# CENTER FOR DRUG EVALUATION AND RESEARCH

**Application Number: NDA 20377/S001**

## APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OF

OCT 18 1995

NDA 20-377/S-001

Wyeth-Ayerst Laboratories
Attention: Joseph L. Morrison, Ph.D.
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr. Morrison:

Please refer to your September 19, 1995 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cordarone (amiodarone HCl) I.V.

The supplemental application provides for incorporation of modifications to the **DOSAGE AND ADMINISTRATION** section to help ensure proper use of the product as follows:

Under **Dosage and Administration,** in the **CORDARONE I.V. DOSE RECOMMENDATIONS** chart, under "Loading Infusions", the words "Rapid" and "Slow" are now preceded by the modifiers "First" and "Followed by," respectively. The chart has been changed from:

**CORDARONE I.V. DOSE RECOMMENDATIONS**
**-FIRST 24 HOURS-**

| | | |
|---|---|---|
| Loading infusions | Rapid: | 150 mg over the FIRST 10 minutes (15 mg/ml). Add 13 mL of Cordarone I.V. (150 mg) to 100 mL $D_5W$ (concentration = 1.5 mg/ml). Infuse 100 mL over 10 minutes. |
| | Slow: | 360 mg over the NEXT 6 hours (1 mg/min). Add 18 mL of Cordarone I.V. (900 mg) to 500 mL $D_5W$ (concentration = 1.8 mg/mL). |
| Maintenance infusion | | 540 mg over the REMAINING 18 hours (0.5 mg/min). Decrease the rate of the slow loading infusion to 0.5 mg/min. |

to:

**CORDARONE I.V. DOSE RECOMMENDATIONS**
**-FIRST 24 HOURS-**

| | |
|---|---|
| Loading infusions First Rapid: | 150 mg over the FIRST 10 minutes (15 mg/ml). Add 13 mL of Cordarone I.V. (150 mg) to 100 mL $D_5W$ (concentration = 1.5 mg/ml). Infuse 100 mL over 10 minutes. |
| Followed by Slow: | 360 mg over the NEXT 6 hours (1 mg/min). Add 18 mL of Cordarone I.V. (900 mg) to 500 mL $D_5W$ (concentration = 1.8 mg/mL). |
| Maintenance infusion | 540 mg over the REMAINING 18 hours (0.5 mg/min). Decrease the rate of the slow loading infusion to 0.5 mg/min. |

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 in the September 19, 1995 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

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
Consumer Safety Officer
(301) 594-5300

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
HF-2/MedWatch (with labeling)
HFD-80 (with labeling)
HFD-110
~~HFD-110/CSO~~
HFD-240 (with labeling)
HFD-613 (with labeling)
HFD-735/DBarash (with labeling)
HFD-110/DWillard
sb/10/16/95;10/17/95
R/D: NStockbridge/10/16/95
NMorgenstern
GBuehler for NMorgenstern

Approval Date: August 3, 1995

APPROVAL