DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 16-860/S-073
NDA 17-971/S-019
NDA 18-152/S-017

SmithKline Beecham Corporation
d/b/a GlaxoSmithKline
Attention: Elizabeth McConnell, Pharm.D.
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Dr. McConnell:

Please refer to the following supplemental new drug applications dated April 2, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Eskalith® (lithium carbonate) Capsules and Eskalith® CR (lithium carbonate) Controlled Release Tablets.

16-860/SLR-073
18-152/SLR-017

These "Changes Being Effected" supplements provide for revisions to the PRECAUTIONS section of labeling to add a statement regarding lithium toxicity associated with concomitant cyclooxygenase-2 inhibitor (COX-2 inhibitor) therapy in patients taking either rofecoxib (Vioxx) or celecoxib (Celebrex) in addition to lithium.

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 final printed labeling (package insert submitted April 2, 2002). Accordingly, these supplemental applications are approved effective on the date of this letter.

We also remind you of a request made in our letter dated May 8, 2002 that, at the next printing of your labels and labeling, you replace the presently used storage recommendations statement under the HOW SUPPLIED section of the package insert as well as the container labels with the following statement:

> "Store at 25°C (77°F), excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]".

This change may be reported in your next annual report.

Finally, with regard to supplemental application NDA 17-871/S-019 for Eskalith® Tablets 300 mg, we note that you no longer manufacture this product and that it has been removed from the combined product labeling. We also note that you have agreed to submit prior approval manufacturing and labeling supplements should this product be re-marketed. Therefore, we will retain this supplemental application in our files with no further action.

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, 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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