DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-972/S-038/S-039

Wyeth Pharmaceuticals, Inc.
Attention: Sharada Truter, Ph.D.
Senior Manager, Global Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr. Truter:

Please refer to your supplemental new drug applications dated November 14, and December 3, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cordarone, (amiodarone HCl) 200 mg Tablets.

These "Changes Being Effected" supplemental new drug applications provide for draft labeling revised as follows:

Proposed revisions for S-038

1. Under **ADVERSE REACTIONS, Postmarketing Reports**, the term "urticaria" was added to the list of events reported.

2. The document number and revision date were updated.

Proposed revisions for S-039

1. In our letter dated October 8, 2008, we requested the following change to the **PRECAUTIONS, Drug Interactions, *HMG-CoA reductase inhibitors*** section in the labeling:

(b) (4)

You proposed the following change instead (the only change from the current approved label is the addition of the underlined text):

> HMG-CoA reductase inhibitors:
> HMG-CoA reductase inhibitors that are CYP3A4 substrates (including simvastatin and atorvastatin) in combination with amiodarone have been associated with reports of myopathy/rhabdomyolysis.

When co-administered with amiodarone, lower starting and maintenance doses of these agents should be considered.

2. The document number and revision date were updated.

We have completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert and submitted labeling (package insert) submitted December 3, 2008.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 18-972/S-038, S-039**." Approval of these submissions by FDA is not required before the labeling is used.

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
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Russell Fortney, Regulatory Project Manager, at (301) 796-1068.

Sincerely,

{See appended electronic signature page}

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

Enclosure:
agreed-upon labeling text

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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