DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 63-083/S-015, S-017, S-019

MAR 18 2003

Watson Laboratories, Inc.
Attention: Meredith Selby
P.O. Box 450
39 Mt. Ebo Road South
Brewster, NY 10509

Dear Madam:

This is in reference to your supplemental new drug applications dated December 21, 2001, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Clindamycin Hydrochloride Capsules USP, 150 mg (base).

Reference is also made to your amendments dated February 25, 2003.

The supplemental applications provide for:

S-015: The addition of a new 300 mg (base) strength capsule;

S-017: associated revisions to the drug product test methods; and

S-019: labels and labeling to reflect the new 300 mg (base) strength.

We have completed the review of these supplemental applications and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the supplemental applications are approved. The Division of Bioequivalence has determined your Clindamycin Hydrochloride Capsules USP, 300 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Cleocin® HCl Capsules, 300 mg (base), of Pharmacia and Upjohn Co.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

rec'd 3/24/03
mcs

We remind you that you must comply with the requirements for an approved abbreviated new drug application described 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 for the new strength. 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 the Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

The materials submitted in support of approval of these supplemental applications is being retained in our files.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research