CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-517/S-038

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

Virginia G. Snyder
Manager
Regulatory Affairs

Merck & Co., Inc.
P.O. Box 4, BLA-20
West Point PA 19486
Tel 610 397 7984
215 652 5000
Fax 610 397 2516

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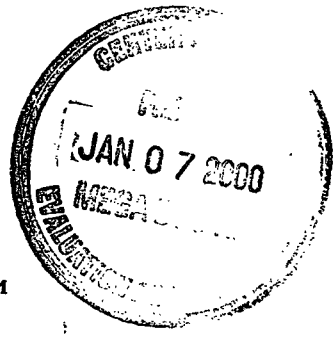
January 6, 2000

MERCK
Research Laboratories

Gary K. Chikami, MD, Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV (CDER)
HFD-520, Room S348
Food and Drug Administration
9201 Corporate Boulevard
Rockville, MD 20850



NDA 50-517/S-038: MEFOXIN™
(Cefoxitin for Injection)

Amendment to a Pending Supplemental New Drug Application

Dear Dr. Chikami:

Reference is made to the supplemental New Drug Application cited above for MEFOXIN™ submitted by Merck Research Laboratories (MRL), a division of Merck & Co., Inc. on April 15, 1996. Reference is also made to the Agency's comments conveyed via facsimile on May 4, 1999 regarding that supplemental New Drug Application.

With this letter, MRL is responding to the Agency's comments of May 4, 1999. The circular has been revised under CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE and REFERENCES sections as illustrated in the annotated circular and the Summary of Revisions. All Agency comments were addressed with the exception that under CLINICAL PHARMACOLOGY "Streptococcus pyrogenes" is retained in List 1 as it is included in the INDICATIONS and USAGE section. Additionally, an editorial revision was made in the REFERENCE section.

As required by Section 306(k)(1) of the Generic Enforcement Act [21 U.S.C. 335a(k)(1)], we hereby certify that, in connection with this application, Merck & Co., Inc. did not and will not use in any capacity the services of any person debarred under subsections 306(a) or (b) of the Act.

ORIGINAL NDA ORIG AMENDMENT

We consider the filing of this Supplemental New Drug Application to be a confidential matter, and request that the Food and Drug Administration not make its content, nor any future communications in regard to it, public without first obtaining the written permission of Merck & Co., Inc.

Please direct questions or need for additional information to Virginia G. Snyder (610/397-7984) or, in my absence, Dennis M. Erb, PhD (610/397-7597).

Sincerely,

Virginia G. Snyder
Manager
Regulatory Affairs

Attachments

Federal Express

APPEARS THIS WAY
ON ORIGINAL

q:graz/nicole/mefoxin/50517

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date APR 23 1996

NDA No.50-517

Henrietta Ukwu, M.D.
Merck Research Laboratories
Sumneytown Pike
West Point, PA 19486

Attention:Henrietta Ukwu, M.D.

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Mefoxin (Sterile Cefoxitin Sodium)

NDA Number: 50-517

Supplement Number: S-038

Date of Supplement: April 15, 1996

Date of Receipt: April 19, 1996

Unless we find the application not acceptable for filing, the filing date will be 60 days from the receipt date above.

All communications concerning this NDA should be addressed as follows:

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

Sincerely yours,

/S/

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

ORIGINAL

Henrietta N. Ukwu, M.D.
Director
Regulatory Liaison

Merck & Co., Inc.
P.O. Box 4, BLA-30A
West Point PA 19486-0004
Fax 610 397 2962
Tel 610 397 7176
215 652 5000

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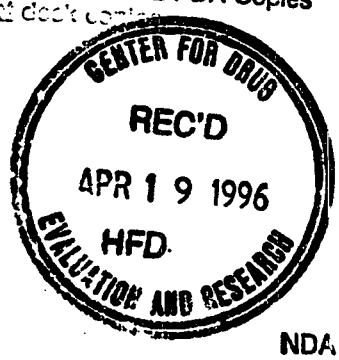


MERCK
Research Laboratories

April 15, 1996

Mary Fanning, M.D., Director
Division of Anti-Infective Drug Products
HFD-520, Room 12B-45
Office of Drug Evaluation II (CDER)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

NDA NO. 50577 REF. NO. S-028
NDA SUPPL FOR Draft

Dear Dr. Fanning:

Supplemental New Drug Application NDA 50-517
MEFOXIN® (Sterile Cefoxitin Sodium)

Pursuant to Section 505(b) of the Food Drug and Cosmetic Act and in accordance with 21 CFR 314.70(b), we submit, for your approval, a supplement to NDA 50-517.

