ANDA 40-306 October 20, 1999

Medeva Pharmaceuticals, Inc.
Attention: Norma J. Cappetti
755 Jefferson Road
P.O. Box 1710
Rochester, NY 14603-1710

Dear Madam:

This is in reference to your abbreviated new drug application dated April 10, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Metadate ER Tablets,
10 mg (Methylphenidate Hydrochloride Extended-release Tablets USP, 10 mg).

Reference is also made to your amendments dated August 3, 1998; and March 1, May 20, June 16, August 13, August 26, September 7, September 23, and October 7, 1999.

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 drug product, Metadate 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 reference 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 USP XXIV 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 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,

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