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APPLICATION NUMBER:

50-662 / S-028

MEDICAL REVIEW

Medical Officer's Review of NDA 50-662/S-028

DEC 22 1999

Date of Application: September 29, 1999

Applicant: Abbott Laboratories
Abbot Park, Illinois

Name of Drug:

Proprietary Name: BIAXIN® FILMTAB®

Established Name: Clarithromycin

Dosage Form: Tablet

Strengths: 250 mg and 500 mg

Route of Administration: Oral

Purpose of Application:

The purpose of this supplemental New Drug Application is to provide changes to the product labeling, namely, revisions to the ADVERSE REACTIONS – Post-Marketing experience section to include updated adverse experience information.

Proposed Labeling Revisions

In the ADVERSE REACTIONS, Post-marketing Experience section, the terms “toxic epidermal necrolysis” and “anorexia” will be added to indicate that post-marketing reports have been received.

Summary of Post-Marketing Reports in Support of Proposed Labeling Revisions

The applicant reviewed the spontaneous adverse drug event database for Biaxin by examining COSTART terms for the period of October 31, 1991, (initial product approval) through February 1st, 1999.

The following reports were found:

“Toxic epidermal necrolysis”

There were 17- post-marketing reports of patients who experience toxic epidermal necrolysis. Seventy six percent (76%) of these reports were of international origin, and 82% were reported with the Filmtab preparation.

Eleven patients (65%) recovered or were improved, 3 patients (18%) had a fatal outcome and in 3 patients (18%), the outcome was not reported.

Two of the deaths occurred in patients with AIDS who also had received multiple concomitant medications. Concurrent illnesses included toxoplasmosis, progressive multifocal leukoencephalopathy, Kaposi's sarcoma, and Mycobacterium avium intracellulare.

The third death occurred in an 82-year-old male who had received concomitant ciprofloxacin and doxycycline.

"Anorexia"

There were 149-post-marketing reports of patients who experienced anorexia while being treated with Biaxin. Indications for treatment included general infection (47%), H. pylori infection or duodenal ulcer (9.4%), Mycobacterium avium complex infection (3.4%), miscellaneous other infections (36.2%), and not reported (4%).

Medical Officer's Conclusion:

The post-marketing adverse experience reports support the applicant's proposed labeling revisions.

Recommendations:

It is recommended that NDA 50-662/S-028 be approved.

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Mercedes S. Albuerno, MD
Medical Team Leader

11/22/99

CC: Orig NDA
HFD-520
HFD-520/DepDir/Gavrilovich
HFD-520/MO/Moledina
HFD-520/Pharm/Osterberg
HFD-520/Micro/Sheldon
HFD-520/Chem/Yu
HFD-520/PM/Cintron

Concurrence Only:
HFD-520/DivDir/Chikami
HFD-520/TLMO/Albuerno

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12/22/99