CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
20-641/SE5-007

Administrative Documents

(CLARITIN Pediatric Exclusivity)

Claim for Pediatric Exclusivity

1. Pursuant to the provisions of Sections 505A(c)(1)(A)(ii), (c)(2)(A) and (c)(2)(B) of the Food, Drug and Cosmetic Act (hereinafter "FDCA"), as amended by Section 111 of Title I of the Food and Drug Administration Modernization Act of 1997, applicant claims that its **CLARITIN** (LORATADINE & LORATADINE-PSEUDOEPHEDRINE) products for all of the the approved indications is eligible to have an additional six (6) months be added to the period during which any application containing a certification submitted under Section 505(b)(2)(A)(iii) or 505(j)(2)(A)(vii)(III) against the following U.S. Patent Nos. listed in the Orange Book for each of the following NDAs:

1. NDA #19-658 for CLARITIN (LORATADINE) Tablets

U. S. Patent Nos	Expiration Date:
4,282,233	June 19, 2002
4,659,716	April 21, 2004
4,863,931	September 15, 2008

NDA Approval Date: April 12,1993

2. NDA #20-641 CLARITIN (LORATADINE) Syrup

U. S. Patent Nos	Expiration Date:
4,282,233	June 19, 2002
4,659,716	April 21, 2004
4,863,931	September 15, 2008

NDA Approval Date: October 10,1996

3. NDA #20-704 CLARITIN (LORATADINE) REDITABS

U. S. Patent Nos	Expiration Date:
4,282,233	June 19, 2002
4,371,516	February 1, 2000
4,659,716	April 21, 2004
4,863,931	September 15, 2008

NDA Approval Date: December 23, 1996

4. NDA #19-670 CLARITIN-D (LORATADINE&PSEUDOEPHEDRINE SULFATE) EXTENDED RELEASE TABLETS

U. S. Patent Nos	Expiration Date:
4,282,233	June 19, 2002
4,659,716	April 21, 2004
4,863,931	September 15, 2008

NDA Approval Date: November 14, 1994

5. NDA #20-470 CLARITIN-D 24 HOUR (LORATADINE&PSEUDOEPHEDRINE SULFATE) EXTENDED RELEASE TABLETS

U. S. Patent Nos	Expiration Date:
4,282,233	June 19, 2002
4,659,716	April 21, 2004
4,863,931	September 15, 2008
5,314,697	October 23, 2012

NDA Approval Date: August 23, 1996

Debarment Certification

Schering Corporation hereby certifies that it did not and will not use in any capacity the services of any person debarred under section 306 of the Federal Food, Drug, and Cosmetic Act in connection with this application.

Trout

Division of Pulmonary and Allergy Drug Products

PROJECT MANAGER ADMINISTRATIVE REVIEW

DEC 16 1999

Application Number: 20-641/S-007
Name of Drug: Claritin Syrup
Sponsor: Schering

Material Reviewed

Submission Date(s): November 24, 1999
Receipt Date(s): November 26, 1999

Review

User Fee Information:

A user fee is not required for this supplement because it is a pediatric supplement.

NDA Summary Volume:

1. FDA form 356h - This form was completed, signed, and dated.

2. FDA form 3397 (User Fee Cover Sheet) - The form was not originally submitted, but was sent via facsimile by the sponsor upon request and was placed in the archival volume.

3. Volume 20.1 contains an index to the NDA that identifies the starting volume for each section. The index does not include any page numbers. Each discipline received a copy of the 20.1 volume.

4. Financial disclosure: The sponsor included a signed form 3454 wherein the sponsor investigator indicated that they have not entered into any financial arrangements with the listed clinical investigator (Dr. Jerry Herron).

Review Discipline Volumes:

1. The pre-clinical section is only one volume and contains no data (pre-clinical is referenced in its entirety to NDA 20-641). Chemistry is also only one volume, containing only the claim for categorical exclusion from environmental assessment. The beginning volumes for clinical and biopharm contain indices indicating what is located in the remaining volumes for that section (no page numbers). The first volume of the statistical section (20.10) was missing. It has been requested from the sponsor.

General Information:

1. Patent information

   The sponsor included patent information for all of its loratadine formulations.

