



NDA 50-785/S-011
NDA 50-785/S-012

SUPPLEMENT APPROVAL

GlaxoSmithKline
Attention: Edward M. Yuhas, Ph.D.
Senior Director, Regulatory Affairs, Antibacterials
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101-7929

Dear Dr. Yuhas:

Please refer to your supplemental new drug applications dated and received October 29, 2009 (S-011), and February 1, 2010 (S-012), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Augmentin XR™ (amoxicillin/clavulanate potassium) Extended Release Tablets, 1000 mg/62.5 mg.

We acknowledge receipt of your amendments dated July 27, and July 29, 2010.

S-011: This “Changes Being Effected” supplemental new drug application provides for updated information in the PRECAUTIONS/Drug Interactions section of the package insert regarding the prolongation of prothrombin time in patients receiving amoxicillin and oral anticoagulants.

S-012: This Prior Approval supplemental new drug application updates the CLINICAL PHARMACOLOGY and PRECAUTIONS/Pediatric Use section of the package insert with information obtained from the pediatric pharmacokinetic study.

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

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending “Changes Being Effected” (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.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 Susmita Samanta, MD, Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Deputy Director for Safety
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-50785	SUPPL-12	GLAXOSMITHKLIN E	AUGMENTIN XR(AMOXICILLIN/CLAVULANAT E POT
NDA-50785	SUPPL-11	GLAXOSMITHKLIN E	AUGMENTIN XR(AMOXICILLIN/CLAVULANAT E POT

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

/s/

SUMATHI NAMBIAR
08/27/2010