DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21078/S-022

SUPPLEMENT APPROVAL

GlaxosSmithKline, LLC
Attention: Munir Abdullah, Ph.D.
Director, Regulatory Affairs
5 Moore Drive
Research Triangle Park, NC 27709

Dear Dr. Abdullah:

Please refer to your Supplemental New Drug Application (sNDA) dated June 6, 2011, received June 7, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Malarone (atovaquone and proguanil hydrochloride) Tablets.

We acknowledge receipt of your amendments dated September 28, 2011 and February 7, March 26, June 5, and November 15, 2012.

This "Prior Approval" supplemental new drug application provides for revisions to the package insert to conform with the requirements of the Physicians Labeling Rule (PLR) format.

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

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 Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, M.D., M.P.H.
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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
02/27/2013