

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**75-188**

**CHEMISTRY REVIEW(S)**

# 2

ANDA 75-188

NAME AND ADDRESS OF APPLICANT

Par Pharmaceutical, Inc.  
U. S. Agent for: Alphapharm Pty. Ltd.  
One Ram Ridge Road  
Spring Valley, NY 10977

PURPOSE OF AMENDMENT/SUPPLEMENT

Response to our major deficiencies dated March 31, 1998

DATE(S) OF SUBMISSION(S)

Original:	August 8, 1997
FDA Acknowledgement:	October 22, 1997
Bio deficiency:	January 12, 1998
New correspondence:	September 16 and October 8, 1997
Amendment:	May 8, 1998
Telephone deficiency:	January 6, 1999
Amendment:	January 7, 1999

PHARMACOLOGICAL CATEGORY

TRADE NAME

Ventricular arrhythmias

NONPROPRIETARY NAME

Amiodarone hydrochloride

DOSAGE FORM

POTENCY

RX OR OTC

Tablet

250 mg

Rx

SAMPLES

RELATED IND/NDA/DMF

STERILIZATION

N/A

See chem/review #1

N/A

LABELING

On October 23, 1998 the firm was directed to answer a telephone amendment. Satisfactory. See review dated 11/24/98.

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Contain Trade Secret,  
Commercial/Confidential  
Information and are not  
releasable.

2/17/99

Amendments (Chemistry Review 2)