CENTER FOR DRUG EVALUATION AND RESEARCH

40-009

APPLICATION NUMBER:

APPROVAL LETTER

ANDA 40-009

DEC 30

Inwood Laboratories, Inc.
Attention: Foma Rashkovsky
909 Third Avenue
New York, NY 10022-4731

Dear Sir:

This is in reference to your abbreviated new drug application dated April 4, 1991, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Isosorbide Dinitrate Extended-release Tablets USP, 40 mg.

Reference is also made to your amendments dated December 15, 1993; April 14, 1995; September 2, October 31, and December 22, 1997; June 26, October 14, October 22, November 2, and November 30, 1998.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Isosorbide Dinitrate Extended-release Tablets USP, 40 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Isordil® Tembids® Controlled-Release Tablets, 40 mg, of Wyeth Ayerst Laboratories Inc.).

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution test and tolerances are:

The dissolution testing should be conducted in 900 mL of simulated gastric fluid, pH 1.2 for the first hour.

The medium should be changed to 900 mL of simulated intestinal fluid, pH 7.5 thereafter.

The test product should meet the following "interim" specifications:

	Time	Amount Dissolved
(pH 1.2)	1 hr	
(pH 7.5)	3 hr	

6 hr
12 hr

The "interim" dissolution test and tolerances should be finalized by submitting dissolution data for the first three production size batches in a supplemental application. The supplemental application should be submitted under 21 CFR 314.70(c)(1) when there are no revisions to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances the supplement should be submitted under 21 CFR 314.70(b)(2)(ii).

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

12/30/98

Roger L. Williams, M.D.
Deputy Center Director for Pharmaceutical Science
Center for Drug Evaluation and Research