DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018972/S-040 **SUPPLEMENT APPROVAL**

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

Dear Dr. Truter:

Please refer to your supplemental new drug application dated April 10, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cordarone (amiodarone HCl) 200 mg Tablets.

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

1. Under WARNINGS/Pulmonary Toxicity, "pleural effusion" has been added to the list of findings in the first paragraph.

2. Under WARNINGS/Pulmonary Toxicity, the parenthetical "(including eosinophilic pneumonia)" has been added to the pneumonitis listing.

3. Under ADVERSE REACTIONS, the following sentence has been added at the end of the second paragraph:

   There have been spontaneous reports of demyelinating polyneuropathy.

4. Under ADVERSE REACTIONS/Postmarketing Reports, the following events have been added to the list of reported events:

   Eosinophilic pneumonia, pleural effusion, and demyelinating polyneuropathy

5. The following has been added to the Medication Guide:

   Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

6. The item number and revision date have been updated.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on April 10, 2009.

LETTERS TO HEALTH CARE PROFESSIONALS

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

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

REPORTING REQUIREMENTS

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}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-18972	SUPPL-40	WYETH PHARMACEUTICALS INC	CORDARONE(AMIODARONE HYDROCHLORIDE)TABLE

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

/s/

MARY R SOUTHWORTH
09/28/2009