

III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES

In review of the Claritin® Liqui-Gels™ container label (blister foils) and carton labeling, DMETS has focused on safety issues relating to possible medication errors. DMETS has identified the following areas of improvement, which might minimize potential user error.

A. GENERAL COMMENTS

The front panel of the submitted labels and labeling is extremely busy with distracting graphics such as the bright and colorful display of balloons, clouds, and grass in the layout. DMETS recommends removing these graphics or revising so that it is not more prominent than the drug names, established name, and product strength.

B. CARTON LABELING

1. As a report from the Drug Quality Reporting System (DQRS) database indicated that the verbiage on the "Children's Claritin" packaging reading "up to 24 days of relief Children's Claritin 24 hours" was misleading to how long the medication would last. DMETS recommends the sponsor remove the "10 capsules for 10 days of relief" to eliminate the potential for overdose from the patient/consumer taking 10 tablets at once to yield 10 days of relief.
2. The flag with the term "New!" may appear on the carton labeling not to exceed a period of 6 months.

APPEARS THIS WAY ON ORIGINAL

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Kimberly Culley-Pedersen
11/17/2006 11:23:23 AM
DRUG SAFETY OFFICE REVIEWER

Alina Mahmud
11/17/2006 11:27:50 AM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
11/17/2006 11:37:56 AM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
11/17/2006 11:41:51 AM
DRUG SAFETY OFFICE REVIEWER

REQUEST FOR CONSULTATION

TO (Division/Office): Division of Medication Errors and Technical Support (DMETS)

FROM: Elaine Abraham, RPM
Div. of Nonprescription Clinical Evaluation, WO22, Room 5410

DATE
April 19, 2006

IND NO.

NDA NO.
21-952

TYPE OF DOCUMENT

DATE OF DOCUMENT
March 15, 2006

NAME OF DRUG
Claritin Liqui-gels (loratadine 10 mg)

PRIORITY CONSIDERATION
High

CLASSIFICATION OF DRUG
3

DESIRED COMPLETION DATE
October 15, 2006

NAME OF FIRM: Schering Plough Consumer Healthcare

REASON FOR REQUEST

I. GENERAL

- | | | |
|--|--|--|
| <input type="checkbox"/> NEW PROTOCOL | <input type="checkbox"/> PRE-NDA MEETING | <input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER |
| <input type="checkbox"/> PROGRESS REPORT | <input type="checkbox"/> END OF PHASE II MEETING | <input type="checkbox"/> FINAL PRINTED LABELING |
| <input type="checkbox"/> NEW CORRESPONDENCE | <input type="checkbox"/> RESUBMISSION | <input type="checkbox"/> LABELING REVISION |
| <input type="checkbox"/> DRUG ADVERTISING | <input type="checkbox"/> SAFETY/EFFICACY | <input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE |
| <input type="checkbox"/> ADVERSE REACTION REPORT | <input type="checkbox"/> PAPER NDA | <input type="checkbox"/> FORMULATIVE REVIEW |
| <input type="checkbox"/> MANUFACTURING CHANGE/ADDITION | <input type="checkbox"/> CONTROL SUPPLEMENT | <input checked="" type="checkbox"/> OTHER (SPECIFY BELOW): Trade name review |
| <input type="checkbox"/> MEETING PLANNED BY | | |

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH

STATISTICAL APPLICATION BRANCH

- TYPE A OR B NDA REVIEW
 END OF PHASE II MEETING
 CONTROLLED STUDIES
 PROTOCOL REVIEW
 OTHER (SPECIFY BELOW):

- CHEMISTRY REVIEW
 PHARMACOLOGY
 BIOPHARMACEUTICS
 OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- DISSOLUTION
 BIOAVAILABILITY STUDIES
 PHASE IV STUDIES

- DEFICIENCY LETTER RESPONSE
 PROTOCOL-BIOPHARMACEUTICS
 IN-VIVO WAIVER REQUEST

IV. DRUG EXPERIENCE

- PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
 DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
 CASE REPORTS OF SPECIFIC REACTIONS (List below)
 COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP

- REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
 SUMMARY OF ADVERSE EXPERIENCE
 POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

CLINICAL

PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS:

We are requesting a trade name review for NDA 21-952. The PDUFA date for this NDA is January 16, 2007. The paper copy of consult and labeling to follow in inter-office mail. Please contact me at 796-0843 if you have any questions.

Attachment:
Claritin label

SIGNATURE OF REQUESTER

{See appended electronic signature page}

METHOD OF DELIVERY (Check one)

MAIL

HAND

SIGNATURE OF RECEIVER

SIGNATURE OF DELIVERER

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Elaine Abraham
4/19/2006 08:17:07 AM