

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-078 / S-005

ADMINISTRATIVE DOCUMENTS
AND
CORRESPONDENCE



NDA 21-078/S-005

CBE-30 SUPPLEMENT

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

Dear Mr. Miller:

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
NDA Number: 21-078
Supplement number: S-005
Date of supplement: November 21, 2002
Date of receipt: November 22, 2002

This supplemental application was submitted as a "Supplement - Changes Being Effected." The appropriateness of reporting the proposed change(s) as changes being effected is under review.

This supplement proposes the following changes:

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on January 21, 2003 in accordance with 21 CFR 314.101(a).

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

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 Yon Yu, Regulatory Project Manager, at (301) 827-2127.

Sincerely yours,

{See appended electronic signature page}

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