CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-078 / S-004

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-078/S-004

GlaxcoSmithKline
Attention: Kevin A. Miller, R.Ph., RAC
Assistant Director, CMC Post-Approval Regulatory Affairs
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709-3398

Dear Mr. Miller:

Please refer to your supplemental new drug application dated January 11, 2002, received January 14, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Malarone Tablets and Malarone Pediatric Tablets.

We acknowledge receipt of your submission dated May 8, 2002.

This supplemental new drug application provides for registration of a dissolution method for atovaquone.

We have completed the review of this supplemental application, and it is approved.

Although not an approval issue, we request that you provide batch release data for atovaquone dissolution for the next several commercial batches of MALARONE Tablets and MALARONE Pediatric Tablets. Please submit the data in your annual reports.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Michael Bourg, RPM, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Norman R. Schmuff, Ph.D.
Chemistry Team Leader for the
Division of Special Pathogen and Immunologic Drug Products, (HFD-590)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Norman Schmuff
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