CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 62-756/S-038

Name: Primaxin I.V. in ADD-Vantage Vials
(Imipenem-Cilastatin Sodium for Injection)

Sponsor: Merck & Co., Inc

Approval Date: October 17, 2002

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 62-756/S-038

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Microbiology Review	
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Correspondence	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 62-756/S-038

APPROVAL LETTER

ANDA 62-756/S-038

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

OCT 17 2002

Dear Madam:

This is in reference to your supplemental new drug application dated July 10, 2002, submitted under section 505 (j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for PRIMAXIN™ I.V. in ADD-Vantage™ Vials, 250 mg and 500 mg.

Reference is also made to your amendment dated September 12, 2002.

The supplemental application, submitted as "Changes Being Effected in 30 days", provides for the use of two new ——— in the manufacture of ——— under DMF ———.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

10/16/02

Florence S. Fang
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 62-756/S-038
FIELD COPY
Division File
HFD-92

Endorsements:
HFD-643/M.Shih/10/3/02 10/10/02
HFD-643/R.Adams/10/7/02 R.C. adams 10/5/02
HFD-617/M.Anderson/10/9/02 M Anderson 10/11/02

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F/T by rd10/10/02

SUPPLEMENT APPROVAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 62-756/S-038

CHEMISTRY REVIEW

ANDA 62-756/S-038

NAME AND ADDRESS OF APPLICANT
Merck & Co. Inc.
Attention: Virginia G. Snyder
P.O. Box 4
Sumneytown Pike, BLA-20
West Point, PA 19486

PURPOSE OF SUPPLEMENT
The "Changes Being Effected in 30 days" supplemental application provides for the use of two new ——— in the manufacture of ——————————————— under DMF ——.

DATE OF SUBMISSION
7/10/02
9/12/02 (Amendment)

PHARMACOLOGICAL CATEGORY	TRADE NAME	NONPROPRIETARY NAME
Antibiotic	PRIMAXIN™ I.V. in ADD-Vantage™ Vials	(Imipenem-Cilastatin)

DOSAGE FORM	POTENCY	RX OR OTC
Powder	250 mg and 500 mg	RX

RELATED IND/NDA/DMF
DMF ——— (Type III)

STERILIZATION	LABELING
N/A	N/A

BIOEQUIVALENCY STATUS N/A

ESTABLISHMENT INSPECTION N/A

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS
1. [redacted]

Similar supplements were filed and approved for ——— applications previously (——— approved ———), seeking the same change in ———.

In this Merck's supplement, not much information is provided except the updated DMF information. Since this is a rather simple issue, we will approve this supplement based on the approval of similar supplements for generic applications on the same issue.

2. Type III DMF —— is referred. Since approval of the above-mentioned supplements, the DMF has been updated (Amendment 10/23/01) with Section III.B Sterilization Process and Validation and Section VIII Microbial Maintenance of Sterility (MOS) ——— (from brief CMC review of DMF #——). According to Micro decision dated 5/24/02, no additional review for this DMF is needed at present.

PACKAGING
See above

STABILITY
N/A

REMARKS AND CONCLUSION
Approval recommended

RECALLS	Reviewer	Date Completed
N/A	Maria C. Shih	10/3/02

The submissions covered by this review was taken in the date order of receipt.

YES _X_

DMF #	TYPE/SUBJECT/HOLDER	ACTION CODE	RESULT OF REVIEW	REVIEW COMPLETED
———	III/ ———————————	1	adequate	3/7/01

Comments: New amendment 10/23/01 regarding Sterilization Process and Microbiological maintenance. Micro staff decides no review is needed 5/24/02.

Comments:

Comments:

Comments:

Comments:

ACTION CODES: (1) DMF Reviewed. Other codes indicate why the DMF was not reviewed, as follows:

(2) Type 1 DMF;
(3) Reviewed previously and no relevant revision since last review;
(4) Sufficient information in application;
(5) Authority to reference not granted;
(6) DMF not available;
(7) Other (explain under "Comments").

Maria C. Shih — Signature — 10/10/02 — 10/3/02

Reviewer — Signature — Date

cc: ANDA 62-756/S-038
FIELD COPY
Division File

Endorsements:
HFD-643/M.Shih/10/3/02 10/10/02
HFD-643/R.Adams/10/7/02 R-C. Adams 10/8/02

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F/T by rad10/10/02

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 62-756/S-038

ADMINISTRATIVE DOCUMENTS

MDA 11.1

SPECIAL

CBE- THIRTY (30) DAY SUPPLEMENT ROUTING FORM

This form is to accompany all CBE-30 Day supplements. Upon completion, return to the OGD Document Room

I. To be completed by the OGD Document Room using information from the applicant Cover letter:

DATE PROCESSED: 7-11-02
APPLICATION #: 62-156 SUPPLEMENT #: SCP-038-AT

II. To be determined by Chemistry Division Staff.

Date and initial appropriate category.

Thirty (30) Day CBEs:

Chemistry Div. Staff	Qualifies as CBE-30 (GR)	Does Not Qualify. This is a CBE-0. (DC)	Does not Qualify. This is an Annual Report (DA)	Does not Qualify. This is a Prior Approval Supp. (DN)
Chemistry/Micro Project Manager(s)	MA 7/15			
Micro and/or Labeling Team Leader (as needed)				
Chemistry Team Leader	RA 7/23/02			
Chemistry Div. Dir. Or Deputy* Dir.				

*Div/Deputy Director signature needed only when: 1) CBE elevated to PAS or 2) PM/TM recommend different actions,
COMMENTS:

III. To Project Manager Chemistry Team 6 :

Prepare letter and notify applicant by telephone when CBE is denied because it is a prior approval supplement. DATE

Notify applicant by telephone that inappropriate CBE category used. DATE

submssion as an Annual Report DATE

IV. To Document Room

File in archival submission

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 62-756/S-038

CORRESPONDENCE

Virginia G. Snyder
Manager
Regulatory Affairs

Merck & Co., Inc.
P.O. Box 4, BLA-20
West Point PA 19486
Tel 484 344 7984
215 652 5000
Fax 484 344 2516

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July 10, 2002

MERCK
Research Laboratories

Gary Buehler, R.Ph., Director
Division of Generic Drug Products
Bldg. MPN2, HFD-600, Room 286 (CDER)
Food and Drug Administration
Metro Park North 2
7500 Standish Place
Rockville, MD 20855

NDA NO 62-756 REF NO SCP-538-AT
NDA SUPPL FOR Packaging Change

Dear Mr. Buehler:

AADA 62-756: PRIMAXIN™ IV in ADD-Vantage™ Vials
(Imipenem and Cilastatin)

RECEIVED
JUL 11 2002
CDER

SUPPLEMENT - CHANGES BEING EFFECTED in 30 Days

Pursuant to Section 505(b) of the Food, Drug and Cosmetic Act and in accordance with 506A(d)(3)(B (i) of the Food and Drug Administration Modernization Act, we submit, for the Agency's review and approval, a supplement to AADA 62-756.

As indicated on the attached Form FDA 356h, this supplemental application provides for changes in the *Chemistry* Section of the approved Abbreviated Antibiotic Drug Application for PRIMAXIN™ IV in ADD-Vantage™ Vials. This application provides for the use of two new ——— for manufacturing the ———. A Letter of Authorization to reference ——— Type III Drug Master File —— is included. The Statement of Organization following this letter describes the sections contained in this application

In accordance with the Prescription Drug User Fee Act of 1992 (PDUFA) and reauthorized in the Food and Drug Administration Modernization Act of 1997 (FDAMA), as indicated in the attached Form 3397, no user fee is required for this supplemental application.

Merck & Co., Inc. is requesting a categorical exclusion for the requirements to prepare an Environmental Assessment under 21 CFR 25.31(a). This supplement meets the requirements of a categorical exclusion under 21 CFR 25.31(a) because it will not increase the use of the active moiety. To the best of the firm's knowledge no extraordinary circumstances exist in regard to this action.

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.

Questions concerning this supplemental application should be directed to Virginia G. Snyder (484-344-7984) or, in my absence, to Dennis M. Erb, Ph.D. (484-344-7597).

Sincerely,

Virginia G. Snyder
Manager
Regulatory Affairs

Attachments

Federal Express #1

Desk Copies: Mr. Mark D. Anderson, Regulatory Project Manager (cover letter)
HFD-640, Room E251
Federal Express #2

Ms. Debra L. Pagano (Item 4 & cover letter)
Philadelphia District Office, FDA
Federal Express #3

Q:\dubs\PRIMAXINaada\ cbe30_jun02

Virginia G. Snyder
Manager
Regulatory Affairs

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Merck & Co., Inc.
P.O. Box 4, BLA-20
West Point PA 19486
Tel 484 344 7984
215 652 5000
Fax 484 344 2516

September 12, 2002

Gary Buehler, R.Ph., Director
Division of Generic Drug Products
Bldg. MPN2, HFD-600, Room 286 (CDER)
Food and Drug Administration
Metro Park North 2
7500 Standish Place
Rockville, MD 20855

MERCK
Research Laboratories

NEW CORRESP
NC-TD
SCP-038

Dear Mr. Buehler:

AADA 62-756/S-038: PRIMAXIN™ IV in ADD-Vantage™ Vials (Imipenem and Cilastatin)

Response to FDA Request for Information

Reference is made to the above cited supplemental Abbreviated Antibiotic Drug Application for PRIMAXIN™ IV in ADD-Vantage™ Vials, Changes Being Effected in 30 Days, submitted on July 10, 2002. Additional reference is made to a September 9, 2002 telephone conversation between Mr. Mark Anderson (FDA) and Mr. Kenneth Kramer (MRL, a Division of Merck & Co., Inc.) in which Mr. Kramer was informed that the *Chemistry* section of supplement S-038 had not been received. By copy of this letter, we are resubmitting the entire Supplemental Application of July 10, 2002 to insure the completeness of the files.

We apologize for any inconvenience this may have caused.

Questions concerning this submission should be directed to Virginia G. Snyder (484-344-7984) or, in my absence, to Dennis M. Erb, Ph.D. (484-344-7597).

Sincerely,

Kenneth Kramer for

Virginia G. Snyder
Manager, Regulatory Affairs

Attachments

Federal Express #1

Desk Copies: Mr. Mark D. Anderson, Regulatory Project Manager (cover letter)
HFD-640, Room E251
Federal Express #2

Ms. Debra L. Pagano (Item 4 + cover letter)
FDA, Philadelphia District Office
Federal Express #3

Q:\dubs\primaxinaada\62_756resubmit S_038

RECEIVED
SEP 13 2002
OGD / CDER