

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**76170**

**APPROVAL LETTER**

JUN 10 2002

Barr Laboratories, Inc.  
Attention: Christine Mundkur  
2 Quaker Road  
Pomona, NY 10970

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated May 11, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Lithium Carbonate Extended-release Tablets USP, 300mg.

Reference is also made to your amendments dated December 28, 2001; and January 22, March 4, March 13, March 20, March 28, April 8, and May 29, 2002.

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 Lithium Carbonate Extended-release Tablets USP, 300 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Lithobid® Slow-Release Tablets, 300 mg, of Solvay Pharmaceuticals). Your dissolution testing should be incorporated into your manufacturing controls and stability program using the same method proposed in your application. The "interim" dissolution test(s) and tolerances are:

The dissolution testing should be conducted in 800 mL of dilute HCl (7 mL in 1000 mL water), using Apparatus I (Basket) at 100 rpm. The test product should meet the following "interim" specifications:

15 minutes:		⊗
45 minutes:		⊗
90 minutes:		⊗
120 minutes:	NLT	⊗

The "interim" dissolution tests and tolerances should be finalized by submitting dissolution data for the first three production size batches in a supplemental application. The supplemental application should be submitted under 21 CFR 314.70 (c)(1) when there are no revisions to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances, the supplement should be submitted under 21 CFR 314.70(b)(2)(ii).

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 final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). 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, at the time of their initial use, be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253.

Sincerely yours,

/S/

Gary Buehler 6/10/02  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research