DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 21-134

MAY 1 - 2000

Parke-Davis Pharmaceutical Research
Warner-Lambert Company
Attention: Ms. LaVonne L. Lang
2800 Plymouth Road
Ann Arbor, MI 48105

Dear Ms. Lang:

Please refer to your new drug application (NDA) dated June 2, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nitrostat (nitroglycerin sublingual) 0.3, 0.4 and 0.6 mg Tablets.

We acknowledge receipt of your submissions dated April 7 and 13, 2000. Your submission of April 13, 2000 constituted a complete response to our March 24, 2000 approvable letter.

This new drug application provides for the use of Nitrostat (nitroglycerin sublingual) Tablets for the acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease.

We have completed the review of this application, as amended, 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 submitted final printed labeling (package insert included with your April 7, 2000 submission, and immediate container and carton labels included with your April 13, 2000 submission). Accordingly, the application is approved effective on the date of this letter.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes 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.

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

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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.

If you have any questions, please contact:

Edward Fromm
Consumer Safety Officer
(301) 594-5313

Sincerely,

/S/

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