

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-078 / S-003

ADMINISTRATIVE DOCUMENTS
AND
CORRESPONDENCE



NDA 21-078/S-003

PRIOR APPROVAL SUPPLEMENT

Smith Kline Beecham Corporation
Attention: Debra S. Hackett
1 Franklin Plaza
FP 1005, P.O.Box 7929
Philadelphia, PA 19101-7929

Dear Ms. Hackett:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: MALARONE™ (atovaquone and proguanil hydrochloride) Tablets,
250 mg atovaquone/100 mg proguanil and 62.5 mg atovaquone/25 mg proguanil

NDA Number: 21-078

Supplement number: S-003

Review Priority Classification: Standard

Date of supplement: October 5, 2001

Date of receipt: October 9, 2001

This supplemental application proposes the following changes:

- Addition of information about pharmacokinetics in geriatric patients,
- Addition of information about pharmacokinetics in patients with mild to moderate hepatic impairment, and
- Addition of information from two active-controlled clinical trials in non-immune travelers.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application will be filed on December 8, 2001, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be August 9, 2002.

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of Special Pathogen and Immunologic Drug Products, HFD-590
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

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Courier/Overnight Mail:

Food and Drug Administration

Center for Drug Evaluation and Research

Division of Special Pathogen and Immunologic Drug Products, HFD-590

Attention: Document Room

9201 Corporate Blvd.

Rockville, Maryland 20850

If you have any questions, call Rene Kimzey, Regulatory Project Manager, at (301) 827-2127.

Sincerely yours,

Ellen C. Frank, R.Ph.

Chief, Project Management Staff

Division of Special Pathogen and

Immunologic Drug Products

Office of Drug Evaluation IV

Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Ellen Frank
11/19/01 07:05:54 PM
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