CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20377/S002

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DF

NDA 20-377/S-002

DEC 10 1997

Wyeth-Ayerst Laboratories
Attention: Ms. Diane Mitrione
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Mitrione:

Please refer to your July 12, 1996 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cordarone (amiodarone HCl) I.V., 50 mg/mL in 3 mL vial.

We also acknowledge receipt of your submissions dated April 25 and October 1, 1997.

The supplemental application provides for final printed labeling revised under **DOSAGE AND ADMINISTRATION** recommending that glass evacuated bottles not be used for admixing Cordarone I.V. as incompatibility with a buffer in the container may cause precipitation. The labeling was further revised to add a **SURGERY** subsection under **PRECAUTIONS/DRUG INTERACTIONS/Potential drug class interactions with Cordarone** subsection to add the words "Volatile Anesthetic Agents: (See "Precautions, SURGERY")." The adverse event term "toxic epidermal necrolysis" has been added under **ADVERSE REACTIONS.**

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling included with your October 1, 1997 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20852-9787

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

If you have any questions, please contact:

Ms. Diana Willard
Regulatory Health Project Manager
(301) 594-5311

Sincerely yours,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Original NDA
HFD-110
HF-2/MedWatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling)
DISTRICT OFFICE
HFD-810/ONDC Division Director
HFI-20/Press Office (with labeling)
HFD-110/DWillard/11/10/97
sb/11/13/97

Approval Date: August 3, 1995

APPROVAL (AP)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-377/S-002

APR 18 1997

Wyeth-Ayerst Laboratories
Attention: Mr. Timothy K. Ressler
P. O. Box 8299
Philadelphia, PA 19101-8299

Dear Mr. Ressler:

Please refer to your July 12, 1996 supplemental new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cordarone (amiodarone HCl) I.V.

We acknowledge receipt of your amendment dated August 1, 1996.

The supplemental application provides for draft labeling revised under Dosage and Administration recommending that glass evacuated bottles not be used for admixing Cordarone I.V. as incompatibility with a buffer in the container may cause precipitation. The draft labeling further provides for the addition of a SURGERY subsection under Precautions as well as the addition of a Precautions/ DRUG INTERACTIONS/Potential drug class interactions with Cordarone subsection to add the words "Volatile Anesthetic Agents: (see "Precautions, SURGERY")."

We have completed the review of this supplemental application as submitted with draft labeling and it is approvable. Before this supplement may be approved, however, it will be necessary for you to submit final printed labeling (FPL). The labeling should be identical in content to the draft labeling included with your July 12, 1996 submission. In addition, all previous revisions as reflected in the most recently approved package insert must be included. To facilitate review of your submission, please provide a highlighted or marked-up copy that shows the changes that are being made.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the FPL may be required.

Please submit sixteen copies of the printed labeling ten of which are individually mounted on heavy weight paper or similar material.

Within 10 days after the date of this letter, you are required to amend this supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of such action, FDA may take action to withdraw this supplemental application.

These changes may not be implemented until you have been notified in writing that this supplemental application is approved.

Should you have any questions, please contact:

Ms. Diana Willard
Regulatory Health Project Coordinator
Telephone: (301) 594-5311

Sincerely yours,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Original NDA
HFD-92
HFD-110
DISTRICT OFFICE
HFD-110/DWillard/3/27/97;4/9/97
sb/3/28/97;4/18/97
R/D: RWolters/4/10/97
JPiechocki
NMorgenstern/4/17/97

Approval Date: August 3, 1995

APPROVABLE