DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 2 8 1999

NDA 20-125

Parke-Davis Pharmaceuticals, Ltd.
Attention: Mr. James A. Parker
Worldwide Regulatory Affairs
201 Tabor Road
Morris Plains, NJ 07950

Dear Mr. Parker:

Please refer to your new drug application (NDA) dated December 13, 1990, received December 14, 1990 and withdrawn on October 27, 1992 and resubmitted with your April 30, 1999 amendment. This application was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Accuretic (quinapril HCl/hydrochlorothiazide) 10/12.5, 20/12.5, and 20/25 mg Tablets.

We acknowledge receipt of your submission dated December 9, 1999.

This new drug application provides for the use of Accuretic (quinapril HCl/hydrochlorothiazide) 10/12.5, 20/12.5, and 20/25 mg Tablets in the treatment of hypertension.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted final printed labeling (package insert included in your December 9, 1999 submission) and immediate container and carton labels included in your November 10, 1999 submission. Accordingly, the application is approved effective on the date of this letter.

We remind you of your agreement to _____ in the drug product stability studies by _____ ) test. A shelf-life acceptance criterion _____ should be established, if appropriate, in addition to the current release limit of _____

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new route of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). We are waiving the pediatric study requirement for this action on this application. Pediatric studies are not required for combination products.

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.

At the time of your next printing, please make the following changes:

Under the ADVERSE REACTIONS/Postmarketing Experience subsection,

1. In the first sentence, please insert the word "been" between the words "have" and "reported."

2. Under Skin and Appendages, please delete the comma between the words "maculopapular" and "rash."

If you have any questions, contact:

Ms. Sandra Birdsong
Regulatory Health Project Manager
(301) 594-5312

Sincerely yours,

/S/

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