018972_5030

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER(S)

18-972/S-030

Trade Name: Cordarone 200 mg Tablets

Generic Name(s): (amiodarone HCl)

Sponsor: Wyeth Pharmaceuticals, Inc.

Agent:

Approval Date: December 3, 2004

Indication: Provides for addition of medication guide

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APPLICATION NUMBER:

18-972/S-030

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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

18-972/S-030

Approval Letter(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-972/S-030

Wyeth Pharmaceuticals, Inc.
Attention: Caroline Henesey, Ph.D.
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr. Henesey:

Please refer to your supplemental new drug application dated August 20, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cordarone (amiodarone HCl) 200 mg Tablets.

We acknowledge receipt of your submission dated October 25, 2004.

This supplemental new drug application provides for the addition of a medication guide to the approved labeling. In addition, a reference to the medication guide has been added to the **PRECAUTIONS** section of the package insert labeling, and to the carton and container labels.

We have completed our review of this application. This application 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 enclosed labeling (text for the package insert, text for the medication guide) and submitted labeling (immediate container and carton labels submitted October 25, 2004).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-972/S-030." 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, HFD-410
FDA
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 contact:

Mr. Russell Fortney

Regulatory Health Project Manager
(301) 594-5311

Sincerely,

/S/

{See appended electronic signature page}

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

Enclosure

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
12/3/04 11:28:26 AM