2. Exclusivity

   The studies supporting this application were requested by the Agency in a written request. However, this application does not contain all the studies from the written request, and therefore a determination of pediatric exclusivity will not be made until the remaining study reports are submitted. In the cover letter the sponsor indicates that they are not requesting a pediatric exclusivity determination at this time (due to the reasons listed above), however, in section 13 (patent information) the sponsor claims that all of its loratadine products are eligible to have an additional six months added to their patent.

3. Debarment certification

   The sponsor certifies that they did not and will not use in any capacity the services of any person debarred under section 306 of the Federal Food, Drug and Cosmetic Act in connection with this application.

Conclusion(s):

1. The application is fileable from an administrative perspective.

/S/

Gretchen Trout
Project Manager

Accepted by: Barnes /S/ 12/16/99

cc:
Orig. NDA 20-641
Div. File
HFD-570/GTrout

PROJECT MANAGER LABELING REVIEW

NDA: 20-641

DATE: 11/22/00

DRUG: Claritin Syrup

APPLICANT: Schering Plough

PROJECT MANAGER: Gretchen Trout

REVIEWING PROJECT MANAGER: Vicky Borders

SUBMISSION: SE5/AL 007 dated October 3, 2000

BACKGROUND: Schering submitted draft labeling October 3, 2000 received October 4, 2000 in response to the September 26, 2000, approvable letter. Changes were made as requested with the following exceptions.

1. In the first paragraph of the Pediatric section, the number of pediatric volunteers for subjects ages 8-12 years is not indicated as 13 in the current draft labeling but was included in the previous draft labeling.

2. In the second paragraph of the Pediatric section, the current draft labeling refers to 5 ml of Claritin Syrup containing 5 mg loratadine as the product used in the single dose pharmacokinetic study as opposed to the Agency's approvable letter dated September 26, 2000 that refers to 5 ml of Claritin Syrup containing 10 mg of loratadine.

3. In the Claritin Syrup subsection of the Adverse Reactions section, age groups are not expressed consistently (i.e. 2-5 years old versus 2 to 5 years old).

4. In the Dosage and Administration section, Claritin Reditabs subsection, impressed with the letter "C" on one side has been added.

CONCLUSIONS:

1. Dr. Young Moon Choi was consulted regarding the number of pediatric volunteers and he agreed that the number "13" should be added for the age group 8 to 12 years old, and suggested that Schering remove the number "13" for the age group 2 to 5 years old (second paragraph).

2. Dr. Young Moon Choi was consulted to confirm the strength of Claritin Syrup used in the single dose pharmacokinetic pediatric study and he agreed to Schering Plough's draft labeling submitted on October 3, 2000.

3. It was noted that the expression of the age group was inconsistent throughout the labeling. Expression of the age groups should be changed where appropriate to read "age to age years old" instead of "age-age years old".

4. Dr. Craig Bertha was consulted to confirm that the addition of "impressed with the letter "C" on one side" is acceptable and he agreed.

/S/

B.V.Borders-Hemphill
Project Manager

/S/ 2/12/2010

INDUSTRY TELECONFERENCE MINUTES

DATE: December 1, 2000
: 20-641/SE5-007
DUCT: Claritin Syrup
SPONSOR: Schering

FDA PARTICIPANTS:

Vicky Borders, Pharm.D., Project Manager

SPONSOR PARTICIPANTS:

Bernadette Knott, Regulatory Affairs

BACKGROUND: Reference is made to the October 3, 2000, submission of draft labeling.

SUMMARY:
Dr. Borders conveyed the following labeling changes to Ms. Knott and she agreed to make these changes to the labeling:

1. In the first paragraph of the Pediatric section, the number 13 is to be added as the number of pediatric volunteers for subjects ages 8 to 12 years old, and the number 13 is to be removed as the number of pediatric olunteers for subjects ages 2 to 5 years old.

2. The expression of the age groups is to be consistent throughout the labeling (e.g. 2 to 5 years old instead of 2-5 years old).

/S/

Vicky Borders, Pharm.D.
Project Manager

Memorandum of Telephone Facsimile Correspondence

Date: September 21, 2000

To: Mary Jane Boyle
908-740-2982

From: Sandy Barnes
Project Manager

Subject: NDA 20-641/S-007

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Thank you.

As discussed, submit draft labeling with the revisions shown in this fax by 2:00, Friday, September 22, 2000.

/S/

Sandy Barnes

4 pages redacted from this section of the approval package consisted of draft labeling