

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-761

**BIOEQUIVALENCE
REVIEW(S)**

Amiodarone HCL
for Injection
3 mL fill (50mg/mL)
in a 3 mL vial
ANDA #75-761

American Pharmaceutical Partners
Melrose Park, IL.
Submission Date:
December 22, 1999

Reviewer: Andre Jackson
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Review of Waiver Request

I. Background:

The firm has requested a waiver of the bioequivalence study requirements for its product Amiodarone for Injection, 3 mL fill in a 3 mL vial. The innovator product is Cordarone® , 3 mL fill in a 3 mL ampul for Injection manufactured by Wyeth Ayerst.

II. Formulations: (Not to be released under FOI)

The formulations of American Pharmaceutical Partners' Amiodarone for injection and Wyeth Ayerst's Cordarone® for injection are shown in Table I.

Table 1. Comparative formulations for the test and reference products.

Contents	Test mg/mL	Reference mg/mL
Amiodarone HCL	50	50
Polysorbate 80, NF	100	100
Benzyl Alcohol, NF	20.2	20.2
Water for Injection, USP	qs	qs

Comments:

1. The active and inactive ingredients and their concentrations for the test products are the same as those of the innovator's Cordarone® , 3 mL fill in a 3 mL ampul for Injection manufactured by Wyeth Ayerst.

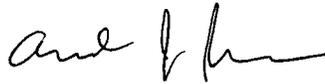
2. The waiver of the in vivo bioequivalence study requirement may be granted based on 21 CFR 320.22(b)(1).

APPEARS THIS WAY
ON ORIGINAL

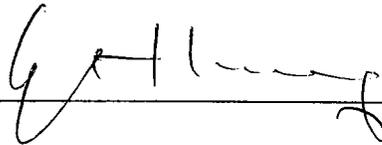
Recommendation:

The Division of Bioequivalence agrees that the information submitted by American Pharmaceutical Partners, demonstrates that Amiodarone for Injection 50mg/mL, 3 mL fill in a 3 mL vial falls under 21 CFR 320.22 (b)(1). The waiver of the in vivo bioequivalence requirement for the test products is granted. From the bioequivalence point of view, the Division of Bioequivalence deems the test injectable formulation, 50mg/mL, 3 mL fill in a 3 mL vial, to be bioequivalent to Cordarone[®], 3 mL fill in a 3 mL ampul for Injection manufactured by Wyeth Ayerst.

The firm should be informed of the above recommendation.

Andre J. Jackson 
Division of Bioequivalence
Review Branch I

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FT INITIALLED YHUANG



Date: 3/14/2000

Concur:  Date: 3/17/00
Dale P. Conner
Director
Division of Bioequivalence

cc: ANDA #75-761, original, HFD-652 (Jackson, Huang), Drug File,
Division File, HFD-650 (Division Director).

BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 75761

APPLICANT: American Pharmaceutical Partners

DRUG PRODUCT: Amiodarone for Injection, 3 mL fill in a 3 mL vial
50mg/mL

The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,



Dale P. Conner, Pharm. D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

CC: ANDA 75761
ANDA DUPLICATE
DIVISION FILE
HFD-651/ Bio Drug File
HFD-652/ Reviewer

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Endorsements: (Final with Dates)
HFD-652/ Reviewer
HFD-652/ Bio team Leader *WJM 3/14/2000*
HFD-650/ D. Conner *DMZ 3/17/00*

BIOEQUIVALENCY-ACCEPTABLE submission date: December 22, 1999

1. **WAIVER** (WAI)

o/c

Strengths: 3mL fill in 3
mL vial (50mg/mL)

Outcome: **AC**

Outcome Decisions: **AC** - Acceptable

WinBio Comments:

**APPEARS THIS WAY
ON ORIGINAL**

**OFFICE OF GENERIC DRUGS
DIVISION OF BIOEQUIVALENCE**

ANDA #: 75-761

SPONSOR: American Pharmaceutical Partners

DRUG AND DOSAGE FORM : Amiodarone HCL for Injection 3 mL fill) in a 3 mL vial

STRENGTH (S) : 50mg/mL

TYPES OF STUDIES : Waiver

CLINICAL STUDY SITE(S) : N/A

ANALYTICAL SITE(S) : N/A

STUDY SUMMARY : N/A

DISSOLUTION : N/A

DSI INSPECTION STATUS

Inspection needed: YES / <u>NO</u>	Inspection status:	Inspection results:
First Generic _____	Inspection requested: (date)	
New facility _____	Inspection completed: (date)	
For cause _____		
Other _____		

PRIMARY REVIEWER : Andre Jackson BRANCH : I

INITIAL : ajj DATE : 3/14/2000

TEAM LEADER : Y.C. Huang BRANCH : I

INITIAL : YCH DATE : 3/14/2000

DIRECTOR, DIVISION OF BIOEQUIVALENCE : DALE P. CONNER, Pharm. D.

INITIAL : DP DATE : 3/17/00