

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-662 / S-028

APPROVAL LETTER

NDA 50-662/S-028

MAR 20 2000

Abbott Laboratories
Attention: Greg Bosco
Product Manager, PPD Regulatory Affairs
100 Abbott Park Road
D-491, AP6B-1SW
Abbott Park, Illinois 60064-3500

Dear Mr. Bosco:

Please refer to your supplemental new drug application dated September 29, 1999, received October 1, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for BIAXIN[®] FILMTAB[®] (clarithromycin tablets). We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This supplemental new drug application provides for proposed changes to the Adverse Reactions- Post-Marketing Experience section of the package insert.

We have completed the review of this supplemental application 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 submitted draft labeling. The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted August 30, 1999). Accordingly, the supplemental application is approved effective on the date of this letter.

In addition, please submit three copies of the introductory promotional materials 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 materials and the package insert directly to:

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

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

NDA 50-662/S-028

Page 2

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, call CDR. Jose Cintron, USPHS, R.Ph., M.A., Project Manager, at (301) 827-2125.

Sincerely,

/s/

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

**APPEARS THIS WAY
ON ORIGINAL**