CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-662 /S-030, S-031

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-662/S-030, S-031

Abbott Laboratories
Attention: MaryClare DeLuca
Regulatory Consultant
D-491/AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. DeLuca:

We acknowledge receipt of your August 2, 2002, submission containing final printed labeling in response to our June 6, 2002, letter approving your supplemental new drug applications for Biaxin® Filmtab® (clarithromycin tablets, USP).

We have reviewed the labeling that you submitted in accordance with our June 6, 2002, letter and we find it acceptable.

We also remind you to implement the following editorial change at the next printing, as it was requested in the approval letter dated June 6, 2002.

> In the **OVERDOSAGE** section, replace the phrase that reads " [redacted]
> with the phrase that reads "Serum digoxin concentrations"

If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-2207.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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/s/

Janice Soreth
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Division of Anti-Infective Drug Products

PROJECT MANAGEMENT REVIEW
OF FINAL PRINTED LABELING

Application Number: NDA 50-662
Name of Drug: Biaxin ® Filmtab® (clarithromycin tablets, USP)
Sponsor: Abbott Laboratories

Material Reviewed:

Submission Date: August 2, 2002 (NDA 50-662/S-030 FA and S-031 FA)

Receipt Date: August 5, 2002

Background and Summary

NDA 50-662/S-030, submitted August 31, 2000, provides for revisions to the ADVERSE REACTIONS-*Post-Marketing Experience*, and PRECAUTIONS-*Drug Interactions* sections of the PI.

NDA 50-662/S-031, submitted October 20, 2002, provides for revisions to the PRECAUTIONS-*Information for Patients* and *Drug Interactions* sections of the PI.

Sponsor submitted proposed draft labeling combining both supplements on May 20, 2002. This labeling was considered acceptable as indicated in the approval letter for the supplements.

Both supplements were approved on June 6, 2002.

Review

For the purposes of this review, the current submission was compared electronically with proposed draft labeling dated May 20, 2002.

Underlined text indicated addition. ~~Strikeout~~ text indicates deletion.

The following changes were observed:

~~[redacted]~~ replaced with "03-5208-R24 Rev. June, 2002".

DESCRIPTION:
4th paragraph, the parenthetical phrase "(clarithromycin tablets, USP)" is added.
7th paragraph, the parenthetical phrase "(clarithormycin extended-release tablets)" is added.
8th paragraph, the parenthetical phrase "(clarithromycin for oral suspension USP) is added.

CLINICAL PHARMACOLOGY: No changes observed.

INDICATIONS AND USAGE:
1st paragraph, parenthetical phrase "(clarithromycin tablets, USP)" is added after the words "BIAXIN Filmtab" and parenthetical phrase "(clarithromycin for oral suspension, USP)" is added after "BIAXIN Granules".

Heading that reads "**Children (BIAXIN Filmtabs and Granules for oral suspension)**" is changed to "**Children (BIAXIN Filmtab tablets and Granules for Oral Suspension)**".

Adults (BIAXIN Filmtab tablets) section, 1st paragraph, [redacted] is replaced with "BIAXIN", and parenthetical phrase that reads "(clarithromycin extended-release tablets)" is added.

CONTRAINDICATIONS: No changes observed.

WARNINGS: No changes observed.

PRECAUTIONS:
Information to Patients section, 1st paragraph, "BIAXIN" is capitalized.

Drug Interactions section:
11th paragraph, 3rd sentence, the phrase " [redacted] " is replaced with the phrase "Serum digoxin concentrations".
Antiarrhythmics section, 3rd sentence, the words " [redacted] "is replaced with the words "Serum concentrations".
Triazolobenziodidiazepines...section, the word ' [redacted] is replaced with word "Erythromycin"
21st paragraph, the word ' [redacted] ' is replaced with the word "clarithromycin".

Changes to the *Drug Interactions* section are acceptable, for they were requested in the approval letter.

ADVERSE REACTIONS:
2nd paragraph, 1st sentence, the parenthetical phrase "(clarithromycin tablets, USP)" is added.
3rd paragraph, 1st sentence, the parenthetical phrase " (Clarithromycin extended-release tablets)" is added.

OVERDOSGE: No changes observed.

Based on approval letter, the phrase that reads "~~Serum digoxin levels~~" should be replaced with the phrase that reads "Serum digoxin concentrations".

DOSAGE AND ADMINISTRATION:
1st paragraph, 1st sentence, the symbol "USP" is added in the two parenthetical phrases to read "BIAXIN Filmtab (clarithromycin tablets, USP) and BIAXIN Granules (clarithromycin for oral suspension, USP).

HOW SUPPLIED:
6th paragraph, added the phrase that reads "ABBO_PAC unit dose strip packages of 100 (NDC 0074-3165-11)".

CLINCAL STUDIES:
Duodenal Ulcer Associated with *H. Pylori* Infection subsection, 2nd paragraph, the word "(clarithromycin)" is added after the word "BIAXIN".

ANIMAL PHARMACOLOGY AND TOXICOLOGY: No changes observed.

Revised: ~~s~~ replaced with

Revised: June 2002
03-5208-R24

Conclusions

These changes are acceptable. Acknowledge and Retain letter should be sent to the sponsor indicating also to implement the change requested for the **OVERDOSAGE** section, as indicated in the approval letter.

Judit Milstein, Regulatory Health Project Manager, August 22, 2002.

Beth Duvall Miller for Frances V. LeSane, Chief Project Management Staff concurrence 8-27-02

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/s/

Judit Milstein
9/3/02 01:39:32 PM
CSO

Beth Duvall-Miller
9/3/02 01:49:26 PM
CSO
BDM acting for FVL

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