CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: NDA 50-678/SE1-003

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Approval Package for:

Application Number: NDA 50-678/SE1-003

Trade Name: DYNABAC

Generic Name:(dirithromycin tablets)

Sponsor: Lilly Research Laboratories

Approval Date: December 19, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number:NDA 50-678/SE1-003

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-678/SE1-003

Lilly Research Laboratories
Attention: Jennifer L. Stotka, M.D.
Director,
U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, Indiana 46285

DEC 19 1997

Dear Dr. Stotka:

Please refer to your supplemental new drug application dated December 18,1996, received on December 20, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dynabac® (dirithromycin tablets). We note that this product is subject to the exception provisions of section 125 (2) of Title 1 of the Food and Drug Administration Modernization Act of 1997.

We acknowledge receipt of your submission dated April 17, 1997. The User Fee goal date for this application is December 20, 1997.

This supplemental new drug application provides for the 5-day use of Dynabac® (dirithromycin) tablets for the treatment of patients with acute bacterial exacerbation of chronic bronchitis due to *Haemophilus influenzae*, *Moraxella catarrhalis*, or *Streptococcus pneumoniae* and for the treatment of patients with uncomplicated skin and skin structure infections due to *Staphylococcus aureus* (methicillin-susceptible strains) or *Streptococcus pyogenes*. The application also provides for the addition of *Haemophilus influenzae* to the presently approved indication for secondary bacterial infections of acute bronchitis.

We have completed the review of this application, including the draft labeling submitted December 18, 1997, 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 draft labeling in the submission dated December 18, 1997. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on December 18, 1997. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case 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 "FINAL PRINTED LABELING" for approved NDA 50-678/SE1-003. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

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

Food and Drug Administration
Division of Drug Marketing, Advertising, and
Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 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, please call Mr.Jose R. Cintron, R.Ph., M.A., Senior Regulatory Management Officer, at (301) 827-2125.

Sincerely yours,

Gary K. Chikami, M.D.
Acting Director
Office of Drug Evaluation IV
Center for Drug Evaluation and Research