DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AADA 63-083

RECEIVED AUG 0 5 1991

JUL 31 1991

Danbury Pharmacal, Inc.
Attention: Edward M. Cohen, Ph.D.
131 West Street, P.O. Box 296
Danbury, CT 06813

Dear Sir:

Reference is made to your abbreviated antibiotic drug application dated October 5, 1988 submitted pursuant to Section 507 of the Federal Food, Drug, and Cosmetic Act for Clindamycin Hydrochloride Capsules USP, 150 mg.

We acknowledge receipt of your additional submissions dated May 30, 1989, July 24, 1989, August 1, 1989, October 27, 1989, June 18, 1990, July 20, 1990, September 19, 1990 and July 24, 1991.

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. Our Division of Bioequivalence deems Danbury's Clindamycin Hydrochloride Capsules USP, 150 mg bioequivalent to the reference product CLEOCIN® (Clindamycin hydrochloride) Capsules 150 mg, manufactured by The Upjohn Company.

Any significant change in the conditions outlined in this abbreviated application requires an approved supplemental application before the change may be made, except for changes made in conformance with other provisions of Section 314.70 of the new drug regulations.

Postmarketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80 and 314.81 of the Regulations.

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

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 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 Advertising and Labeling (HFD-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

For Subsequent Campaigns: We call your attention to Section 314.81(b)(3) of the Regulations which requires that materials for any subsequent advertising of promotional campaign, at the time of their initial use, be submitted to our Division of Drug Advertising and Labeling (HFD-240) with a completed Form FD-2253.

Sincerely yours,

Roger L. Williams, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research