DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-008/S-002

SmithKline Beecham Corporation d/b/a/ GlaxoSmithKline
Attention: Leo Lucisano, R.Ph., Regional Director, CMC Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Mr. Lucisano:

Please refer to your supplemental new drug application dated July 1, 2008, received July 1, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for REQUIP® XL™ (ropinirole) Extended-Release Tablets.

We acknowledge receipt of your submission dated December 11, 2008, which constituted a complete response to our October 31, 2008 action letter.

This "Prior Approval" supplemental new drug application provides for a new 6 mg strength.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1) in structured product labeling (SPL) format submitted on December 11, 2008, with the editorial revision listed below.

- Please update the revision date in your SPL to December 2008.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to, except for including the revisions listed above, the enclosed labeling text for the package insert. These revisions are terms of the NDA approval. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplemental NDA 22-008/S-002."

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Teshara G. Bouie, Regulatory Health Project Manager, at (301) 796-1649.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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/

Jim Vidra

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