DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-500/S-010

SmithKline Beecham Corporation d/b/a GlaxoSmithKline
Attention: Debra Hackett
Director, U.S. Regulatory Affairs
One Franklin Plaza
200 N. 16th Street, FP1005
Philadelphia, PA 19102

Dear Ms. Hackett:

Please refer to your supplemental new drug application dated and received December 7, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mepron® (atovaquone) Suspension, 750 mg/5 mL.

We acknowledge your December 20, 2007 complete response to our Approvable letter dated June 7, 2007.

This supplemental new drug application provides for the following revisions to the package insert (additions are indicated by underlined and deletions are indicated by ~~strikethrough~~):

1. In the header, ~~**PRODUCT**~~ **INFORMATION** is replaced with **PRESCRIBING INFORMATION**.

2. The following text was added as the third paragraph under **PRECAUTIONS/General** subsection:

   Rare cases of hepatitis, elevated liver function tests and one case of fatal liver failure have been reported in patients treated with atovaquone. A causal relationship between atovaquone use and these events could not be established because of numerous confounding medical conditions and concomitant drug therapies. (See **ADVERSE REACTIONS**.)

3. Under the **ADVERSE REACTIONS** section, the header was changed from ~~**Observed During Clinical Practice**~~ **to Postmarketing Experience:** and the following changes were made to this section:

   Blood and Lymphatic System Disorders: Methemoglobinemia, thrombocytopenia.
   Immune System Disorders: Hypersensitivity reactions including angioedema, bronchospasm, throat tightness, and urticaria.
   Eye Disorders: Vortex keratopathy.
   ~~***Hepatobiliary Tract***~~ ***Gastrointestinal*** ~~***and Pancreas***~~ ***Disorders:*** Pancreatitis
   ~~***Skin:*** Allergic reactions including erythema multiforme.~~

   ~~***Urology***~~ ***Hepatobiliary Disorders:*** Rare cases of hepatitis and one case of fatal liver failure have been reported with atovaquone usage.

Skin and Subcutaneous Tissue Disorders: Erythema multiforme, Stevens-Johnson syndrome, and skin desquamation have been reported in patients receiving multiple drug therapy including atovaquone.

Renal and Urinary Disorders: Acute renal impairment.

4. Under **HOW SUPPLIED** section:

~~U.S. Patent No. 5,053,432~~
~~USU.S. Patent No. 4,981,874 (Use Patent)~~

~~GlaxoWellcome~~
~~Glaxo Wellcome Inc.~~

GlaxoSmithKline
Research Triangle Park, NC 27709

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We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text dated December 20, 2007.

If you have any questions, please call Christine Lincoln, RN, M.S., MBA, Regulatory Health Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Transplant Products
Office Antimicrobial Products
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/

Renata Albrecht

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