

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-517/S-031

ADMINISTRATIVE DOCUMENTS
AND
CORRESPONDENCE

FEB 25 1997

NDA 50-517/S-031

NDA 50-581/S-020

REVIEW OF FINAL PRINTED LABELING (FPL)

APPLICANT: Merck & Co., Inc.
P.O. Box 4, BLA-20
West Point, PA 19462

DATE OF SUBMISSIONS: December 4, 1996

DATE OF REVIEW: February 18, 1997

NAME OF DRUG: NDA 50-517 Mefoxin^R (sterile cefoxitin sodium)
NDA 50-581 Mefoxin^R (cefoxitin sodium injection)

GENERIC NAME: See above

SUBMISSION HISTORY:

November 8, 1991: The Applicant submitted supplemental applications 50-517/S-031 and 50-581/S-020 providing for changes to the **DESCRIPTION, ADVERSE REACTIONS, COMPATIBILITY AND STABILITY** and **HOW SUPPLIED** sections of the labeling.

April 15, 1993: The Agency issued an approvable letter.

December 4, 1996: The Applicant submitted final printed labeling in response to the April 15, 1993 approvable letter.

COMMENTS:

The applicant has submitted labeling that is in compliance with the changes requested in the April 15, 1993 approvable letter.

HFD-520



Food and Drug Administration
Rockville MD 20857

Date NOV 14 1991

NDA No. 50-517

Merck Sharp & Dohme Research
Laboratories
West Point, Pennsylvania 19486

Attention: Ronald A. Salerno, Ph.D

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Mefoxin (sterile cefoxitin sodium, MSD)

NDA Number: 50-517

Supplement Number: S-031

Date of Supplement: November 8, 1991

Date of Receipt: November 12, 1991

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research, HFD-520
Attention: Document Control Room 12B-30
5600 Fishers Lane
Rockville, MD 20857

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For Supervisory Consumer Safety Officer
Division of Anti-Infective Drug Products
Center for Drug Evaluation and Research

Henrietta N. Ukwu
Senior Director
Worldwide Regulatory Liaison
Biologics/Vaccines

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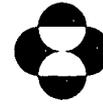
Merck & Co., Inc.
P.O. Box 4, BLA-20
West Point PA 19486
Fax 610 397 2962
Tel 610 397 7176

ORIGINAL

NDA SUPPL AMEND
SLR-031 (AF)

December 4, 1996

David W. Feigal, M.D., M.P.H. - Director
Division of Ant-Infective Drug Products
Center for Drug Evaluation and Research
Office of Drug Evaluation IV, HFD-520
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857



MERCK
Research Laboratories

Dear Dr. Feigal:

Supplemental New Drug Application: NDA 50-517/S-031
MEFOXIN (Sterile Cefoxitin Sodium)

Reference is made to the Supplemental New Drug Application 50-517/S-031 for MEFOXIN submitted on November 8, 1991. Reference is also made to your approvable letter dated April 15, 1993 regarding that supplemental application.

As requested in your approvable letter, attached are 15 mounted copies of circular #7882333.

This supplemental application (S-031) originally provided for the addition of "dyspnea" to the *Allergic Reactions* subsection of the ADVERSE REACTIONS section, for the addition of "sealed under nitrogen" to the DESCRIPTION section, editorial revisions to the COMPATIBILITY AND STABILITY section, changes to the HOW SUPPLIED section, and updating of the AHFS Category.

Questions concerning this supplemental application should be directed to Henrietta N. Ukwu, M.D. (610/397-7176) or, in my absence David W. Blois, Ph.D. (610/397-2304).

Sincerely yours,

Henrietta Ukwu, M.D.
Senior Director
Regulatory Liaison

Attachments

Certified No. P 914 184 015
Q/YARB/SAR/LTR/50517SS

**APPEARS THIS WAY
ON ORIGINAL**