DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 15 1997

TRANSMITTED VIA FACSIMILE

Barbara Hagins
Regulatory Affairs Specialist, Advertising
Abbott Laboratories
Dept. 491, Bldg. AP6B-1
100 Abbott Park Road
Abbott Park, IL 60064-3500

RE: NDA # 50-698
Biaxin (clarithromycin)
MACMIS ID # 5667

Dear Ms. Hagins:

Reference is made to Abbott Laboratories' (Abbott) March 21, 1997, April 30, 1997, and May 8, 1997, submissions of promotional materials under cover of FDA Form 2253 for Biaxin (clarithromycin). These submissions included brochure # 610-023-7588/A4641, and journal ads 612-023-7820A and 612-02307820B. The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed these promotional materials and finds them to be misleading and in violation of the Federal, Food, Drug, and Cosmetic Act and the applicable regulations.

Presentation of Safety Information

The presentations in the above promotional materials are misleading because they fail to present adequate risk information associated with the use of Biaxin. Promotional materials must present information relating to side effects and contraindications with a prominence and readability reasonably comparable with any presentation of information relating to effectiveness. The above materials contain efficacy claims and the most common side effects associated with the use of Biaxin, but they fail to include an adequate presentation of information concerning the contraindications for this drug.

Specifically, these promotional materials fail to include the information that Biaxin is contraindicated in patients with a known hypersensitivity to clarithromycin, erythromycin, or any of the macrolide antibiotics. Biaxin is also contraindicated in

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NDA# 50-698

patients receiving terfenadine, cisapride or pimozide who have pre-existing cardiac abnormalities or electrolyte disturbances. Failure to include this information renders the presentation of promotional messages misleading in the aforementioned submissions.

In order to address these objections, DDMAC recommends that Abbott take the following actions:

1. Immediately discontinue the use of the brochure and journal ads and any other like promotional materials for Biaxin that contain the same or similar violations.

2. Provide a written response to DDMAC of your intent to comply with the above request and a list of promotional materials, containing the misleading presentations, that will be discontinued.

Abbott's response should be received no later than August 25, 1997. If Abbott has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

In all future correspondence regarding this particular matter, please refer to MACMIS ID # 5667 in addition to the NDA number.

Sincerely,

Jo Ann Spearmon, Pharm.D., M.P.A.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications