DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018972/S-052

SUPPLEMENT APPROVAL

Wyeth Pharmaceuticals, Inc., a subsidiary of Pfizer, Inc.
Attention: Marcio De Godoy, PhD.
Sr. Manager, Worldwide Safety and Regulatory
500 Arcola Drive
G-4347
Collegeville, PA 19426

Dear Dr. De Godoy:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 12, 2016 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cordarone (amiodarone hydrochloride) 200 mg Tablets.

This supplemental new drug application provides for revisions to the approved label as follows (additions are shown as underlined text and deletions are shown as ~~strikethrough~~ text):

1. Under **PRECAUTIONS**, **Drug Interactions**, the following text was added:

   Drugs lowering heart rate or causing automaticity or conduction disorders
   Concomitant use of drugs with depressant effects on the sinus and AV node (e.g., digoxin, beta blockers, verapamil, diltiazem, ivabradine, clonidine) can potentiate the electrophysiologic and hemodynamic effects of amiodarone, resulting in bradycardia, sinus arrest, and AV block. Monitor heart rate in patients on amiodarone and concomitant drugs that slow heart rate.

2. The revision date and version number were updated.

There are no other changes from the last approved package insert.

APPROVAL & LABELING

We have completed our review of this supplemental application and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package

insert, Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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:

Lori Anne Wachter, RN, BSN, RAC
Regulatory Project Manager for Safety
(301) 796-3975

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
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

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
11/22/2016