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APPLICATION NUMBER: NDA 20377/S001

CHEMISTRY REVIEW(S)

DF

NOV 27 1995

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

NDA #: 20-377

DATE REVIEWED: November 16, 1995

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
AMENDMENT AL	12-05-95	15-05-95	17-05-95
SUPPLEMENT S-001 (SLR)	19-09-95	21-09-95	26-09-95

Amendment provides for:

AL An updated draft package insert, as per our second approvable letter dated April 25, 1995.

Supplement provides for:

SLR-001 a "Special Supplement - Changes Being Effected" which incorporates minor changes in the package insert language to ensure proper use of the product.

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:

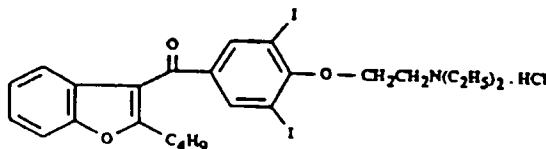
50 mg/mL (150 mg/ampul)

ROUTE OF ADMINISTRATION:

IV

DISPENSED:☒ Rx ☐ OTCCHEMICAL 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: C₂₅H₂₆I₂NO₃•HCl

M.W.: 681.78

CONCLUSIONS & RECOMMENDATIONS:

The submitted labeling has been reviewed and appears acceptable from a chemistry perspective.

cc:

Org. NDA 20-377

HFD-110/Division File

HFD-110/JTPlechocki/11-16-95

HFD-110/DMWillard

R/D Init by: RJWolters

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/S/

11-16-95

Joseph T. Plechocki, Ph.D., Chemist