DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-812/SCP-021

Roxane Laboratories, Inc.
Attention: Ann M. Maloney
Director, Drug Regulatory Affairs-Approved Products
P.O. Box 16532
Columbus, OH 43216

Dear Ms. Maloney:

Please refer to your supplemental new drug application dated February 14, 2001, received February 15, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lithium Carbonate Capsules, USP, 150, 300 and 600 mg .

This supplemental new drug application provides for an alternate supplier of the capsule shells for the 300 mg strength and an alternate closure for the bottle of 100 capsules.

We have completed the review of this supplemental application, and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Doris Bates, Ph.D., Regulatory Project Manager, at (301) 594-5536.

Sincerely,

{See appended electronic signature page}

Robert H. Seevers, Ph.D.
Chemistry Team Leader, Psychiatric Drugs for the
Division of Neuropharmacological Drug Products,
(HFD-120)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Robert H. Seevers
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