DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-658/S013

SmithKline Beecham Corp
Attention: Leslie C. Rogers, M.D., Senior Director
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Dr. Rogers:

Please refer to your supplemental new drug application dated July 3, 2003, received July 7, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for REQUIP (ropinirole hydrochloride) 0.25mg. 0.5mg, 1mg, 2mg, 3mg, 4mg, 5mg Tablets

We acknowledge receipt of your submissions dated:

March 3, 2005	March 4, 2005	March 13, 2005	March 17, 2005
March 22, 2005	April 13, 2005	April 29, 2005	May 2, 2005

Your submission of March 3, 2005 constituted a complete response to our February 24, 2005 action letter.

This supplemental new drug application provides for the use of Requip (ropinirole hydrochloride) Tablets for:

> **Restless Legs Syndrome:** REQUIP is indicated for the treatment of moderate-to-severe primary Restless Legs Syndrome (RLS).
>
> Key diagnostic criteria for RLS are: an urge to move the legs usually accompanied or caused by uncomfortable and unpleasant leg sensations; symptoms begin or worsen during periods of rest or inactivity such as lying or sitting; symptoms are partially or totally relieved by movement such as walking or stretching at least as long as the activity continues; and symptoms are worse or occur only in the evening or night. Difficulty falling asleep may frequently be associated with moderate-to-severe RLS.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, and text for the patient package insert) and submitted labeling (2-week sample pack provided in a May 2, 2005 email).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved** supplement **NDA 20-658/S-013**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for all pediatric patients.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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

If you have any questions, call CDR Teresa Wheelous, Sr. Regulatory Project Manager, at (301) 594-2850.

Sincerely,

{See appended electronic signature page}

Russell Katz, MD
Director
Division of Neuropharmacological Drug Products
Office of Evaluation I
Center for Drug Evaluation and Research Sincerely,

Enclosure

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

5/4/05 02:55:24 PM