CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-761

CSO LABELING REVIEW(S)

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: **75-761** Date of Submission: **December 22, 1999**

Applicant's Name: **American Pharmaceutical Partners, Inc.**

Established Name: **Amiodarone Hydrochloride Injection, 50 mg/mL, 3 mL vials**

Labeling Deficiencies:

1. CONTAINER 3 mL

   a. Space permitting, we encourage you to include the storage temperature recommendations.

   b. Space permitting, we encourage you to include the statement "Retain in carton until time of use."

2. CARTON 10 x 3 mL

   Satisfactory in draft.

3. INSERT

   a. GENERAL COMMENT

      Delete HCl from the established name except in the TITLE, DESCRIPTION, INDICATIONS AND USAGE (first instance), CONTRAINDICATIONS (first instance), and HOW SUPPLIED sections and in general wherever the name is associated with a specific dose.

   b. TITLE

      We encourage you to add "Rx only" to immediately below the title.

   c. DESCRIPTION

      First sentence - Amiodarone Hydrochloride Injection, for intravenous use, contains ...

   d. PRECAUTIONS

      Labor and Delivery, first sentence - ... whether the use ... (add "the")

   e. DOSAGE AND ADMINISTRATION

      Second table - Delete the terminal zeroes in the concentrations stated (i.e., "1" and "6" rather than "1.0" and "6.0")

Please revise your insert labeling, as instructed above, and submit 4 draft copies for a tentative approval or 12 final printed copies for a full approval of this application. If draft labeling is provided, please be advised that you will be required to submit 12 final printed copies of all labels and labeling at least 60 days prior to full approval of this application. In addition, you should be aware that color and other features (print size, prominence, etc) in final printed labeling could be found unacceptable and that further changes might be requested prior to approval.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following website for any approved changes –

http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL