

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**50-775/S001**

**CORRESPONDENCE**



**ABBOTT**

**Pharmaceutical Products Division**

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

September 28, 2000

Mellon Bank  
Three Mellon Bank Center  
27th Floor ( [redacted] )  
Pittsburgh, PA 15259-0001

**Subject: USER FEE I.D. NUMBER 4027**

Dear Sir or Madam:

Enclosed is a check in the amount of [redacted] to cover the user fee payment for the following application:

Product Name:	Biaxin® XL Filmtab®
Generic Name:	Clarithromycin Extended-Release Tablets
Indication for Use:	Community-Acquired Pneumonia
Type of Submission:	Efficacy Supplement
NDA Number:	NO50775
Name of Sponsor:	Abbott Laboratories
Address:	D-491, Building AP6B-1SW PPD Regulatory Affairs 100 Abbott Park Road Abbott Park, Illinois 60064-6108
Contact Person:	Peter Noblin
Telephone Number:	(847) 937-5091

We would appreciate receiving a receipt for this payment: for your convenience, I have enclosed a self-addressed, stamped envelope.

Sincerely,

Peter Noblin  
Associate Director, Regulatory Affairs

Enclosures: Abbott Check Number [redacted] User Fee Cover Sheet,  
Self-Addressed, Stamped Envelope

cc: Peter Noblin, D-491, AP6B-1  
Greg Bosco, D-491, AP6B-1  
Paula Bourland, D-404, AP9A-1  
Sandra Harder, D-387, AP6C-1  
Kathy Christianson, D-344, AP6D-1



**ABBOTT**

**Pharmaceutical Products Division**

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

June 20, 2001

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



SE1-001/c  
SUPPL NEW CORRE:

**Re: BIAXIN® XL Filmtab®  
(clarithromycin extended release tablets)  
NDA 50-775, S-001**

**REQUEST FOR INFORMATION**

Dear Sir or Madam:

The sponsor, Abbott Laboratories, is submitting the following information as requested in a teleconference call with Dr. Nasim Moledina and Mr. Jose Cintron on 6/12/01.

- I. Draft labeling incorporating changes to the Microbiology, Indications and Usage, and Dosage and Administration sections. The changes consist of the removal of the microorganism *Legionella pneumophila* as requested. This file was created and saved in a MS Word file. Only the FDA archival copy will include the diskette.

Please note, this file includes information from a supplement that has been approved since the original submission of S-001 (i.e., NDA 50-662, S-029). Other pending submissions (i.e., NDA 50-662, S-030 and S-031) are not reflected in this labeling.

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

**DUPLICATE**



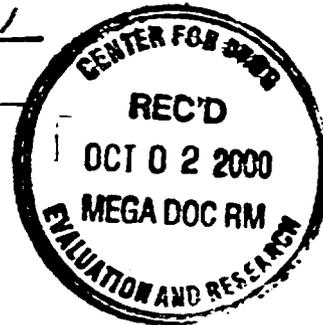
ABBOTT

Pharmaceutical Products Division

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

NDA NO. SEI REF. NO. 001

NDA SUPPL FOR 50-775



September 29, 2000

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® XL Filmtab®**  
(clarithromycin extended release tablets)  
NDA 50-775 (S-001)

**EFFICACY SUPPLEMENT**

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 add: "Pneumonia due to *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Moraxella catarrhalis*, *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Chlamydia pneumoniae* (TWAR), *Legionella pneumophila*, or *Mycoplasma pneumoniae*" to the Biaxin XL label in the Indications and Usage section under the subcategory entitled "Adults (BIAXIN XL Filmtab tablets)". The microorganism *Legionella pneumophila* is also being moved in the Microbiology section of the package insert from the *in vitro* subsection to the *in vivo* subsection. The information provided in this supplement supports this change in labeling.

To aid in the review of this supplement, please find:

1. FDA Forms (356h, User Fee, Debarment Certification, Financial Disclosure).
2. Request for waiver of pediatric study requirement (21 CFR 314.55(c)(2)).
3. Draft labeling incorporating changes to the Microbiology, Indications and Usage, and Dosage and Administration sections.

ORIGINAL

4. Microbiology, clinical and statistical data sections to support the labeling changes.
5. Per recent requests for electronic versions of the key sections, the following information is being provided. Only the FDA Archival copy will include the electronic media.

Disk #1 (3.5" Diskette)

Draft Label\*

Section 7.0 - Microbiology

Section 8.5 - ISE

Section 8.6 - ISS

Disk #2 (3.5" Diskette)

M99-077 - Protocol

Section 8.4.1.1 - M99-077 Study Report

Disk #3 (3.5" Diskette)

M98-927 - Protocol

Section 8.4.1.2 - M98-927 Study Report

Disk #4 (Compact Disk)

SAS Datasets

- \* Please note, this file was created and saved in Adobe Acrobat. Due to pending supplements that have been submitted to the Division which affect the Biaxin label (NDA 50-662, S-029; [REDACTED]) a MS Word file is not being provided at this time. Prior to approval of this supplement, a MS Word file can be provided.

Should you have any questions regarding this information, or need any additional 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