DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-500/S-005

Glaxo Wellcome, Inc.
Attention: Mr. Thomas K. Shumaker
US Regulatory Affairs
5 Moore Drive
PO Box 13398
Research Triangle Park, NC 27709

JAN 5 1999

Dear Mr. Shumaker:

Please refer to your supplemental new drug application dated March 5, 1998, received March 6, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mepron® (atovaquone) Suspension.

We acknowledge receipt of your submissions dated January 19, February 23, May 12, May 18, July 14, July 29, August 14, September 4, October 13, November 12, December 11, December 15, 1998 and January 4, 1999.

This supplemental new drug application provides for the use of Mepron® for prevention of *Pneumocystis carinii* pneumonia (PCP).

We have completed the review of this supplemental application, as amended, and 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, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted January 4, 1999, and immediate container and carton labels submitted December 15, 1998). 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 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-500/S-005." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, contact Brenda Atkins, Project Manager, at (301) 827-2127.

Sincerely yours,

Mark J. Goldberger, M.D., M.P.H, Director
Division of Special Pathogen
and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research