Medical Officer's Memorandum
NDA 50-785/S012 – Labeling Phase 4 Commitment
Augmentin XR™

Date Submitted: July 26, 2010
Date Reviewed: July 27, 2010

Background:

Reference is made to the FDA's December 7, 2009 communication, where it was indicated that it was necessary for GSK to submit a labeling supplement to add relevant information from the pediatric pharmacokinetic study in the product labeling for AUGMENTIN XR to satisfy our Phase IV requirement.

On February 1, 2010, GSK submitted a Prior Approval supplement (S-012) to incorporate pediatric pharmacokinetic data from the final study report into the prescribing information for AUGMENTIN XR. Subsequently, an email was sent to the applicant on July 12, 2010 proposing revisions to this supplement.

Based on clinical review of the pharmacokinetic study, the proposed pediatric use statement in the **PRECAUTIONS** section of the label was as follows:

> **Pediatric Use:** The safety and effectiveness of AUGMENTIN XR have been established for pediatric patients weighing ≥ 40 kg who are able to swallow tablets. Use of AUGMENTIN XR in these pediatric patients is supported by evidence from adequate and well-controlled trials of adults with acute bacterial sinusitis and community-acquired pneumonia with additional data from a pediatric pharmacokinetic study.
> A pharmacokinetic study in pediatric patients (7-15 years of age and weighing ≥ 40 kg) was conducted (see CLINICAL PHARMACOLOGY).
> The adverse event profile in 44 pediatric patients who received at least one dose of AUGMENTIN XR was consistent with the established adverse event profile for the product in adults.

The labeling proposal included additional revisions to the **CLINICAL PHARMACOLOGY** section, as described in the clinical pharmacology review.

The applicant has submitted draft labeling incorporating these changes.

Medical Officer's Review:

The change of the age range from "7-15 years" to "7 to 15 years" in 3 instances in the label is acceptable. All other proposed changes by the applicant to the draft labeling are acceptable.

Medical Officer's Recommendations:

The proposed labeling is recommended for approval.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-50785	SUPPL-12	GLAXOSMITHKLINE	AUGMENTIN XR(AMOXICILLIN/CLAVULANATE POT

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/s/

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07/31/2010
Medical Officer's Memo for Pediatric Use labeling supplement

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08/02/2010