

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

40136

APPROVAL LETTER

JUN 30 1997

Luitpold Pharmaceuticals, Inc.
Attention: Robert J. Anderson, J.D.
One Luitpold Drive
Shirley, NY 11967

Dear Sir:

This is in reference to your abbreviated new drug application dated February 17, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Hydralazine Hydrochloride Injection USP, 20 mg/mL.

Reference is also made to your amendments dated January 22, 1997, March 6, and March 21, 1997, May 29, 1997, and June 13, 1997.

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 Hydralazine Hydrochloride Injection USP, 20 mg/mL to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Apresoline® HCl Injection, 20 mg/mL of Novartis Pharmaceutical Corporation.

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. 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-240). 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-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

/S/

for/
Douglas L. Sporn
Director

Office of Generic Drugs
Center for Drug Evaluation and Research

6/30/97