CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: NDA 50-662/S-013

Trade Name: BIAXIN

Generic Name:(clarithromycin tablets)

Sponsor: Abbott Laboratories

Approval Date: December 20, 1996

Indication: Provides for several proposed changes to the CONTRAINDICATIONS, Drug Interations, and ADVERSE REACTIONS (Post-marketing Experience) sections of the package insert. These revisions include updated information from the post-marketing experience with Biaxin.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: NDA 50-662/S-013

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter				
Approvable Letter				
Final Printed Labeling		X		
Medical Review(s)	X			
Chemistry Review(s)				
EA/FONSI				
Pharmacology Review(s)				
Statistical Review(s)				
Microbiology Review(s)				
Clinical Pharmacology Biopharmaceutics Review(s)				
Bioequivalence Review(s)				
Administrative Document(s)	X			
Correspondence	X			

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 50-662/S-013

APPROVAL LETTER

5e 1A

NDA 50-662/S-013

DEC 20 1996

Abbott Laboratories
Attention: Ms. Jeanne M. Fox
Director PPD Regulatory Affairs
One Abbott Park Road
Abbott Park, Illinois 60064-3500

Dear Ms. Fox:

Please refer to your May 23, 1996 supplemental new drug application submitted under section 507 of the Federal Food, Drug, and Cosmetic Act for BIAXIN (clarithromycin tablets).

The supplemental application provides for several proposed changes to the **CONTRAINDICATIONS**, *Drug Interactions*, and **ADVERSE REACTIONS** (*Post-marketing Experience*) sections of the package insert. These revisions include updated information from the post-marketing experience with Biaxin.

We have completed the review of this supplemental application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling submitted on May 23, 1996. Accordingly, the supplemental application is approved effective on the date of this letter.

At the next printing, the following revisions must be made:

The final printed labeling (FPL) must be identical to the draft labeling submitted on May 23, 1996.

Please submit sixteen copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved supplemental NDA 50-662/S-013. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call: Mr. Jose R. Cintron, R.Ph., M.A., Project Manager at (301) 827-2125.

Sincerely yours,

12-20-96

David W. Feigal, Jr., M.D., M.P.H.
Acting Division Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

cc:
Original NDA 50-662
HFD-520/Div. files
HFD-520/PM/JCintron
HFD-520/LGirardi 11/25/96
HFD-104/TNearing
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-80 (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613 (with labeling)
HFD-735/(with labeling) - for all NDAs and supplements for adverse reaction changes.

Concurrence Only:
HFD-520/CPMS/JBona 11/22/96
HFD-520/TL/MAlbuerne 11/26/96
HFD-520/Act.Div.Dir/DFeigal

drafted: /October 17, 1996/
r/d Initials:
final:

APPROVAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 50-662/S-013

MEDICAL REVIEW(S)

SEP 11 1996

MEDICAL REVIEW OF SUPPLEMENT

NDA: 50-662/S-013

DATE OF SUBMISSION: May 23,1996

DATE REVIEW STARTED: June 6, 1996

DATE REVIEW COMPLETED: June 25, 1996

APPLICANT: ABBOTT LABORATORIES

DRUG NAME: BIAXIN

GENERIC NAME: clarithromycin

DOSAGE FORM AND ROUTE OF ADMINISTRATION: Tablets and suspension for oral administration

CATEGORY: macrolide

Materials submitted: Draft labeling and post-marketing adverse experiences

PURPOSE OF SUPPLEMENT

The purpose of this supplement is to provide several proposed changes to the **CONTRAINDICATIONS**, *Drug Interactions, and* **ADVERSE REACTIONS**, *Post-marketing Experience sections of the package insert.* These revisions include updated information from the post-marketing experience with Biaxin.

One of the changes,
section, was specifically requested by Dr. Nasim Moledina, Medical Officer.

DISCUSSION

The proposed revisions are as follows:

Redacted 3

pages of trade

secret and/or

confidential

commercial

information

RECOMMENDATIONS:

It is recommended that this supplemental application be approved. The sponsor should be notified to submit final printed labeling with the proposed changes. In addition, the following sentence should be added at the end of the proposed paragraph under **CONTRAINDICATIONS:**

Mercedes S. Albuerne, M.D.
Team Leader

cc: Orig. NDA
HFD HFD-638
HFD-520/TL/Albuerne
HFD-520/MO/Girardi
HFD-520/MO/Moledina
HFD-520/CSO/LeSane
msa/6/25/96.

7/15/96

Concurrence Only:
Acting Div. Director/Feigal

9-11-96

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:NDA 50-662/S-013

ADMINISTRATIVE DOCUMENTS

NOV 7 1997

NDA 50-662/S-013

Abbott Laboratories
Attention: Mr. Gregg Bosco
Director PPD Regulatory Affairs
100 Abbott Park Road
Abbott Park, Illinois 60064-3500

Dear Mr. Bosco:

We acknowledge the receipt of your February 24, 1997 submission containing final printed labeling in response to our letter dated December 20, 1996, for NDA 50-662/S-013, approving your new drug application for BIAXIN® (clarithromycin tablets).

We have reviewed the labeling that you have submitted in accordance with our letter dated December 20, 1996, for NDA 50-662/S-013, and we find it acceptable.

