CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20545

APPROVAL LETTER

DEPARTMENT OF HE. .TH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DF

JAN 3 1 1996

NDA 20-545

Parke-Davis Pharmaceutical Company
Division of Warner-Lambert Company
Attention: Ms. Mary E. Taylor
2800 Plymouth Road
P.O. Box 1047
Ann Arbor, MI 48106-1047

Dear Ms. Taylor:

Please refer to your December 21, 1994 new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Procanbid (procainamide HCl), 500 and 1000 mg, Extended Release Tablets.

We acknowledge receipt of your correspondence dated December 12, 1995 and your amendment dated December 18, 1995.

This new drug application provides for the use of Procanbid for the treatment of documented ventricular arrhythmias, such as sustained ventricular tachycardia, that in the judgment of the physician are life-threatening.

We have completed the review of this application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling included in your December 18, 1995 submission. Accordingly, the application is approved effective on the date of this letter.

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-240
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug 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, please contact:

Ms. Diana Willard
Regulatory Health Project Manager
(301) 594-5311

Sincerely yours,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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Parke-Davis Pharmaceutical Research
Division of Warner-Lambert Company
Attention: Ms. Mary E. Taylor
2800 Plymouth Road
P.O. Box 1047
Ann Arbor, MI 48106-1047

Dear Ms. Taylor:

Please refer to your December 21, 1994 new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Procanbid (procainamide HCl), 500 and 1000 mg, Extended Release Tablets.

We acknowledge receipt of your amendments dated January 10 and 19, February 2, 7, 13, and 24, March 6, 7, 8, and 15, April 10 and 21, May 1, 5, 15, and 19, June 14, 23, and 30, August 1 and 21, September 5, and October 25, 1995.

We have completed the review of this application as submitted with draft labeling. Before the application may be approved, however, it will be necessary for you to submit final printed labeling (FPL) for the drug. The labeling should be identical in content to the enclosed marked-up draft. If additional information relating to the safety or effectiveness of this drug becomes available, revision of the FPL may be required.

Please submit sixteen copies of the printed labels and other labeling, ten of which are individually mounted on heavy weight paper or similar material.

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:

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5600 Fishers Lane
Rockville, Maryland 20857

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of such action FDA may take action to withdraw the application.

The drug may not be legally marketed until you have been notified in writing that the application is approved.

Should you have any questions, please contact:

Ms. Diana Willard
Consumer Safety Officer
Telephone: (301) 594-5311

Sincerely yours,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure