CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

76394

CORRESPONDENCE

ANDA 76-394

JUN - 6 2002

Apotex Corp.
Attention: Marcy Macdonald
50 Lakeview Parkway
Suite 127
Vernon Hills, IL 60061

Dear Madam:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

NAME OF DRUG: Amiodarone Hydrochloride Injection, 50 mg/mL, 3 mL vials

DATE OF APPLICATION: April 4, 2002

DATE (RECEIVED) ACCEPTABLE FOR FILING: April 10, 2002

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Stanley Sheppardson
Project Manager
(301) 827-5849

Sincerely yours,

/S/

Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

APOTEX CORP.

50 LAKEVIEW PARKWAY • SUITE 127 • VERNON HILLS • ILLINOIS 60061 • TEL (847) 573-9999 • FAX: (847) 573-1001

labeling review
drafted 10/22/02
A. Vega

October 11, 2002

ORIG AMENDMENT
N/Am
FPL

Office of Generic Drugs
CDER, FDA
MPN II, HFD-600
7500 Standish Place
Rockville, MD 20855

MINOR AMENDMENT

RE: Amiodarone Hydrochloride Injection
50 mg/mL, 3 mL Vials
ANDA No. 76-394

To Whom It May Concern:

Apotex Corp., is hereby submitting in duplicate a minor amendment in response to the FDA minor deficiency letter dated August 13, 2002.

If you have any further questions, please do not hesitate to contact me.

Sincerely,

Marcy Macdonald

Marcy Macdonald
Director, Regulatory Affairs
Ext. 223

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OCT 15 2002
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MM 10/8/02

APOTEX CORP.

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Labeling reviewed
Drafted 11/13/02
A. Vega

ORIG AMENDMENT

N/AF

November 5, 2002

Office of Generic Drugs
CDER, FDA
MPN II, HFD-600
7500 Standish Place
Rockville, MD 20855

LABELING AMENDMENT

RE: Amiodarone Hydrochloride Injection
50 mg/mL, 3 mL Vials
ANDA No. 76-394

To Whom It May Concern:

Apotex Corp., is hereby submitting in duplicate a labeling amendment in response to the telephone conversation between Lillie Golson, FDA and Marcy Macdonald, Apotex Corp., on November 4, 2002.

If you have any further questions, please do not hesitate to contact me.

Sincerely,

Marcy Macdonald

Marcy Macdonald
Director, Regulatory Affairs
Ext. 223

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APOTEX CORP.

50 LAKEVIEW PARKWAY • SUITE 127 • VERNON HILLS • ILLINOIS 60061 • TEL: (847) 573-9999 • FAX: (847) 573-1001

labeling review drafted 11/13/02 A.V.

October 25, 2002

ORIG AMENDMENT

N/AF

FPL

Office of Generic Drugs
CDER, FDA
MPN II, HFD-600
7500 Standish Place
Rockville, MD 20855

LABELING AMENDMENT

RE: Amiodarone Hydrochloride Injection
50 mg/mL, 3 mL Vials
ANDA No. 76-394

To Whom It May Concern:

Apotex Corp., is hereby submitting in duplicate a labeling amendment in response to the FDA labeling deficiency letter dated October 24, 2002.

If you have any further questions, please do not hesitate to contact me.

Sincerely,

Marcy Macdonald

Marcy Macdonald
Director, Regulatory Affairs
Ext. 223

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APOTEX CORP.

50 LAKEVIEW PARKWAY • SUITE 127 • VERNON HILLS • ILLINOIS 60061 • TEL: (847) 573-9999 • FAX: (847) 573-1001

ORIG AMENDMENT
N/AM

January 24, 2003

Office of Generic Drugs
CDER, FDA
MPN II, HFD-600
7500 Standish Place
Rockville, MD 20855

RESPONSE TO
MICROBIOLOGY DEFICIENCY

RE: Amiodarone Hydrochloride Injection
50 mg/mL, 3 mL Vials
ANDA No. 76-394

To Whom It May Concern:

Apotex Corp., is hereby submitting in duplicate a microbiology amendment in response to the FDA minor deficiency letter dated December 18, 2002.

If you have any further questions, please do not hesitate to contact me.

Sincerely,

Marcy Macdonald
Director, Regulatory Affairs
Ext. 223

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JAN 28 2003
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50 LAKEVIEW PARKWAY • SUITE 127 • VERNON HILLS • ILLINOIS 60061 • TEL: (847) 573-9999 • FAX: (847) 573-1001

ORIG AMENDMENT
N/AM

January 29, 2003

Office of Generic Drugs
CDER, FDA
MPN II, HFD-600
7500 Standish Place
Rockville, MD 20855

MINOR AMENDMENT

RE: Amiodarone Hydrochloride Injection
50 mg/mL, 3 mL Vials
ANDA No. 76-394

To Whom It May Concern:

Apotex Corp., is hereby submitting in duplicate a minor amendment in response to the FDA minor deficiency letter dated December 18, 2002. A field copy is also included. The microbiology response was submitted on January 24, 2003.

If you have any further questions, please do not hesitate to contact me.

Sincerely,

Marcy Macdonald

Marcy Macdonald
Director, Regulatory Affairs
Ext. 223

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JAN 31 2003
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APOTEX CORP.

50 LAKEVIEW PARKWAY • SUITE 127 • VERNON HILLS • ILLINOIS 60061 • TEL: (847) 573-9999 • FAX: (847) 573-1001

NEW CORRESP

NC

April 16, 2003

Office of Generic Drugs
CDER, FDA
MPN II, HFD-600
7500 Standish Place
Rockville, MD 20855

RESPONSE TO
TELEPHONE AMENDMENT

RE: Amiodarone Hydrochloride Injection
50 mg/mL, 3 mL Vials
ANDA No. 76-394

To Whom It May Concern:

Apotex Corp., is hereby submitting in duplicate a telephone amendment in response to the telephone conversation between Stanley Shepperson, FDA and Rashmi Amin, Apotex Corp., on April 16, 2003.

If you have any further questions, please do not hesitate to contact me.

Sincerely,

Rashmi M-Amin
for

Marcy Macdonald
Director, Regulatory Affairs
Ext. 223

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APR 17 2003

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APOTEX CORP.

50 LAKEVIEW PARKWAY • SUITE 127 • VERNON HILLS • ILLINOIS 60061 • TEL: (847) 573-9999 • FAX: (847) 573-1001

6/4/02 Note for filing 505(b)(2)

Concur. 05-JUN-2002

April 4, 2002

Document Control Room
Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

RE: Amiodarone Hydrochloride Injection
50 mg/mL
Original Abbreviated New Drug Application

To Whom It May Concern:

Pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, as amended September 24, 1994, Apotex Corp., hereby submits an original abbreviated new drug application (ANDA) for Amiodarone Hydrochloride Injection 50 mg/mL.

We are submitting an archival copy under blue cover, a chemistry review and two additional copies of the analytical methods section under red cover, and the bioavailability/bioequivalence review section under orange cover.

Apotex Corp. hereby certifies that in accordance with 21 CFR 314.94(d)(5), a true field copy of the technical sections of this submission under a burgundy cover is also included.

We appreciate an expeditious review of this application. Please direct any inquiries regarding this application to me at the addresses listed above.

Sincerely,

Marcy Macdonald

Marcy Macdonald
Associate Director
Regulatory Affairs
Ext. 223

RECEIVED
APR 10 2002
OGD / CDER