DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 17-812/S-011, S-013, S-014, S-016, S-017
NDA 18-421/S-011, S-013, S-014, S-015, S-016

Roxane Laboratories, Inc.
Attn: Ms. Ann Malony
P.O. Box 16532
Columbus, Ohio 43216

Dear Ms. Maloney:

Please refer to the following supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lithium Carbonate Capsules and Lithium Citrate Syrup.

17-812/SLR-011 (dated December 23, 1987)
18-421/SLR-011 (dated November 2, 1987)

These "Changes Being Effected" supplements provide for revisions to the package insert in response to an Agency letter dated May 9, 1986, which requested all lithium NDA holders to revise their labeling to include 1) a “Usage in Children” subsection, 2) add the terms “acute dystonia” and “downbeat nystagmus” to the ADVERSE REACTIONS section, and 3) revise the indomethacin/lithium drug interaction language.

17-812/SLR-013 (dated September 29, 1989 and amended May 22, 1990)
18-421/SLR-013

These "Changes Being Effected" supplements provide for revisions to the package insert in response to an Agency letter dated March 15, 1989, which requested all lithium NDA holders to revise the PRECAUTIONS section of labeling to include a statement about lithium intoxication occurring after the addition of ACE inhibitors (enalapril or captopril) to the regimen of patients taking lithium.

17-812/SLR-014 (dated December 4, 1991)
18-421/SLR-014

These "Changes Being Effected" supplements provide for revisions to the package insert in response to an Agency letter dated July 11, 1991, which requested all lithium NDA holders to

revise their labeling to expand the existing description of the drug interaction that occurs when lithium and diuretics or angiotensin converting enzyme (ACE) inhibitors are used concomitantly.

17-812/SLR-016 (dated December 6, 1994)
18-421/SLR-015

These "Changes Being Effected" supplements provide for revisions to the package insert in response to an Agency letter dated August 22, 1994 sent by HFD-600 (Generic drugs to NDA 18-558). The ADVERSE REACTIONS (Cardiovascular) section of labeling was revised to include severe bradycardia.

17-812/SLR-017 (dated June 23, 1995)
18-421/SLR-016

These "Changes Being Effected" supplements provide for revisions to the unit-dose carton labeling to state that “Blisters are not child-resistant. Use child-resistant closure if dispensing to outpatients.”

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (carton/container submitted June 23, 1995; package insert submitted December 6, 1994). Accordingly, these supplemental applications are approved effective on the date of this letter.

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 Management Officer, at (301) 594-2850.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz

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