CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 11642/S012

ADMINISTRATIVE DOCUMENTS

RHPM Review of Final Printed Labeling JUN 16 1999
NDA 11-642/S-012

Sponsor: The Purdue Frederick Company

Product: Cardioquin (quinidine polygalacturonate)

Date of Submission: February 9, 1999

Date of Receipt: February 12, 1999

Type of Submission: Final Printed Labeling

Background: Supplement 012 was submitted to address the labeling changes requested in the July 1, 1998 approval letter

Evaluation: When compared with the labeling approved July 1, 1998 for S-011, the following changes were noted:

1. In the header before the **DESCRIPTION** section, the "Rx" symbol has been deleted.

2. Under **PRECAUTIONS/Non-interaction of quinidine with other drugs,** the word has been deleted in the first sentence of the second paragraph. This sentence has been changed from:

   to:

   > Conversely, the pharmacokinetics of quinidine are not significantly affected by **caffeine, ciprofloxacin, digoxin, felodipine, omeprazole,** or **quinine**.

3. Under **OVERDOSAGE/Accelerated removal,** the word has been added to the fourth paragraph. This sentence has been changed from:

   to:

   > Following quinidine overdose, drugs that delay elimination of quinidine (cimetidine, carbonic-anhydrase inhibitors, diltiazem, thiazide diuretics) should be withdrawn unless absolutely required.

4. Under **HOW SUPPLIED,**

a. The storage statement has been changed from:

to:

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F). [See USP Controlled Room Temperature.]

b. The
statement has been deleted.

Comments/Recommendations: The July 1, 1998 approval letter for S-011 requested that the
statement be changed to "Rx only." During a May 28, 1999 telephone conversation between Ms. Pavlik of Purdue Frederick and Ms. Willard of the Cardio-renal Division, Ms. Pavlik noted that under the FDA Modernization Act of 1997, the "Rx only" statement is not required in the package insert. Also during this conversation, Ms. Willard stated that the structural formula had not been changed as requested in the July 1, 1998 approval letter for S-011. Ms. Pavlik apologized for this oversight and stated that the change would be made at time of the next printing. This is acceptable to the FDA chemist (Attachment 2).

The changes under 1 and 4b above are provided for under the FDA Modernization Act of 1997.

The changes under 2, 3, and 4a above were requested in the July 1, 1998 approval letter for S-011.

An approval letter that requests the change in the structural formula noted in the July 1, 1998 approval letter for S-011 should issue for this supplement.

/S/

Diana M. Willard
Regulatory Health Project Manager

cc: originals
HFD-110
HFD-110/DWillard
HFD-110/SBenton
HF-2/MedWatch