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APPLICATION NUMBER:

21-078 / S-005

APPROVAL LETTER



NDA 21-078 / S-005

GlaxoSmithKline
Attention: Kevin A. Miller
Assistant Director, CMC Regulatory Affairs
PO Box 13398
Five Moore Drive
Research Triangle Park, NC 27709-3398

Dear Mr. Miller:

Please refer to your supplemental new drug application dated November 21, 2002, received November 22, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MALARONE™ (250 mg atovaquone/100 mg proguanil hydrochloride) Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for scale-up in the manufacturing process and equipment for MALARONE™ (250 mg atovaquone/100 mg proguanil hydrochloride) Tablets.

We have completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Yon Yu, Pharm.D., Regulatory Project Manager, 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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