Food and Drug Administration
Rockville MD 20857

NDA 87-946

CONFIDENTIAL

FEB 10 1983

Par Pharmaceutical, Inc.
Attention: Mr. Ashok Patel
12 Industrial Avenue
Upper Saddle River, NJ 07458

Gentlemen:

Reference is made to your abbreviated new drug application dated December 15, 1980, submitted pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act for Isosorbide Dinitrate Tablets, 30 mg, Oral.

We acknowledge receipt of your communication dated October 19, 1982, enclosing additional control information, stability data, and dissolution data.

We call to your attention that your samples will be analyzed using our high pressure liquid chromatography method and this Administration expects you to work to resolve any technical issues that might result from this analysis.

We have reviewed this abbreviated new drug application and have concluded that the information in the application is satisfactory and the drug is safe for use as recommended in the submitted labeling. Accordingly, the application is conditionally approved.

Any significant change in the conditions outlined in this abbreviated new drug application, requires a conditionally approved supplemental application before the change may be made, except for changes made in conformance with other provisions of Section 314.8 of the new drug regulations.

This Administration should be advised of any change in the marketing status of this drug.

The requirement for adequate data to assure the biologic availability is delayed at the present time. However, our action in conditionally approving this application is based upon an understanding that this requirement will be performed with the appropriate procedures.

For Initial Campaigns: We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your immediate advertising or promotional campaigns. Please submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Advertising and Labeling (HFN-240).

For Subsequent Campaigns: We call your attention to Regulation 21 CFR 310.300(b)(3) which requires that all material for any subsequent advertising or promotional campaigns at the time of their initial use be submitted to our Division of Drug Advertising and Labeling (HFN-240) with a completed form FD-2253. A copy of Form FD-2253 is enclosed for your convenience.

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

Sincerely yours,

Marvin Seife, M. D.
Director
Division of Generic Drug Monographs
Office of the Associate Director
for Drug Monographs
Office of Drugs
National Center for Drugs and Biologics

Enclosures:
Conditions of Approval of a New Drug Application
Records & Reports Requirements
Form FD-2253