



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 18-972/S-037

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 17, 2008, 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 draft labeling revised as follows:

1. Under **WARNINGS/Pulmonary Toxicity**, the following sentence has been added to the end of the first paragraph:

Post-marketing reports describe cases of pulmonary toxicity in patients treated with low doses of Cordarone; however, reports suggest that the use of lower loading and maintenance doses of Cordarone are associated with a decreased incidence of Cordarone-induced pulmonary toxicity.

2. Under **WARNINGS/Pulmonary Toxicity/Interstitial /alveolar pneumonitis**, the last sentence ["Reports suggest that the use of lower loading and maintenance doses of Cordarone are associated with a decreased incidence of Cordarone-induced pulmonary toxicity."] has been deleted.
3. Under **WARNINGS**, the following new section has been added:

**Implantable Cardiac Devices**

In patients with implanted defibrillators or pacemakers, chronic administration of antiarrhythmic drugs may affect pacing or defibrillating thresholds. Therefore, at the inception of and during amiodarone treatment, pacing and defibrillation thresholds should be assessed.

4. The document number and revision date have been updated.

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 agreed-upon labeling text. The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted on October 17, 2008).

Within 14 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the submitted electronic draft labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplement NDA 19-439/S-022." Approval of this submission 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  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

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 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

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/s/

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Norman Stockbridge  
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