

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-517/S-031

APPROVAL LETTER

NDA 50-517/S-031
NDA 50-581/S-020

FEB 27 1997

Merck & Co., Inc.
Attention: Henrietta Ukwu, M.D.
Senior Director
Regulatory Liaison
P.O. Box 4, BLA-20
West Point, PA 19462

Dear Dr. Ukwu:

Please refer to your November 8, 1991 supplemental new drug applications submitted under section 507 of the Federal Food, Drug, and Cosmetic Act for Mefoxin® (sterile cefoxitin sodium), NDA 50-517/S-031 and Mefoxin® (cefoxitin sodium injection), NDA 50-581/S-020.

We also refer to Agency approvable letter dated April 15, 1993, and your submission dated December 4, 1996.

These supplemental applications provided for changes to the **DESCRIPTION, ADVERSE REACTIONS, COMPATIBILITY AND STABILITY**, and **HOW SUPPLIED** sections of the labeling.

We have completed the review of these supplemental applications, including the submitted final printed labeling, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the final printed labeling in the submissions dated December 4, 1996. Accordingly, these supplemental applications are approved effective on the date of this letter.

Should additional information relating to the safety and effectiveness of the drugs become available, revision of that labeling may be required.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

**APPEARS THIS WAY
ON ORIGINAL**

NDA 50-517/S-031
NDA 50-581/S-020

If you have any questions, please contact:

Carmen DeBellas
Consumer Safety Officer
(301) 827-2125

Sincerely yours,

/S/ *2-27-97*
David W. Feigal, Jr., M.D., M.P.H.
Acting Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

cc:

Original NDA 50-517

NDA 50-581

HFD-520/Div. files

HFD-520/CSO/C.DeBellas */S/* *2/22/97*

HFD-520/ MO/Viraraghavan

HFD-104/T. Nearing

HFD-101/L. Carter

HFD-830/E. Sheinin

DISTRICT OFFICE

HF-2/Medwatch (with labeling)

HFD-80 (with labeling)

HFD-613 (with labeling)

HFD-735/(with labeling) - for all NDAs and supplements for adverse reaction changes.

drafted: /February 18, 1997/

r/d Initials:

final: APPROVAL

Concurrence:

HFD-520/SCSO/Bona */S/* *2/22/97*

HFD-520/SMO/Soreth */S/* *2/20/97*

HFD-520/DivDir/Feigal

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-517/S-031

APPROVABLE LETTER

NDA 50-517/S-031

NDA 50-581/S-020

Ronald A. Salerno, Ph.D.
Associate Director
Regulatory Affairs
Merck Sharp & Dohme Research Laboratories
Division of Merck & Co., Inc.
West Point, Pennsylvania 19486

APR 15 1993

Dear Dr. Salerno:

Reference is made to your supplemental New Drug Applications (NDA's) dated November 8, 1991, submitted pursuant to Section 507 of the Federal Food, Drug, and Cosmetic Act for NDA 50-517, Mefoxin^R (sterile cefoxitin sodium) and NDA 50-581, Mefoxin^R (sterile cefoxitin sodium injection).

These supplemental applications provide 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 _____

We have completed our review of these supplemental applications and have concluded that the applications are approvable. However, before the applications can be approved, we request that you remove the _____ from the labeling.

Within 10 days after the date of this letter, you are required to amend the applications, or notify us of your intent to file amendments, or follow one of the other options under 21 CFR 314.110. In the absence of such actions, the Food and Drug Administration may take action to withdraw these applications.

Should additional information relating to the safety and effectiveness of this drug product become available, further revision of the labeling may be required.

NDA 50-517/S-031
NDA 50-581/S-020
Page 2

If you have any questions concerning these applications, please contact Mr. Carmen DeBellas, Project Management Staff, at 301-443-6797.

Sincerely yours,

/S/ 4/14/93

Murray M. Lumpkin, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

CC: Orig NDA's
50-517
50-581

Concurrence:

HFC-130
HFD-82
HFD-473
~~HFD-520~~
HFD-735
HFD-500
HFD-638
HFD-520/DivDir/M. Lumpkin /S/ 4/16/93
HFD-520/SMO/Albrecht /S/ 4/23/93
HFD-520/MO/Leiss /S/ 4/23/93
HFD-520/CSO/DeBella /S/ 4/23/93
HFD-520/Label File/DeSa.itis
APPROVABLE

HFD-520/SCSO/Bor

/S/ 2/22/93

**APPEARS THIS WAY
ON ORIGINAL**