Sincerely yours,

Gary K. Chikami, M.D.
Acting Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

cc:
Original NDA 50-662
HFD-520/Div. Files
HF-2/Medwatch (with labeling)
HFD-104/FLESANE (with labeling)
HFD-520/PMS/JCintron
HFD-520/MO/LGirardi 10/7/97
HFD-40/DDMAC (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling)

Concurrence Only:
HFD-520/CPMS/JBona 10/6/97
HFD-520/TLMO/MAlbuerne msw 10/30/97
HFD-520/Act.Dir./GChikami
11/5/97

Drafted by: jrc/October 3, 1997/
Initialed by:
final:

ACKNOWLEDGE AND RETAIN (AR)

OCT 30 1997

PROJECT MANAGER'S REVIEW OF LABELING

SPONSOR: Abbott Laboratories
One Abbott Park Road
Abbott Park, Illinois 60064-3500

DATE OF SUBMISSION: February 24, 1997

NAME OF DRUG: Biaxin® (clarithromycin)

DOSAGE FORM: Tablets

DESCRIPTION OF SUBMISSION: The supplemental application provides for several proposed changes to the **CONTRAINDICATIONS**, *Drug Interactions*, and **ADVERSE REACTIONS** (*Post-marketing Experience*) sections of the package insert. These revisions include updated information from the post-marketing experience with Biaxin.

COMMENTS: The final printed labeling (FPL) submitted on February 24, 1997, (Nos 2586, 3163, 3368) 03-4686-R11-Rev. January, 1997 is acceptable.

RECOMMENDATION: An acknowledge and retain letter should be issued informing the applicant that the FPL is acceptable.

Jose R. Cintron, R.Ph., M.A.
Project Manager

Luigi Girardi, M.D.
Medical Officer

cc:
Original NDA 50-662
HFD-520/Div/File
HFD-520/MO/LGirardi 10/7/97
HFD-520/PM/JCintron
Revided

Concurrence Only:
HFD-520/CPMS/JBona 10/24/97 10/30/97
HFD-520/TLMO/MAlbuerne
HFD-520/Act Dir/GChikami 11/5/97

FINAL PRINTED LABELING REVIEW

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date MAY 31 1996

NDA No. 50-662

Jeanne M. Fox
Abbott Laboratories
One Abbott Park Road
Abbott Park, Illinois 60064-3500

Attention: Jeanne M. Fox

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Biaxin (clarithromycin tablets)

NDA Number: 50-662

Supplement Number: S-013

Date of Supplement: May 23, 1996

Date of Receipt: May 24, 1996

Unless we find the application not acceptable for filing, the filing date will be 60 days from the receipt date above.

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Attention: Document Control, Room 12B-30
5600 Fishers Lane
Rockville, MD 20857

Sincerely yours,

Supervisory Consumer Safety Officer
Division of Anti-Infective Drug Products
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 50-662/S-013

CORRESPONDENCE

ABBOTT

ORIGINAL

Pharmaceutical Products Division

Abbott Laboratories
100 Abbott Park Road
Abbott Park, Illinois 60064-3500

FA
SLR-013

February 24, 1997

Division of Anti-Infective Drug Products, HFD-520
1st Floor Document Control Room
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, Maryland 20850

Re: BIAXIN® (clarithromycin tablets)
NDA 50-662
Supplement 013

FINAL PRINTED LABELING

Dear Sir or Madam:

Please refer to your correspondence to us dated December 20, 1996 stating that supplemental New Drug Application (S-013) is approved.

This submission contains 16 copies of final printed labeling as requested in the approval letter.

Should you have any additional questions regarding this information, please do not hesitate to call me at the number listed below. Thank you for your consideration in this matter.

Sincerely,

Greg Bosco

Greg Bosco
Product Manager
PPD Regulatory Affairs
(847) 937-6970

REVIEWS COMPLETED
CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO
CSO INITIALS DATE

FEB 25 1997
EVALUATION AND RESEARCH

ABBOTT

ORIGINAL

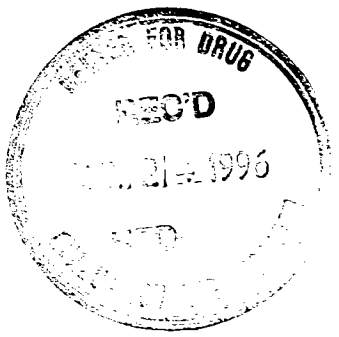
Pharmaceutical Products Division

Abbott Laboratories
One Abbott Park Road
Abbott Park, Illinois 60064-3500

NDA NO. 50662 REF. NO. S-013

NDA SUPPL FOR Draft

May 23, 1996



Division of Anti-Infective Drug Products, HFD-520
1st Floor Document Control Room
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, Maryland 20850

Re: BIAXIN (clarithromycin tablets)
NDA 50-662
Supplement 013

LABELING SUPPLEMENT
EXPEDITED REVIEW REQUESTED

Dear Sir or Madam:

The sponsor, Abbott Laboratories, Submits this supplement to a New Drug Application under the provisions of Section 505(i) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.70(b)(3).

The purpose of this supplement is to provide several proposed changes to the product labeling. Revisions to the Contraindications, Drug Interactions, and Adverse Reactions (Post-Marketing Experience) sections of the package insert are proposed to include updated information from the post-marketing experience with Biaxin. The proposed revisions are shown by highlighted text in the package insert (Attachment I). The supporting documentation from the post-marketing experience is provided as Attachement II.

Please note that one of these changes
was specifically requested by Dr. Nasim Moledina, Medical Officer for the Division. We are requesting an expedited review of this supplement to facilitate addition of this updated safety information to the labeling in a rapid manner.

Should you have any questions concerning this submission, or need any additional information, please contact me at the number provided below.

Sincerely,

Jeanne M. Fox

Jeanne M. Fox
Director
PPD Regulatory Affairs
(847) 937-5533

Desk Copy: Dr. Nasim Moledina, HFD-520