CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-775

CORRESPONDENCE

ABBOTT

Pharmaceutical Products Division

Abbott Laboratories
100 Abbott Park Road
D-491, AP6B-1SW
Abbott Park, Illinois 60064-6105

March 2, 2000

Division of Anti-Infective Drug Products, HFD-520
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
1st Floor Document Control Room
Rockville, Maryland 20850-3202

Re: **BIAXIN® XL Filmtab®**
(clarithromycin extended release tablets)
NDA 50-775

REQUEST FOR INFORMATION

Dear Sir or Madam:

The sponsor, Abbott Laboratories, is submitting the following information as requested in a teleconference call with Dr. Shrikant Pagay, Dr. David Katague and Mr. Jose Cintron on 3/2/00.

I. A summary of issues agreed to by Abbott and the Division regarding the composition of the dosage form and post-approval stability testing for manufacturing impurities.

II. Revised pages from Section 4.4.2 Composition of Dosage Form.

If you have any questions regarding this submission, please feel free to contact me at the number listed below. Thank you for your consideration in this matter.

Sincerely,

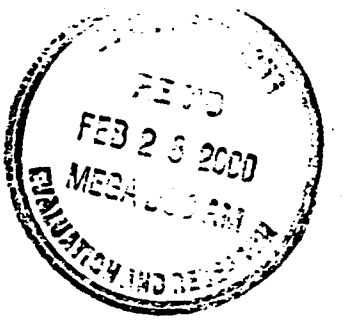
Greg Bosco
Sr. Product Manager
PPD Regulatory Affairs
(847) 937-6970

ABBOTT

Pharmaceutical Products Division

Abbott Laboratories
100 Abbott Park Road
D-491, AP6B-1SW
Abbott Park, Illinois 60064-6108

NC



February 25, 2000

Division of Anti-Infective Drug Products, HFD-520
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
1st Floor Document Control Room
Rockville, Maryland 20850-3202

Re: BIAXIN® XL Filmtab®
(clarithromycin extended release tablets)
NDA 50-775

GENERAL CORRESPONDENCE

Dear Sir or Madam:

Please refer to the unofficial correspondence to Abbott received by fax on 2/11/00, regarding draft comments relating to the chemistry review of this application from Dr. Shirkant Pagay of the Division of Anti-Infective Drug Products. In response to this correspondence, this submission contains the following:

1. Responses to each comment. Dr. Pagay's comments are printed in bold type, followed by our response printed in normal type. This information is also being provided on diskette. Only one FDA copy will include the diskette. Please note, the file was saved in Word Perfect 6.1.

If you have any questions regarding this submission, please feel free to contact me at the number listed below. Thank you for your consideration in this matter.

Sincerely,

Greg Bosco

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

DUPLICATE

ABBOTT

Pharmaceutical Products Division

Abbott Laboratories
100 Abbott Park Road
D-491, AP6B-1SW
Abbott Park, Illinois 60064-6108

February 24, 2000

Division of Anti-Infective Drug Products, HFD-520
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
1st Floor Document Control Room
Rockville, Maryland 20850-3202

Re: BIAXIN® XL Filmtab®
(clarithromycin extended release tablets)
NDA 50-775

REQUEST FOR INFORMATION

Dear Sir or Madam:

In response to a request from Jose Cintron and Dr. Mercedes Albuerne of the Division of Anti-Infective Drug Products on February 23, 2000, this submission contains the following:

1. The requested case report forms (CRF's) from NDA 50-775 (M97-667). The specific CRF's are provided for the following patients: 6213, 6214, 6215, 6217, 6219, 6220, 6309, 6310, 6311 and 6312.

If you have any questions regarding this submission, please feel free to contact me at the number listed below. Thank you for your consideration in this matter.

Sincerely,

Greg Bosco

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

ABBOTT

NEW CORRESP
NC

Pharmaceutical Products Division

Abbott Laboratories
100 Abbott Park Road
D-491, AP6B-1SW
Abbott Park, Illinois 60064-6108

December 7, 1999

Division of Anti-Infective Drug Products, HFD-520
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
1st Floor Document Control Room
Rockville, Maryland 20850-3202

Re: BIAXIN® XL Filmtab®
(clarithromycin extended release tablets)
NDA 50-775

REQUEST FOR INFORMATION

Dear Sir or Madam:

- In response to a request from Jose Cintron of the Division of Anti-Infective Drug Products on November 19, 1999, this submission contains the following:

  I. The package insert from NDA 50-775, provided on diskette. Only one FDA copy will include the diskette. Please note, this file was created and saved in Word Perfect 6.1.

If you have any questions regarding this submission, please feel free to contact me at the number listed below. Thank you for your consideration in this matter.

Sincerely,

Greg Bosco

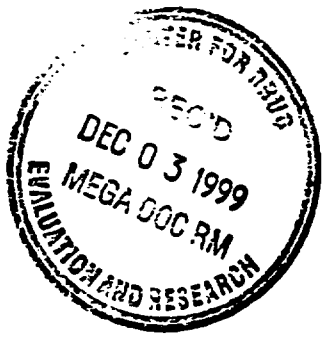
Greg Bosco
Sr. Product Manager
PPD Regulatory Affairs
(847) 937-6970

ABBOTT

Pharmaceutical Products Division

Abbott Laboratories
100 Abbott Park Road
D-491, AP6B-1SW
Abbott Park, Illinois 60064-6108

BC



December 2, 1999

Division of Anti-Infective Drug Products, HFD-520
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
1st Floor Document Control Room
Rockville, Maryland 20850-3202

Re: **BIAXIN® XL Filmtab®**
(clarithromycin extended release tablets)
NDA 50-775

AMENDMENT

Dear Sir or Madam:

In response to a request from Dr. Shirkant Pagay of the Division of Anti-Infective Drug Products on November 5, 1999, this submission contains the following:

I. A revised page from Section 3.4 NDA Summary - Chemistry, Manufacturing & Controls (Vol. 1, page 146 from the original NDA submitted 4/30/99). This page clarifies the name of the Abbott facility in Puerto Rico which can perform the last step [redacted] of the drug substance process. The original submission incorrectly named this facility as Abbott Chemical International (ACI) instead of the correct name which is Abbott Fermentation Products de Puerto Rico (AFP).

