DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-785

GlaxoSmithKline
Attention: Cynthia D'Ambrosio, Ph.D.
Director, Regulatory Affairs
One Franklin Plaza
P.O. Box 7929
Philadelphia, Pennsylvania 19101-7929

Dear Dr. D'Ambrosio:

Please refer to your new drug application (NDA) dated December 20, 2000, received December 20, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Augmentin XR™ (amoxicillin/clavulanate potassium) 1000 mg/62.5 mg extended release tablets. This application is subject to the exemption provisions in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated March 29; April 17 and 30; July 26; August 8, 23, 27 and 30; September 6, 10, 18 and 24, 2002. The March 29, 2002 submission constituted a complete response to our December 12, 2001 action letter.

This new drug application provides for the use of Augmentin XR™ (amoxicillin/clavulanate potassium) 1000 mg/62.5 mg extended release tablets for the treatment of infections caused by designated organisms in acute bacterial sinusitis and community-acquired pneumonia.

We completed our review of this application, as amended and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 50-785**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens must contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (21 CFR 314.55).

Based on the information submitted, we conclude the following for the approved indications:

We are waiving the pediatric study requirement for these indications in patients less than 3 months of age.

We are deferring submission of pediatric studies for patients from 3 months to 16 years of age until September 25, 2004.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Anti-Infective Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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, M.D., Regulatory Project Manager at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure

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

/s/

Janice Soreth

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