CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-775

CHEMISTRY REVIEW(S)

DIVISION OF ANTI-INFECTIVE DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 50-775 **CHEM.REVIEW #:** 3 **REVIEW DATE:** 03-Mar-00

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL	30-May-99	04-May-99	05-May-99
Gen. correspondence	19-Mar-99		Info
(Review document for Biopharm on dissolution specification)			
AMENDMENT/BC	02-Dec-99	03-Dec-99	07-Dec-99
(Stability data update and clarification on DS facilities)			
AMENDMENT/BC	04-Feb-00	07-Feb-00	15-Feb-00
(Response to clarification/additional information as per 1/20/00 telecon)			
AMENDMENT/BC	25-Feb-00	28-Feb-00	28-Feb-00
(Response to draft deficiency comments faxed on 2/11/00)			
AMENDMENT/BC	02-Mar-00		03-Mar-00
(Response to 3/2/00 teleconference- faxed response reviewed)			

NAME & ADDRESS OF APPLICANT: Abbott Laboratories
100 Abbott Park Road
Abbott Park IL 6064-3500

DRUG PRODUCT NAME

Proprietary:	Biaxin® XL Filmtab®
Nonproprietary/USAN:	Clarithromycin extended release tablets
Code Names/#'s:	NA
Chemical Type/ Therapeutic Class:	3S

ANDA Suitability Petition/DESI/Patent Status:
N/A [if applicable]

PHARMACOLOGICAL CATEGORY/INDICATION: Anti-infective

DOSAGE FORM: Tablet
STRENGTHS: 500 mg
ROUTE OF ADMINISTRATION: Oral
DISPENSED: X **Rx** _____ **OTC**

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:

6-O-methylerythromycin.
$C_{38}H_{69}NO_{13}$
747.95

SUPPORTING DOCUMENTS

Letters of authorization for the following packaging DMFs provided in the application.

Table 1: Authorization to refer DMF

Packaging Component	Manufacturer Name	DMF#

RELATED DOCUMENTS (if applicable):

The drug substance was approved under NDA 50-662.

CONSULTS:

The following consultations were requested:

Table 2: Consultations

Consultation for:	Request Date	Status
Methods Validation	7/2699	Complete
Trademark Review	8/2/99	Complete
Facility Inspection	8/10/99	Complete

REMARKS/COMMENTS:

Review 3 provides information sent to the applicant as an Attachment 1 with the action letter. Attachment 1 included the acceptance of 24 months shelf life, regulatory specifications and stability commitments for the drug

product. Other pertinent information included in this review are approved manufacturing facilities for the drug product and drug substance and regulatory specifications for the drug substance. For all other information that was considered to be adequate, please see Review 1 and Review 2.

CONCLUSIONS & RECOMMENDATIONS:

The application is approved for manufacturing and controls under 505(b) of the act.

/S/ 3/8/00

Shrikant Pagay,
Review Chemist

cc: Orig. NDA 50-775 (other NDA's may be included if appropriate)
HFD-520/Division File
HFD-520/Pagay/date
HFD-520/Albuerne
HFD/520/Moledina
HFD-520/Ellis
HFD/520/Pelsor
HFD/520/Sun
HFD-520/Sheldon
HFD/520/Dong
HFD-520/Cintron
HFD-520/830 Katague
R/D Init by: SUPERVISOR/Team Leader /S/ 3/3/00

13 page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable.

DIVISION OF ANTI-INFECTIVE DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 50-775 **CHEM.REVIEW #:** 2 **REVIEW DATE:** 28-Feb-00

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL	30-May-99	04-May-99	05-May-99
AMENDMENT/BC (Stability data update and clarification on DS facilities)	02-Dec-99	03-Dec-99	07-Dec-99
AMENDMENT/BC (Response to clarification or additional information as per 1/20/00 telecon)	04-Feb-00	07-Feb-00	15-Feb-00
AMENDMENT/BC (Response to draft deficiency comments faxed on 2/11/00)	25-Feb-00	28-Feb-00	28-Feb-00

NAME & ADDRESS OF APPLICANT: Abbott Laboratories
100 Abbott Park Road
Abbott Park IL 6064-3500

DRUG PRODUCT NAME

Proprietary:	Biaxin® XL Filmtab®
Nonproprietary/USAN:	Clarithromycin extended release tablets
Code Names/#'s:	NA
Chemical Type/ Therapeutic Class:	3S

ANDA Suitability Petition/DESI/Patent Status:
N/A [if applicable]

PHARMACOLOGICAL CATEGORY/INDICATION: Anti-infective

DOSAGE FORM: Tablet
STRENGTHS: 500 mg
ROUTE OF ADMINISTRATION: Oral
DISPENSED: X **Rx** _____ **OTC**

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:

6-O-methylerythromycin.
$C_{38}H_{69}NO_{13}$
747.95

SUPPORTING DOCUMENTS

Letters of authorization for the following packaging DMFs provided in the application.