II. Revised pages from Section 4.3 Drug Substance (Vol. 2, pages 031 - 034 from the original NDA submitted 4/30/99). These pages were revised to add the full address and Central File Number for each of the three drug substance manufacturing facilities.

III. Updated primary stability tables which reside in Section 4.4.7.4 Tabular Stability Data (Vol. 7, pages 025 - 191 from the original NDA submitted 4/30/99).

ORIGINAL

If you have any questions regarding this submission, please feel free to contact me at the number listed below. Thank you for your consideration in this matter.

Sincerely,

Greg Bosco

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

ABBOTT

Pharmaceutical Products Division

Abbott Laboratories
100 Abbott Park Road
D-491, AP6B-1SW
Abbott Park, Illinois 60064-6108

ORIG AMENDMENT
BM

September 7, 1999

Division of Anti-Infective Drug Products, HFD-520
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
1st Floor Document Control Room
Rockville, Maryland 20850-3202

Re: BIAXIN® (clarithromycin tablets)
NDA 50-775

REQUEST FOR INFORMATION

Dear Sir or Madam:

In response to a telephone conversation between Jose Cintron and Dr. Joel Jiang of the Division and myself on August 26, 1999, this submission contains the following:

I. The requested SAS datasets for the two pivotal clinical studies, M97-667 and M97-756, provided on one compact disc. Only one FDA copy will include the disc. The information on the disc includes the following: transportable SAS data files which include efficacy and safety data for M97-667 and M97-756, variable description files and PROC CONTENTS outputs which describe variables included in the data files and the READ ME file which explains the structure of the compact disc.

If you have any questions regarding this submission, please feel free to contact me at the number listed below. Thank you for your consideration in this matter.

Sincerely,

Greg Bosco

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

ORIGINAL

ABBOTT

Pharmaceutical Products Division

Abbott Laboratories
100 Abbott Park Road
D-491, AP6B-1SW
Abbott Park, Illinois 60064-6108

August 4, 1999

Division of Anti-Infective Drug Products, HFD-520
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
1st Floor Document Control Room
Rockville, Maryland 20850-3202

Re: BIAXIN® (clarithromycin tablets)
NDA 50-775

REQUEST FOR WAIVER
OF PEDIATRIC STUDY REQUIREMENT

Dear Sir or Madam:

Please refer to your correspondence to us dated June 14, 1999 which stated March 3, 2000 as the user fee goal date for this application. Also included in this correspondence was a request for the assessment of the safety and effectiveness of this drug product in pediatric patients.

In accordance with the provisions of 21 CFR 314.55(c) we are requesting a full waiver of the pediatric study requirement. The justification for this request is attached.

Should you have any 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
Sr. Product Manager
PPD Regulatory Affairs
(847) 937-6970

cc: Mr. Jose Cintron, HFD-520

ABBOTT

Pharmaceutical Products Division

Abbott Laboratories
100 Abbott Park Road
D-491, AP6B-1SW
Abbott Park, Illinois 60064-3500

April 30, 1999

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
12229 Wilkins Ave.
Rockville, Maryland 20852

Re: **BIAXIN® XL Filmtab®**
(clarithromycin extended release tablets)
NDA 50-775
Original Submission

Dear Sir or Madam:

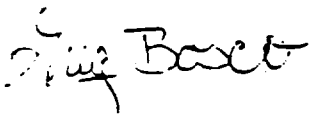
The sponsor, Abbott Laboratories, submits the following information under the provisions of Section 505(b) of the Federal Food, Drug and Cosmetic Act and 21 CFR 314.50. This information consists of an NDA containing an Application Summary and all applicable technical sections (Chemistry, Manufacturing and Controls, Human Pharmacokinetics and Bioavailability, Microbiology, Clinical and Statistical). For information relating to the technical section for Non-Clinical Pharmacology and Toxicology please refer to the original NDA for clarithromycin (NDA 50-662, approved 10/31/91). The NDA number which has been preassigned for clarithromycin extended release tablets is NDA 50-775.

Clarithromycin is an antibiotic drug which has approved NDA's for an immediate release tablet (NDA 50-662), granules for suspension (NDA 50-698), indications for the treatment and prophylaxis of mycobacterium avium complex (NDA 50-697 & NDA 50-721, respectively) and a number of IND's residing in the Division of Anti-Infective Drug Products. Development of this NDA has also been discussed with the appropriate persons in that Division.

This submission consists of 97 volumes, numbered 1 through 97. Two copies of each volume, Archival and Technical, are included. Two additional copies of Volume 8 containing the Methods Validation information are being submitted (in Red jackets) as requested in 21 CFR 314.50(e)(2)(i). A copy of Volume 1 which contains the Cover Letter, Forms (356h, User Fee, Debarment Certification, Field Copy Certification and Financial Disclosure), Comprehensive Index and NDA Summary has been included for each of the Technical Sections.

Should you have any 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
Product Manager
PPD Regulatory Affairs
(847) 937-6970

cc: Desk Copy, Volume 1 - Jose Cintron, HFD-520