DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-658/S-020
NDA 20-658/S-018
NDA 20-658/S-021

SmithKline Beecham Corporation d/b/a GlaxoSmithKline
Attention: Leslie Rogers, M.D.
Senior Director, Neurology, U.S. Regulatory Affairs
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101

Dear Dr. Rogers:

Please refer to your supplemental new drug applications dated and received October 3, 2006, (supplement 20), dated July 22, 2005, received July 25, 2005 (supplement 18), and dated and received April 24, 2007 (supplement 21), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Requip (ropinirole) Tablets.

Supplements 18 and 20 provide for the addition of information regarding intense urges to gamble, increased sexual urges, and other intense urges in patients using medications to treat Parkinson's disease. Supplement 21 provides for the addition of information regarding melanoma to the PRECAUTIONS section of the package insert.

We completed our review of these applications and they are 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, text for the patient package insert).

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-020, S-018 and S-021**." Approval of this submission by FDA is not required before the labeling is used.

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 inserts directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Beverly Conner, PharmD, Regulatory Project Manager, at (301) 796-1171.

Sincerely,

{See appended electronic signature page}

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

Enclosure: labeling

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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