# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**65-027**

# APPROVAL LETTER

ANDA 65-027

JUN 29 2001

Abbott Laboratories
Hospital Products Division
Attention: Tom Sampogna
200 Abbott Park Road, D-37K AP30
Abbott Park, IL 60064-6157

Dear Sir:

This is in reference to your abbreviated new drug application dated August 31, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Clindamycin in 5% Dextrose Injection, packaged in 300 mg/50 mL (6 mg/mL), 600 mg/50 mL (12 mg/mL), and 900 mg/50 mL (18 mg/mL) single-dose form fill seal plastic flexible containers. We note that this product is subject to the exception provisions of Section 125(d)(2) of Title I of the Food and Drug Administration Modernization Act of 1997.

Reference is also made to your amendments dated May 16, 2000, and May 11, 2001.

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 Clindamycin in 5% Dextrose Injection, 6 mg/mL, 12 mg/mL and 18 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (Cleocin® Phosphate I.V. Solution in Galaxy Plastic Containers, 6 mg/mL, 12 mg/mL, and 18 mg/mL, respectively, of Pharmacia and Upjohn Co.).

Under Section 506A of the Act, 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 that 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,

Gary Buehler 6/29/01
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research