CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

76170

ADMINISTRATIVE DOCUMENTS

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 76-170 Date of Submission: March 20, 2002

Applicant's Name: Barr Laboratories, Inc.

Established Name: Lithium Carbonate Extended Release Tablets USP, 300 mg

Labeling Deficiencies:

INSERT

a. WARNINGS

Replace the subsection headings, "Usage in Pregnancy", "Usage in Nursing Mothers" and "Usage in Children" with "Pregnancy", "Nursing Mothers" and "Pediatric Use", respectively and relocate the subsections to the end of the PRECAUTIONS section per 21 CFR 201.57.

b. PRECAUTIONS

Revise the seventh sentence to read "...intake (2500-3000 mL) at..."

c. ADVERSE REACTIONS (Neuromuscular)

Revise to read "...deep tendon reflexes."

d. DOSAGE AND ADMINISTRATION

Delete all trailing zeros after decimal points.

e. Switch the DOSAGE AND ADMINISTRATION section with the OVERDOSAGE section per 21 CFR 201.56.

Please revise your labeling as instructed above and submit 12 final printed copies of labels and labeling for a full approval of this application.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following website for any approved changes –

http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

/S/

Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 76-170

JUL - 3 2001

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

Dear Madam:

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

We have given your application a preliminary review, and we find that it is not sufficiently complete to merit a critical technical review.

We are refusing to receive this ANDA under 21 CFR 314.101(d)(3) for the following reasons:

You have failed to submit **complete** comparative *in vitro* dissolution data between your proposed drug product and the reference listed drug. Dissolution profiles should be generated in aqueous media of the following pH ranges: 1 - 1.5, 4 - 4.5, 6 - 6.5 and 7 - 7.5 and in 0.1 N HCl.

The following should also be provided:

1. SOP for reassay of samples
2. SOP or criteria for acceptance of reassay values
3. Raw data including individual peaks with areas, etc. for 20 percent of the subjects in the study(ies)

Please check the appropriate box on the 356h form under the proposed marketing status section.

Thus, it will not be received as an abbreviated new drug application within the meaning of Section 505(j) of the Act.

Upon receipt of this communication, you may either amend your application to correct the deficiencies or withdraw your application under 21 CFR 314.99. If you have any questions please call:

Beth Fritsch
Project Manager
(301) 827-5862

Sincerely yours,

/S/

Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research