DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-662/S-030, S-031

Abbott Laboratories
Attention: Greg Bosco
Associate Director, PPD Regulatory Affairs
200 Abbott Park Road
D-491, AP30-1E
Abbott Park, IL 60064-6157

Dear Mr. Bosco:

Please refer to your supplemental new drug applications dated August 31, 2000 (S-030) and October 20, 2000 (S-031), received September 1, 2000, and October 23, 2000, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Biaxin ® Filmtab® (clarithromycin tablets, USP). We note that these applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submission dated May 20, 2002.

These supplements provide for revisions to the ADVERSE REACTIONS-*Post-Marketing Experience, and* PRECAUTIONS-*Drug Interactions* sections; the addition of an OVERDOSAGE section to the package insert (S-030); and revisions to the PRECAUTIONS-*Information to Patients* and *Drug Interactions* sections of the package insert (S-031).

We have completed the review of these supplemental applications, as amended, 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 agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The following editorial changes should be implemented at the next printing.

1. In the **PRECAUTIONS** section, *Drug Interactions* subsection,

   a. Replace the phrase(b)(4) with the phrase " Serum digoxin concentrations"

      1.) In the paragraph beginning with "Elevated Digoxin Serum Concentrations…" and

      2.) In the paragraph beginning with "Antiarrhythmics:…"

   b. Replace the word (b)(4) with the word "Erythromycin" at the beginning of the *Triazolobenziodidiazepines* subsection.

   c. Replace the word (b)(4) with the word "clarithromycin" in the paragraph beginning with "Concomitant adm

2. In the **OVERDOSAGE** section, replace the phrase(b)(4) with the phrase " Serum digoxin concentrations" in the paragraph beginning …"

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted May 20, 2002).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplements NDA 50-662/S-030, and S-031." Approval of these submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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

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 Judit Milstein, Regulatory Project Manager, at (301) 827-2207.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Janice Soreth

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