DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20658/S-024, S-026, S-027, S-030, S-032

SUPPLEMENT APPROVAL

GlaxoSmithKline LLC
Attention: Jaisri Giridhar, PhD, DABT, RAC,
Manager, Global Regulatory Affairs
5 Moore Drive
PO Box 13398
Research Triangle Park, NC 27709-3398

Dear Dr. Giridhar:

Please refer to the following Supplemental New Drug Applications (sNDA), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for REQUIP (ropinirole) Oral Tablets, 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg, and 5mg:

S-024		
	Supplement Type:	Prior Approval
	Dated:	December 12, 2008
	Received:	December 12, 2008
	Proposes:	Addition of information into the Full Prescribing Information regarding dosing recommendations for patients with end stage renal disease based on a pharmacokinetic study (Study RRL103628)
S-026		
	Supplement Type:	Changes Being Effected
	Dated:	May 18, 2009
	Received:	May 18, 2009
	Proposes:	Addition of information into the Full Prescribing Information and Patient Information regarding hypersensitivity reactions
S-027		
	Supplement Type:	Prior Approval
	Dated:	July 20, 2009
	Received:	July 20, 2009
	Amended:	August 15, 2011
	Proposes:	Addition of information into the Full Prescribing Information and Patient Information regarding augmentation and rebound in Restless Leg Syndrome based on a postmarketing study (ROR104836)

S-030

Supplement Type:	Prior Approval
Dated:	June 23, 2010
Received:	June 23, 2010
Amended:	June 28, 2011, January 24, 2012, February 6, 2012, February 8, 2012, April 16, 2012, April 24, 2012, May 18, 2012, June 21, 2012, and September 23, 2013
Proposes:	Updated labeling format for compliance with the Federal Register final rule issued January 24, 2006, "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products" [21 CFR 201.56 and 201.57], commonly referred to as the physician labeling rule (PLR)

S-032

Supplement Type:	Prior Approval
Dated:	June 18, 2013
Received:	June 18, 2013
Amended:	June 21, 2013
Proposes:	Addition of information into the Full Prescribing Information and Patient Information regarding aggressive behavior, compulsive spending or buying, binge eating and compulsive eating based on postmarketing reports

APPROVAL & LABELING

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

WAIVER OF HIGHLIGHTS SECTION

We acknowledge your request to waive the requirements of 21 CFR 201.57(d)(8) regarding the length of the Highlights of prescribing information. As previously discussed with you, we are denying your request.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and the text for the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

REPORTING REQUIREMENTS

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 Tracy Peters, Senior Regulatory Project Manager, at (301) 796-2953.

Sincerely,

{See appended electronic signature page}

Eric Bastings, M.D.
Deputy Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ERIC P BASTINGS
08/28/2014