ANDA 76-264

Mallinckrodt Inc.
Attention: Marianne Robb
675 McDonnell Blvd
P.O. Box 5840
St. Louis, MO 63134

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated October 31, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Naltrexone Hydrochloride Tablets USP, 25 mg, 50 mg, and 100 mg.

Reference is also made to your amendments dated February 11, and February 18, 2002.

We note that the 25 mg and 100 mg strengths of this drug product were included in the application through the ANDA Suitability Petition process. A Suitability Petition for these strengths was submitted under Section 505(j)(2)(C) of the Act, and approved on April 13, 2000.

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 Naltrexone Hydrochloride Tablets, USP 50 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Revia® Tablets, 50 mg of Bristol Myers Squibb Pharmaceutical Company). In addition, your Naltrexone Hydrochloride Tablets USP, 25 mg and 100 mg, can be expected to have the same therapeutic effect as that of equivalent doses of Revia Tablets. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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
Director
Office of Generic Drugs
Center for Drug Evaluation and Research