NDA 20500/S-019

SUPPLEMENT APPROVAL

GlaxoSmithKline LLC
Attention: Linda Rebar
Director Global Regulatory Affairs
5 Crescent Drive
Philadelphia, PA 19112

Dear Ms. Rebar:

Please refer to your supplemental new drug application (sNDA) dated May 16, 2019, received May 16, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for MEPRON (atovaquone) Suspension, 750 mg/5 mL.

This Prior Approval supplemental new drug application is in response to the April 17, 2019, Supplement Request letter and provides for revisions to the following sections of the prescribing information (PI):

CLINICAL PHARMACOLOGY (12)

1. The **Pharmacodynamics (12.2)** subsection has been revised to include an updated table (originally found in subsection 12.3) and language relevant to pharmacodynamics.
2. The **Pharmacokinetics (12.3)** subsection has been revised to:
   a. Include pharmacokinetics language from the deleted Dose Proportionality subheading;
   b. Under the subheadings: Absorption, Effect of Food, Dose Proportionality, Elimination, Excretion, Drug Interactions for *Trimethoprim/ Sulfamethoxazole, Metoclopramide, and Zidovudine,* edits have been made as described in the attached labeling.
   c. An HIV-Infected Subjects subheading has been added.

CLINICAL STUDIES (14)

3. The **Treatment of PCP (14.2)** subsection has been revised to remove related text and reference to the **Pharmacokinetics (12.3)** subsection, and replacement with a reference to the **Pharmacodynamics (12.2)** subsection.

Additionally, minor editorial revisions have been made throughout the PI.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

If you have any questions, call Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, M.D., Ph.D.
Deputy Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
    - Prescribing Information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DMITRI IARIKOV
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