

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20377/S002

CHEMISTRY REVIEW(S)

DIVISION OF CARDIO-RENAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

DF
MAR 27 1997

NDA #: 20-377

DATE REVIEWED: 17-March-1997

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
------------------------	----------------------	------------------	----------------------

SUPPLEMENT

SNC	07-06-96	13-08-96	13-08-96
S-002 (SLR)	12-07-96	16-07-96	22-07-96

Supplements provide for:

SNC ADR report regarding the inability to prepare diluted solutions of the product for infusion, according to insert instructions.
SLR-002 Changes in the package insert language to ensure proper preparation of dilute solutions of the product for infusion.

AMENDMENT

To SLR-002	01-08-96	06-08-96	08-08-96
------------	----------	----------	----------

Amendment provides for:

SLR-002 Additional literature articles to support labeling changes proposed in original supplement.

NAME & ADDRESS OF APPLICANT:

Wyeth-Ayerst Laboratories
P.O. Box 8299
Philadelphia, PA 19101
(215) 314-2204

DRUG PRODUCT NAME

<u>Proprietary:</u>	Cordarone® HCl
<u>Nonproprietary/Established/USAN:</u>	Amiodarone HCl
<u>Code Name and/or Number:</u>	CAS-19774-82-4
<u>Code Name/#:</u>	WY-48776-HCl
<u>Chem.Type/Ther.Class:</u>	3D

ANDA Suitability Petition / DESI / Patent Status: N/A [if applicable]

PHARMACOLOGICAL CATEGORY/INDICATION:

Emergency use in patients with refractory ventricular tachycardia/fibrillation when other drugs have been ineffective or not well tolerated.

DOSAGE FORM:

IV

STRENGTHS:

50 mg/mL (150 mg/ampul)

ROUTE OF ADMINISTRATION:

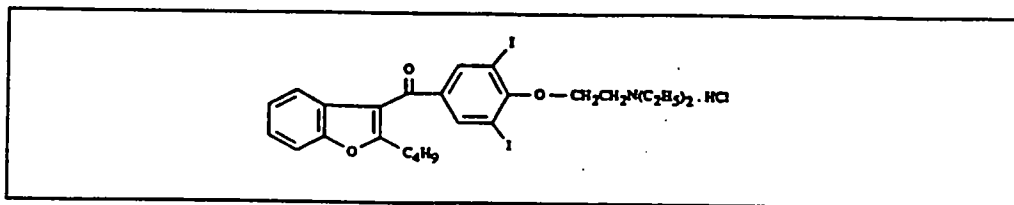
IV

DISPENSED:

Rx OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

(2-Butyl-3-benzofuranyl)[4-(diethylamino)ethoxy]-3, 5-diiodophenyl]methanone hydrochloride
 Methanone, (2-butyl-3-benzofuranyl)[4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl]



Mol. Formula: $C_{25}H_{29}I_2NO_3 \cdot HCl$

M.W.: 681.78

CONCLUSIONS & RECOMMENDATIONS:

The submitted labeling has been reviewed and does not appear acceptable from a chemistry perspective.

cc:

Org. NDA 20-377

HFD-110/Division File ✓

HFD-110/JTPiechocki/3-17-97 *JTP*

HFD-110/DMWillard

R/D Init by: RJWolters

20377S02.jtp

ISI

3/18/97

Joseph T. Piechocki, Ph.D., Chemist

JTP
3/18/97