DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-972/S-029

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) 200 mg Tablets.

We acknowledge receipt of your submission dated October 1, 2004.

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, sinus arrest, hepatitis, cholestatic hepatitis, cirrhosis, epididymitis, impotence, vasculitis, pseudotumor cerebri, syndrome of inappropriate antidiuretic hormone secretion (SIADH), thrombocytopenia, angioedema, bronchiolitis obliterans organizing pneumonia (possibly fatal), bronchospasm, possibly fatal respiratory disorders (including distress, failure, arrest, and ARDS), fever, dyspnea, cough, hemoptysis, wheezing, hypoxia, pulmonary infiltrates, pleuritis, pancreatitis, toxic epidermal necrolysis (sometimes fatal), myopathy, muscle weakness, rhabdomyolysis, hemolytic anemia, aplastic anemia, pancytopenia, neutropenia, erythema multiforme, Stevens-Johnson syndrome, exfoliative dermatitis, pruritus, hallucination, confusional state, disorientation, and delirium also have been reported in patients receiving Cordarone.

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 final printed labeling submitted on October 1, 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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