CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-008

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-008

GlaxoSmithKline
Attention: Elizabeth A. McConnell, Pharm.D.
Project Director, Regulatory Affairs
Five Moore Drive; P.O. Box 13398
Research Triangle Park, NC 27709-3398

Dear Dr. McConnell:

Please refer to your new drug application (NDA) dated and received February 9, 2007, 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 submissions dated March 9 and 22, May 15 and 24, June 11 and 26, October 8, November 7, 13, 19, and 30, and December 5 and 6, 2007.

We completed our review of this application, as amended, and it is approvable. Before this application may be approved, however, you must submit draft labeling revised as attached.

In addition, we note that adequate fixed dose-response studies have never been performed with any formulation of ropinirole. We believe that this is critical, because current dosing recommendations may lead to treatment with inappropriately high doses. Therefore, before the application may be approved, we expect that you would agree to adequately characterize dose-response as part of a formal Phase 4 commitment. The specific details of this Phase 4 commitment will need to be agreed to prior to approval.

In addition, as required by 21 CFR 314.550, submit three copies of all promotional materials including promotional labeling and advertisements that you intend to use within 120 days following approval of 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 proposed package insert 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

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the

application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with this division to discuss what steps need to be taken before the application may be approved.

The drug product(s) may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, call Susan Daugherty, Project Manager, at (301) 796-0878.

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

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
12/7/2007 06:08:42 PM