CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20545

CORRESPONDENCE

JUN 29

NDA 20-545

Parke-Davis Pharmaceutical Research
Division of Warner-Lambert Company
Attention: Mr. Alan V. McEmber
2800 Plymouth Road
P.O. Box 1047
Ann Arbor, MI 48106-1047

Dear Mr. McEmber:

Please refer to your new drug application for Procanbid (procainamide HCl) Extended Release Tablets.

In reviewing your submission of December 21, 1994, our Medical Officer, Chemist, Pharmacologist and Environmental Officer have raised a number of questions that require your attention. Our concerns with your submission are detailed as part of this correspondence (see enclosures).

We would appreciate your written response.

Sincerely yours,

Natalia A. Morgenstern
Chief, Project Management Staff
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosures
- Medical Review
- Chemist Review
- Pharmacology review
- Environmental Assessment Review

cc:
Original NDA
HFD-80/DDIR
HFD-110
HFD-110/CSO
HFD-110/DWillard/6/20/95;6/26/95
sb/6/21/95;6/28/95
R/D: RWolters/6/26/95
NMorgenstern/6/27/95

GENERAL CORRESPONDENCE

NDA 20-545

NOV 17 1995

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 new drug application for Procanbid (procainamide HCl) Extended-Release Tablets.

In reviewing your submission of December 21, 1994, our Medical Officer, Statistician and Biopharmaceutist have raised a number of questions that require your attention. Our concerns with your submission are detailed as part of this correspondence (see enclosures).

We would appreciate your written response.

Sincerely yours,

Natalia A. Morgenstern
Chief, Project Management Staff
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosures
Medical Review
Statistical Review
Biopharmaceutical Review

cc:
Original NDA
HFD-80/~~DDIR~~
HFD-110
HFD-110/Project Manager
HFD-110/DWillard;11/14/95
sb/11/13/95;11/16/95
R/D: NMorgenstern/11/14/95

GENERAL CORRESPONDENCE

Diana Willard

DEPARTMENT OF HE' TH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-545

MAR 15 [illegible]

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 pending December 21, 1994 new drug application submitted under section 505(b) of the Federal Food, Drug and Cosmetic Act for Procanbid (procainamide HCl) Extended Release Tablets.

We have completed our review of the chemistry section of your submission and have identified the following deficiencies:

1. Please provide elemental analysis, mass spectra analysis and NMR data on your recent synthesized batches of drug substance to characterize them further.

2. Please provide the analytical test specification protocol for the in-house working standard. We request that you conduct complete USP analytical testing on the working standard.

3. You have indicated in the stability data for the drug substance that the assay specification for the drug substance is [ ]% for shipment to Parke-Davis, Rochester. Please clarify why is this specification for the Rochester site. Also, please claify the relevance of this information to the NDA submission, as the drug product is manufactured at your facility in

4. Please submit 6 months data on each of three commercial lots for each strength in each of the proposed market packages that are at least [illegible]% of the production batches or [ ]units; whichever is larger.

5. Please specify the approximate humidity conditions at 30°C in your stability studies protocol for the drug product.

6. Please describe the packaging operations, including the type of equipment and operative conditions.

7. In the **DESCRIPTION** section of the package insert, the ingredients [ ] have been included. These two excipients are not part of your present formulation for the drug product. Please delete these from the list of ingredients.

8. In the **HOW SUPPLIED** section of the package insert, note that the USP 23 has redefined controlled temperature. Please revise your labeling appropriately.

9. Please provide curriculum vitae for each of the preparers of the EA, stating their expertise, experience and professional discipline. In addition, please list any persons or agencies who were consulted during the preparation of environment assessment as required by 21 CFR 25-31.

We may have further comments regarding the environment assessment and dissolution specifications at a later date.

Your proposed trademark has been reviewed by our Labeling and Nomenclature Committee and is acceptable. Please note that we consider your trademark to be one word. You, therefore, should not emphasize or set off the "bid" suffix of the name in any labeling or advertising for this drug product.

We would appreciate your prompt written response so we can continue our evaluation of your NDA.

If you have any questions, please contact:

Ms. Diana Willard
Consumer Safety Officer
(301) 594-5300

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