As indicated on the attached Form FDA 356h, the supplemental application provides for changes in Item 4(c)i of the approved New Drug Application for MEFOXIN ®.

Attached for approval is an annotated draft package circular, a Summary of Revisions and supportive information. The circular has been revised under CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE and REFERENCES according to the January 26, 1993 NDA Holders Letter for Microbiological Labeling Information.

As required by Section 306(k)(1) of the Generic Enforcement Act [21 U.S.C. 335a(k)(1)], we hereby certify that, in connection with this application, Merck & Co., Inc. did not and will not use in any capacity the services of any person debarred under subsections 306(a) or (b) of the Act.

We consider the filing of this Supplemental New Drug Application to be a confidential matter, and request the Food and Drug Administration not to make its content, nor any future communications in regard to it, public without first obtaining the written permission of Merck & Co., Inc.

Questions concerning this supplemental application should be directed to Henrietta N. Ukwu M.D. (610/397-7176) or, in my absence Bonnie J. Goldmann, M.D. (610/397-2383).

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS DATE

Sincerely yours,

Henrietta Ukwu, M.D., Director
Regulatory Affairs

Attachments

Certified No. P 914 178 776
Q/YARB/SARF/LTR/FPL50517

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314)

Form Approved: OMB No. 0910-0001
Expiration Date: June 30, 1992
See OMB Statement on Page 3.

FOR FDA USE ONLY	
DATE RECEIVED	DATE FILED
DIVISION ASSIGNED	NDA/ANDA NO. ASS.

NOTE: No application may be filed unless a completed application form has been received *(21 CFR Part 314)*.

NAME OF APPLICANT	DATE OF SUBMISSION
Merck Research Laboratories	4-15-96
ADDRESS *(Number, Street, City, State and Zip Code)*	TELEPHONE NO *(Include Area Code)*
Sumneytown Pike West Point, PA 19486	(610)397-7176
	NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER (If previously issued) 50-517

DRUG PRODUCT

ESTABLISHED NAME *(e.g., USP/USAN)*	PROPRIETARY NAME *(If any)*
Sterile Cefoxitin Sodium	MEFOXIN®

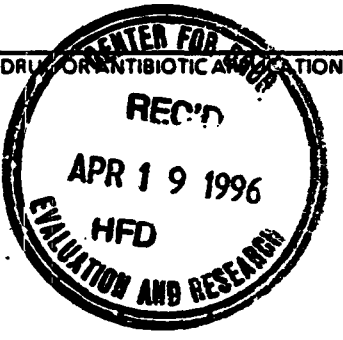
CODE NAME *(If any)*	CHEMICAL NAME
	sodium salt of 3-(hydroxymethyl)-7α methoxy-8-oxo-7-[2-(2-thienyl)acetamidol]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate carbamate (ester).

DOSAGE FORM	ROUTE OF ADMINISTRATION	STRENGTH(S)
	I.M.	1 gm 2 gm
	I.V.	10 gm

PROPOSED INDICATIONS FOR USE

Treatments of serious infections caused by susceptible strains of designated microorganisms.

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS *(21 CFR Part 312)*, NEW DRUG OR ANTIBIOTIC APPLICATIONS *(21 CFR Part 314)*, AND DRUG MASTER FILES *(21CFR 314 420)* REFERRED TO IN THIS APPLICATION:



INFORMATION ON APPLICATION

TYPE OF APPLICATION *(Check one)*

☐ THIS SUBMISSION IS A FULL APPLICATION *(21 CFR 314.50)* ☐ THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG	HOLDER OF APPROVED APPLICATION

STATUS OF APPLICATION *(Check one)*

☐ PRESUBMISSION ☐ ORIGINAL APPLICATION ☐ AN AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION ☒ SUPPLEMENTAL APPLICATION

PROPOSED MARKETING STATUS *(Check one.*

☒ APPLICATION FOR A PRESCRIPTION DRUG PRODUCT *(Rx)* ☐ APPLICATION FOR AN OVER - THE - COUNTER PRODUCT *(OTC)*