

ANDA 40-410

February 9, 2001

Danbury Pharmacal, Inc.  
Attention: Ann Mullarkey  
Mt. Ebo Drive South, Route 22  
Brewster, NY 10509

Dear Madam:

This is in reference to your abbreviated new drug application dated April 28, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Methylphenidate Hydrochloride Extended-release Tablets USP, 20 mg.

Reference is also made to your amendments dated June 15, and December 19, 2000; and January 25, and February 2, 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 Methylphenidate Hydrochloride Extended-release Tablets USP, 20 mg, to be bioequivalent and, therefore, therapeutically equivalent to Ritalin-SR 20 mg Tablets of Novartis Pharmaceuticals Corp. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution test(s) and tolerances are:

The dissolution testing should be conducted in 500 mL of water at 37° C using USP 24 Apparatus II (paddle) at 50 rpm. The test product should meet the following tentative specifications:

Time	Amount Dissolved
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The "interim" dissolution test and tolerances should be finalized by submitting dissolution data for the first three production size batches in a supplemental application. A

"Special Supplement - Changes Being Effected" (zero) should be submitted if there are no revisions proposed to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances a Prior Approval supplement should be submitted.

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

