DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-377/S-016

Wyeth Pharmaceuticals, Inc.
Attention: Caroline Henesey, Ph.D.
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr. Henesey:

Please refer to your supplemental new drug application dated March 9, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cordarone (amiodarone HCl) Intravenous 50 mg/ml.

This "Changes Being Effected" supplemental new drug application provides for labeling revised as follows:

1. The following paragraph has been added to the **PRECAUTIONS/Proarrhythmia** section:

   Fluoroquinolones, macrolide antibiotics, and azoles are known to cause QTc prolongation. There have been reports of QTc prolongation, with or without TdP, in patients taking amiodarone when fluoroquinolones, macrolide antibiotics, or azoles were administered concomitantly. (See **Drug Interactions**, ***Other reported interactions with amiodarone***.)

2. The following paragraph has been added to the **PRECAUTIONS/Drug Interactions/*Other reported interactions with amiodarone*** section:

   Fluoroquinolones, macrolide antibiotics, and azoles are known to cause QTc prolongation. There have been reports of QTc prolongation, with or without TdP, in patients taking amiodarone when fluoroquinolones, macrolide antibiotics, or azoles were administered concomitantly. (See **PRECAUTIONS, Proarrhythmia**.)

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the labeling submitted on March 9, 2004. We note that you are no longer manufacturing Cordarone Intravenous, and therefore have not provided final printed labeling. Should you resume manufacture in the future, we request that you submit final printed labeling identical in content to the labeling submitted on March 9, 2004

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Russell Fortney
Regulatory Health Project Manager
(301) 594-5311

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge

9/2/04 04:01:06 PM