Table 1: Authorization to refer DMF

Packaging Component	Manufacturer Name	DMF#
[redacted]	[redacted]	[redacted]

RELATED DOCUMENTS (if applicable):

The drug substance was approved under NDA 50-662.

CONSULTS:

The following consultations were requested:

Table 2: Consultations

Consultation for:	Request Date	Status
Methods Validation	7/2699	Complete
Trademark Review	8/2/99	Complete
Facility Inspection	8/10/99	Complete

REMARKS/COMMENTS:

All attachments referenced in this review without the original reference came from the Amendment dated 2/25/00.

CONCLUSIONS & RECOMMENDATIONS:
The application is approvable for manufacturing and controls under 505(b) of the act after the following concurrence from the applicant:

Acceptance of regulatory specifications and stability commitments.

The applicant will revise the drug product composition based on target quantities and adjust only the amount of [redacted] for the potency of the drug substance lot used in manufacturing the drug product.

Applicant will monitor impurity profile of the first three production batches of the drug product and the related drug substance lot/s. The data will be submitted in the Annual report at the end of stability studies.

/S/

Shrikant Pagay,
Review Chemist 2-28-00

cc: Orig. NDA 50-775 (other NDA's may be included if appropriate)
HFD-520/Division File
HFD-520/Pagay/date
HFD-520/Albuerne
HFD/520/Moledina
HFD-520/Ellis
HFD/520/Pelsor
HFD/520/Sun
HFD-520/Sheldon
HFD/520/Dong
HFD-520/Cintron
HFD-520/830 Katague
R/D Init by: SUPERVISOR/Team Leader /S/ 3/1/00

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DIVISION OF ANTI-INFECTIVE DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 50-775 **CHEM.REVIEW #:** ONE **REVIEW DATE:** 08-Feb-00

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL	30-May-99	04-May-99	05-May-99
AMENDMENT/BC	02-Dec-99	03-Dec-99	07-Dec-99

(Stability data update and clarification on DS facilities)

NAME & ADDRESS OF APPLICANT: Abbott Laboratories
100 Abbott Park Road
Abbott Park IL 6064-3500

DRUG PRODUCT NAME

Proprietary:	Biaxin® XL Filmtab®
Nonproprietary/USAN:	Clarithromycin extended release tablets
Code Names/#'s:	NA
Chemical Type/ Therapeutic Class:	**3S**

ANDA Suitability Petition/DESI/Patent Status:
N/A [if applicable]

PHARMACOLOGICAL CATEGORY/INDICATION: Anti-infective

DOSAGE FORM: Tablet
STRENGTHS: 500 mg
ROUTE OF ADMINISTRATION: Oral
DISPENSED: X **Rx** _____ **OTC**

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Table 1: Authorization to refer DMF

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RELATED DOCUMENTS (if applicable):

The drug substance was approved under NDA 50-662.

CONSULTS:

The following consultations were requested:

Table 2: Consultations

Consultation for:	Request Date	Status
Methods Validation	7/2699	Complete
Trademark Review	8/2/99	Complete
Facility Inspection	8/10/99	Complete

REMARKS/COMMENTS:

CONCLUSIONS & RECOMMENDATIONS:
The application is not approvable for manufacturing and controls under 505(b) of the act. The specific items which are not approvable are identified under the following heading: Drug Substance [synthesis and stability]; Drug product [components/composition, manufacturing and packaging, in-process controls, reprocessing, specifications and methods for drug product, container/closure, stability, investigational formulations, environmental assessment and labeling].

/S/ 2/8/00
Shrikant Pagay,
Review Chemist

cc: Orig. NDA 50-775 (other NDA's may be included if appropriate)
HFD-520/Division File
HFD-520/Pagay/date
HFD-520/Albuerne
HFD/520/Moledina
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HFD/520/Pelsor
HFD/520/Sun
HFD-520/Sheldon
HFD/520/Dong
HFD-520/Cintron
HFD-520/830 Katague
R/D Init by: SUPERVISOR/Team Leader /S/ 2/9/00

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