CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40257

APPROVAL LETTER

ANDA 40-257

AUG 4 1998

Mallinckrodt Chemical, Inc.
Attention: Marianne Robb
16305 Swingley Ridge Drive
Chesterfield, MO 63017

Dear Madam:

This is in reference to your abbreviated new drug application dated June 30, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Oxycodone and Acetaminophen Capsules USP, 5 mg/500 mg.

Reference is also made to your amendments dated March 12, and July 3, 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 Oxycodone and Acetaminophen Capsules USP, 5 mg/500 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Tylox® Capsules, 5 mg/500 mg of RW Johnson Pharmaceutical Research Institute). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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,

/S/

8/3/98

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research