



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
ROCKVILLE, MARYLAND 20857

NDA 86-923

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

DEC 13 1979

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Isosorbide Dinitrate Tablets, 5 mg. - Oral.

Reference is also made to your amendment dated October 9, 1979 and December 6, 1979.

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.

Promotion of a product marketed under an abbreviated new drug application must not convey the impression that the product is a new entity.

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

Sincerely yours,

*Marvin Seife*  
Marvin Seife, M.D.

Director

Division of Generic Drug Monographs

Office of Drug Monographs

Bureau of Drugs

Enclosures:

Conditions of Approval of a New Drug Application

Records & Reports Requirements

Isosorbide Dinitrate Standards and Stability



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
ROCKVILLE, MARYLAND 20857

NDA 86-925

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

DEC 11 1979

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Isosorbide Dinitrate Tablets, 10 mg. - Oral.

Reference is also made to your amendment dated October 9, 1979.

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.

Promotion of a product marketed under an abbreviated new drug application must not convey the impression that the product is a new entity.

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

Sincerely yours,

*Marvin Seife*  
Marvin Seife, M.D.

Director

Division of Generic Drug Monographs  
Office of Drug Monographs  
Bureau of Drugs

Enclosures:

Conditions of Approval of a New Drug Application

Records & Reports Requirements

Isosorbide Dinitrate Standards & Stability



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

NDA 87-537

DEC 15 1981

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

Gentlemen:

Reference is made to your abbreviated new drug application dated March 9, 1981 submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Isosorbide Dinitrate Oral Tablets, 20 mg.

Reference is also made to your amendment dated June 25, 1981.

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.

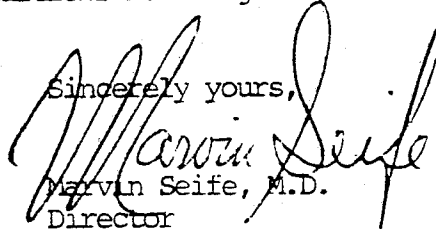
The requirement for adequate data to assure the biologic availability is delayed at the present time. However, our action in conditionally approving this application is based upon an understanding that this requirement will be performed with the appropriate procedures.

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 (HFD-170).

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 (HFD-170) 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 conditional approval of this application.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Marvin Seife". The signature is written in dark ink and is positioned above the printed name and title.

Marvin Seife, M.D.

Director

Division of Generic Drug Monographs

Office of Drug Monographs

Bureau of Drugs

Enclosures:

Conditions of Approval of a New Drug Application

Records & Reports Requirements

Form FD 2253

CONFIDENTIAL

FEB 10 1983

Pañ 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.

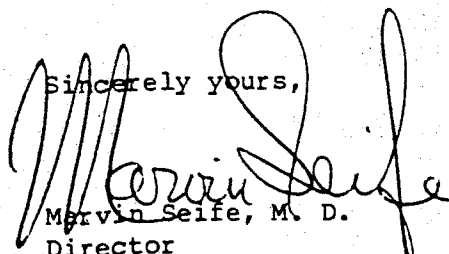
The requirement for adequate data to assure the biologic availability is delayed at the present time. However, our action in conditionally approving this application is based upon an understanding that this requirement will be performed with the appropriate procedures.

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