DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-377/S-017

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 May 11, 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:

> The **ADVERSE REACTIONS/Postmarketing Reports** section has been revised to indicate that some reports of toxic epidermal necrolysis were fatal, and to add the terms hallucination, confusional state, disorientation and delirium. The section now reads as follows:
>
> **Postmarketing Reports**
> In postmarketing surveillance, hypotension (sometimes fatal), sinus arrest, pseudotumor cerebri, syndrome of inappropriate antidiuretic hormone secretion (SIADH), toxic epidermal necrolysis (sometimes fatal), exfoliative dermatitis, pancytopenia, neutropenia, erythema multiforme, angioedema, bronchospasm, possibly fatal respiratory disorders (including distress, failure, arrest, and ARDS), fever, dyspnea, cough, hemoptysis, wheezing, hypoxia, pulmonary infiltrates, anaphylactic/anaphylactoid reaction (including shock), hallucination, confusional state, disorientation, and delirium also have been reported with amiodarone therapy.
>
> Also, in patients receiving recommended dosages, there have been postmarketing reports of the following injection site reactions: pain, erythema, edema, pigment changes, venous thrombosis, phlebitis, thrombophlebitis, cellulitis, necrosis, and skin sloughing (see **DOSAGE AND ADMINISTRATION**).

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 May 11, 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 May 11, 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

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