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Application Number:NDA 11642/S012

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 11-642/S-012

JUN 16 1999

The Purdue Frederick Company
Attention: Ms. Michele M. Pavlik
100 Connecticut Avenue
Norwalk, CT 06850-3590

Dear Ms. Pavlik:

Please refer to your supplemental new drug application dated January 11, 1999, received January 14, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cardioquin (quinidine polygalacturonate) Tablets, 275 mg.

We also refer to your May 28, 1999 conversation with Ms. Diana Willard of this Division regarding the correct structural formula for Cardioquin (quinidine polygalacturonate) Tablets.

We acknowledge receipt of your submission dated February 9, 1999.

This supplemental application provides for final printed labeling (FPL) revised to reflect changes requested in the July 1, 1998 approval letter for supplemental application S-011. Changes were made under **PRECAUTIONS/Non-interaction of quinidine with other drugs** and under **OVERDOSAGE/Accelerated removal** to reflect the interaction between quinidine and diltiazem. In addition, a change was made in the storage statement under **HOW SUPPLIED**. The statement under **HOW SUPPLIED** has been deleted.

We note that the following changes have been made in this FPL:

1. In the header above the **DESCRIPTION** section, the _____ 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delay elimination of quinidine (cimetidine, carbonic-anhydrase inhibitors, diltiazem, thiazide diuretics) should be withdrawn unless absolutely required.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.

We have completed the review of this supplemental application, as amended, and it is permitted. The changes proposed in the supplement are permitted without approval pending completion of all the requirements detailed in the Federal Register notices of September 8, 1972 and January 7, 1977 concerning this drug.

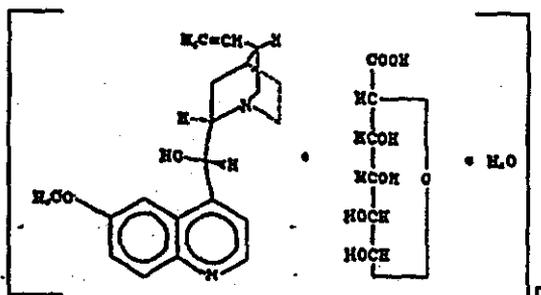
The final printed labeling (FPL) must be identical to the draft labeling included in your February 9, 1999 submission.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for permitted supplement NDA 11-642/S-012." Approval of this submission by FDA is not required before the labeling is used.

At the time of your next printing, please make the following change:

1. Under **DESCRIPTION**, the structural formula should be changed from:

to:



If you have any questions, please contact:

Ms. Diana Willard
Regulatory Health Project Manager
(301) 594-5311

Sincerely yours,

/S/ 6/16/99

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc.

Archival NDA 11-642

HFD-110/Div. Files

HFD-101/ADRA (with labeling)

HFD-95/DDMS (with labeling)

HFD-40/DDMAC (with labeling)

HFD-613/OGD (with labeling)

HFD-735/OPDRA (with labeling)

DISTRICT OFFICE

HFD-110/D. Willard; 6/8/99 *D. Willard 6/15/99*

sb/6/2/99; 6/15/99

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SUPPLEMENT PERMITTED (PA)