DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-860/S-074
NDA 17-971/S-020
NDA 18-152/S-020

Elizabeth A. McConnell, Pharm.D.
Associate Director, Regulatory Affairs
GlaxoSmithKline
PO Box 13398
Five Moore Drive
Research Triangle Park
North Carolina 27709

Dear Dr. McConnell:

Please refer to your above referenced supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Eskalith® (lithium carbonate) Capsules, 300 mg; Tablets, 300 mg; and Eskalith® CR (lithium carbonate) Tablets, 450 mg. These supplements were submitted concomitantly on September 11, 2003.

These "Changes Being Effected" labeling supplements provide for:

1. Revisions in the PRECAUTIONS: Drug Interactions section of the combined package insert for Eskalith® and Eskalith CR®.
2. Revision of the manufacturer's address to reflect a change of name for the product manufacturer, from International Processing Corporation to Cardinal Health. We note your commitment to include similarly revised container labeling in your next NDA Annual Reports.
3. Minor editorial changes throughout the text of the package insert

With respect to NDA 16-860/S-074 and NDA 18-152/S-020, we have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that these drug products are safe and effective for use as recommended in the submitted labeling text (package insert submitted September 10, 2003). Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed, submitted labeling. We note that such identical FPL has been posted on the firm's Web site for this product, and we therefore request that FPL for this submission be submitted electronically according to the guidance for industry titled, "Providing Regulatory Submissions in Electronic Format – NDA". For administrative purposes, this submission should be designated "FPL For Approved Supplement NDA 16-860/S-074, NDA 18-152/S-020".

Alternatively, you may submit paper copies of the FPL in the next Annual Report for these NDAs, along with the revised container labeling per your commitment under item 2. above.

With respect to supplemental application NDA 17-971/S-020, we note that you no longer manufacture Eskalith® Tablets 300 mg and that it has been removed from the combined package insert. We also note that this NDA remains open and that you have agreed to submit prior approval manufacturing and labeling supplements should this product again be marketed. Therefore, we are retaining this supplemental application in our files with no further action at this time.

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

If you have any questions, please contact Doris Bates, Regulatory Project Manager, at 301-594-2850.

Sincerely yours,

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

Enclosure (Approved Submitted Labeling Text)

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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