ANDA 75-629

May 9, 2000

Mallinckrodt, Inc.
Attention: Marianne Robb
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134-0840

Dear Madam:

This is in reference to your abbreviated new drug application dated April 30, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Methylin™ ER Tablets (Methylphenidate Hydrochloride Extended-release Tablets USP), 10 mg and 20 mg.

Reference is also made to your amendments dated July 2, August 30, October 29, and November 17, 1999; and February 14, and April 14, 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 Methylin ER Tablets, 20 mg (Methylphenidate Hydrochloride Extended-release Tablets USP, 20 mg) to be bioequivalent, and therefore therapeutically equivalent, to the listed drug (Ritalin SR Tablets, 20 mg, of Novartis Pharmaceuticals Corp.). The drug product, Methylin ER Tablets, 10 mg (Methylphenidate Hydrochloride Extended-release Tablets USP, 10 mg) can be expected to have the same therapeutic effect as that of the listed drug product upon which the Agency relied as the basis of safety and effectiveness. 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
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research