CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 18118

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-118

The Wellcome Research Laboratories
Burroughs Wellcome Company
Attention: Mr. D. A. Knight
3030 Cornwallis Road
Research Triangle Park, NC 27709

JUL 26 1982

Dear Mr. Knight:

Please refer to your new drug application dated January 9, 1978 submitted under Section 505 (b) of the Federal Food, Drug and Cosmetic Act for the preparation Lanoxicaps (brand of Digoxin Solution in soft gelatin capsules).

The application was filed on May 18, 1982.

We have completed the review of this application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved.

The enclosures summarize the conditions relating to the approval of this application.

In addition, please consider adding to the package insert at the next printing the following:

1. A statement regarding vaginal epithelium cornification in the Adverse Reactions section.

2. A statement about calcium channel blockers potential for interaction and potential changes in serum digoxin levels under the Precautions section (General and Drug Interactions Subsections).

Please submit one market package of the drug when available.

Sincerely yours,

Robert J. Temple, M.D.
Acting Director
Office of New Drug Evaluation
National Center for
Drugs and Biologics

Enclosures: Records and Reports Requirement (21 CFR 310.300)
Conditions of Approval of NDA