DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-972/S-025

Wyeth Laboratories
Attention: Ms. Patricia Kuker Staub
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Staub:

Please refer to your supplemental new drug application dated October 23, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cordarone (amiodarone HCl) 200 mg Tablets.

This supplemental new drug application provides for final printed labeling, revised to read as follows:

1. Under **PRECAUTIONS/Drug Interactions**, the following new subsection has been added after the ***Immunosuppressives*** subsection :

   ***HMG-CoA Reductase Inhibitors*:**
   Simvastatin (CYP3A4 substrate) in combination with amiodarone has been associated with reports of myopathy/rhabdomyolysis.

2. Under **ADVERSE REACTIONS/Postmarketing Reports**, the term "rhabdomyolysis" has been added after "…toxic epidermal necrolysis, myopathy."

We 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 included in the submission of October 23, 2002

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}

Douglas C. Throckmorton, M.D.
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/

Doug Throckmorton

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