CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-188

APPROVAL LETTER

ANDA 75-188

FEB 24 1999

Par Pharmaceutical, Inc.
Attention: Robert A. Fermia, Ph.D.
U.S. Agent for: Alphapharm Pty. Limited
One Ram Ridge Road
Spring Valley, NY 10977

Dear Sir:

This is in reference to your abbreviated new drug application dated August 8, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Amiodarone Hydrochloride Tablets, 200 mg.

Reference is also made to your amendments dated February 12 (2 submissions), May 8, July 30, August 19, August 27 and October 26, 1998; and January 7, 1999.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Amiodarone Hydrochloride Tablets, 200 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Cordarone® Tablets, 200 mg, of Wyeth Ayerst Laboratories, Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

/S/

1/99

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research