DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020763/S-001, S-002, and S-010

SUPPLEMENT APPROVAL AND RETAIN PENDING BUT SUPERSEDED SUPPLEMENT

GlaxoSmithKline
Attention: Elizabeth A. McConnell, PharmD
Manager, Global Regulatory Affairs
Five Moore Drive
PO Box 13398
Research Triangle Park, NC 27709-3398

Dear Dr. McConnell:

Please refer to your Supplemental New Drug Application (sNDA) dated and received on June 29, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Amerge (naratriptan hydrochloride) tablets.

We acknowledge receipt of your amendments dated June 28, 2013, September 12, 2013, and September 30, 2013.

Prior Approval supplemental application S-010 provides for labeling changes to comply with the final rule, "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products," published on January 24, 2006.

We also refer to your supplemental applications S-001, submitted on February 27, 1998; and S-002 submitted on September 21, 1999. Supplemental application S-001 provides for changes to the Contraindications, Adverse Reactions, Dosage and Administration, and Information for Patients sections of labeling. Supplement application S-002 provides for changes to the Adverse Reactions section of labeling.

APPROVAL & LABELING

We have completed our review of NDA 020763/S-010, as amended and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We note that your supplemental application S-010 supersedes supplemental applications S-001 and S-002). Therefore, we will not review these supplemental applications but they will be retained in our files.

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 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).

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 Lana Chen, Regulatory Project Manager, at (301) 796-1056.

Sincerely,
{See appended electronic signature page}
Eric Bastings, MD
Acting 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
10/16/2013