



NDA 21-078/S-006

GlaxoSmithKline
Attention: Ms. Debra Hackett
Associate Director, US Regulatory Affairs
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101

Dear Ms. Hackett:

Please refer to your supplemental new drug application dated May 30, 2003, received June 2, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Malarone[®] (atovaquone and proguanil hydrochloride) Tablets, 250 mg/100 mg and Pediatric Tablets, 62.5 mg/25 mg.

We acknowledge receipt of your submissions dated:

August 18, 2003	November 10, 2003
August 25, 2003	November 21, 2003
October 23, 2003	December 2, 2003
November 4, 2003	

This supplemental new drug application provides for the use of Malarone (atovaquone and proguanil hydrochloride) Pediatric Tablets, 62.5 mg/25 mg for the treatment of *Plasmodium falciparum* malaria in pediatric patients weighing 5 kg to 11 kg.

We completed our review of this application, as amended. We have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted on December 2, 2003). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-078/S-006.**" Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this population. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Special Pathogen and Immunologic Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81). All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 21-078 for this drug product.

If you have any questions, call Yon Yu, Pharm D., Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
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
this page is the manifestation of the electronic signature.**

/s/

Renata Albrecht
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