DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-678/S-010

Eli Lilly and Company
Attention: Bryn Bright, RAC
Senior Regulatory Associate
U. S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Ms. Bright:

Please refer to your supplemental new drug application dated August 23, 1999, received August 24, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dynabac ® (dirithromycin) 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.

We acknowledge receipt of your submission dated April 2, 2002.

This supplemental new drug application provides for revised geriatric labeling.

We have completed the review of this supplemental application, 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 and with the minor editorial revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

In the PRECAUTIONS section, revise the Geriatric Use subsection to read as follows:

"In a clinical pharmacology study, 19 healthy geriatric volunteers (65 to 83 years of age) with normal renal and hepatic function had no statistically significant differences in AUC or C_{max} when compared with 10 healthy adult volunteers (19 to 50 years of age). (See CLINICAL PHARMACOLOGY section).
Of 3299 patients in controlled clinical studies of dirithromycin, 381 (11.5%) were 65 years of age or older. In these clinical trials in geriatric patients who received the usual recommended adult dose (500 mg q.d. P.O.), clinical efficacy and safety were comparable with results in non-geriatric adult patients.
Dynabac may contain up to 1.6 mg (0.07 mEq) of sodium per tablet."

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (package insert submitted August 23, 1999). These revisions are terms of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically 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 supplement NDA 50-678/S-010." Approval of this submission by FDA is not required before the labeling is used.

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-42
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 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

Please submit one market package of the drug product when it is available.

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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