CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-517/S-038

APPROVAL LETTER

NDA 50-517/S-038

Merck & Co., Inc.
Attention: Virginia G. Snyder
Manager, Regulatory Affairs
Sumneytown Pike
P.O. Box 4, BLA-20
West Point, PA 19486

Dear Ms. Snyder:

Please refer to your supplemental new drug application dated April 15, 1996, received April 19, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mefoxin® (cefoxitin for injection) Injection, 1 gm, 2 gm, and 10 gm. We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submission dated January 6, 2000. We also refer to our facsimile dated May 4, 1999.

This supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE,** and **REFERENCES** sections of the label. Specifically, 1) the ***Microbiology*** subsection has been updated in response to the Agency's January 26, 1993 letter to All NDA Holders; 2) the **INDICATIONS AND USAGE** section has been revised to reflect updated names of microorganisms; and 3) the **REFERENCES** section has been updated to reflect 1997 approved standard documents.

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 and with the minor editorial revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

1. Under **Aerobic gram-positive microorganisms** in the ***Microbiology*** subsection of the **CLINICAL PHARMACOLOGY** section, please insert a space (line) between reference "a" and the sentence that reads "Most strains of enterococci, e.g., *Enterococcus faecalis*, are resistant."

2. In the **REFERENCES** section, please update your third reference as follows:

"National Committee for Clinical Laboratory Standards. Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria - Fourth Edition. Approved Standard NCCLS Document M11-A4, Vol. 17, No. 22, NCCLS, Wayne, PA, December 1997."

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (package insert submitted January 6, 2000). These revisions are terms of the NDA approval.

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 50-517/S-038." Approval of this submission by FDA is not required before the labeling is used.

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, call Beth Duvall-Miller, Project Manager, at (301) 827-2125.

Sincerely yours,

Gary K. Chikami, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

/s/

Beth Duvall-Miller
2/15/00 07:46:50 AM
CSO
Mefoxin approval letter dated 2/14/00.
Just sign off.

Frances LeSane
2/24/00 10:47:41 AM
CSO

James Blank
2/28/00 11:15:34 AM
MICROBIOLOGIST

Janice Soreth
1/7/01 02:50:21 PM
MEDICAL OFFICER

Gary Chikami
2/20/01 03:44:05 PM
MEDICAL OFFICER