DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022345/S-009

SUPPLEMENT APPROVAL

GlaxoSmithKline
Attention: Elizabeth A. McConnell, Pharm.D.
Manager, Global Regulatory Affairs
5 Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Dr. McConnell:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 12, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Potiga (ezogabine) tablets, with subsequent amendments submitted on October 4, 2013, December 17, 2014, and May 1, 2015.

We also refer to our September 6, 2013, REMS modification notification letter and our letter dated October 5, 2014.

This prior approval supplemental new drug application provides for proposed modifications to the approved risk evaluation and mitigation strategy (REMS) for Potiga (ezogabine).

The most recent amendment, which was submitted on May 1, 2015, proposes that FDA no longer require a REMS for Potiga (ezogabine).

We have completed our review of this supplemental application and it is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

A REMS for Potiga (ezogabine) was approved on June 10, 2011, and the most recent REMS modification was approved on March 19, 2012, to ensure the benefits of the drug outweigh the risk of urinary retention. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

In our September 6, 2013 letter, we notified you that in order to address the new safety information pertaining to the risks of retinal pigmentary abnormalities, potential vision loss, and skin discoloration, the Potiga REMS must be modified to include a Medication Guide, a revised communication plan, elements to assure safe use (ETASU), an implementation system, and a timetable for submission of assessments.

After consideration of additional data, in our letter dated October 5, 2014, we communicated to you that the Agency had determined that the requirement that results of visual monitoring be submitted for each patient and the requirement that each patient using the drug be enrolled in a registry are not necessary to ensure the benefits of the drug outweigh the risks of pigmentary abnormalities of the retina, potential vision loss, and skin discoloration. In addition, we determined that it is not necessary to include the Medication Guide as an element of the approved REMS. The Medication Guide continues to be a part of the approved labeling in accordance with 21 CFR 208.

We have reviewed the additional data that you submitted on February 15, 2015. These data do not indicate that either the retinal pigmentary abnormalities or skin discoloration lead to serious sequelae, including vision loss, in patients treated with Potiga. We have determined that these risks, as understood to date, are adequately addressed at this time through the approved product labeling.

Further, because the communication plan has been completed and the most recent assessment, submitted to the Agency on June 5, 2014, demonstrates that the communication plan has met its goals, we have determined that it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risk of urinary retention.

Therefore, based on our current understanding of the risks of pigmentary abnormalities of the retina, potential vision loss, and skin discoloration, and because the communication plan is no longer necessary to ensure the benefits of the drug outweigh the risk of urinary retention, a REMS is no longer required for Potiga (ezogabine).

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 Stephanie N. Parncutt, MHA, Regulatory Project Manager, at (301) 796-4098.

Sincerely,

{See appended electronic signature page}

Alice T.D. Hughes, M.D.
Deputy Director for Safety
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/

ALICE HUGHES
11/25/2015