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November 13, 2002

OVERNIGHT COURIER 11/13/02

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition in quadruplicate under Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act and 21 CFR §10.20, 10.30, and 314.93 to request the Commissioner of the Food and Drug Administration to make a determination that an Abbreviated New Drug Application may be submitted for Amiodarone Hydrochloride Injection, 50 mg / mL, in a strength of 300 mg / 6 mL and 450 mg / 9 mL.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration make a determination to permit a change in the strength (total drug content) to allow for submission of an Abbreviated New Drug Application for Amiodarone Hydrochloride Injection, 50 mg / mL, in strengths of 300 mg / 6 mL and 450 mg / 9 mL. The basis of the Petition is the reference-listed drug, Cordarone® I.V., marketed by the innovator Wyeth Ayerst. Cordarone® Intravenous is available in only one strength; a single-use ampoule containing 150 mg / 3 mL of Amiodarone Hydrochloride Injection. Wyeth Ayerst received approval for the 150 mg / 3 mL ampoule product under NDA 20-377 on August 3, 1995.

B. Statement of Grounds

Section 505(j)(2)(C) of the Food, Drug and Cosmetic Act provides for submission of an ANDA for a new drug that differs in strength from a listed drug provided that FDA has approved a petition seeking permission to file such an application. The subject of this petition for Amiodarone Hydrochloride Injection is to permit a change in strength (total drug content) from that of the listed drug. The reference listed drug product, Cordarone® Intravenous, marketed by the innovator, Wyeth Ayerst, is available as an ampoule containing 150 mg / 3 mL. The proposed drug product will be in the same concentration, 50 mg / mL, as the reference listed drug product, but in strengths of 300 mg / 6 mL and 450 mg / 9 mL.

02P-0484

CP 1

Product	Dosage Form	Route of Administration	Strength
Wyeth Ayerst's Cordarone®	Liquid	Intravenous	Amiodarone Hydrochloride 150 mg / 3 mL
Proposed Amiodarone Hydrochloride Injection	Liquid	Intravenous	Amiodarone Hydrochloride 300 mg / 6 mL and 450 mg / 9 mL

The proposed strengths are clearly contemplated in the approved labeling of the listed drug. The proposed strengths contain the drug amount recommended in the approved labeling for dilution with 500 mL D₅W to make an Amiodarone Hydrochloride Infusion, which is administered over a specified period of time.

Amiodarone Hydrochloride Injection is currently approved in one fill size, that is 150 mg / 3 mL. However, the approved labeling for Cordarone® Intravenous clearly contemplates use of doses of up to 900 mg administered by slow intravenous infusion. The proposed strengths (600 mg and 900 mg total drug content) will provide practitioners with convenient alternatives to the currently approved strength. The proposed strengths will allow preparation of approved doses of up to 900 mg by use of two 450 mg / 9 mL vials / ampoules or three 300 mg / 6 mL vials / ampoules compared to the six 150 mg / 3 mL ampoules that are currently required for the listed drug. The proposed strengths clearly conform to the dosage and administration recommendations listed in the approved package insert. Since the need to open multiple ampoules will be reduced, the proposed drug product will minimize the potential for contamination resulting from the handling of the product, such as blood borne pathogens from cut fingers and glass particles. The proposed presentation will also provide a reduction in hazardous waste disposal and cost for the course of therapy.

The subject drug is intended for use only as described in the **Indications and Dosage and Administration** sections of the approved labeling. Draft labeling is provided in **Attachment I**.

Included in **Attachment II** is the package insert for Cordarone® Intravenous, marketed by Wyeth Ayerst. The labeling for the proposed drug is essentially identical to that of Wyeth Ayerst's Cordarone®, but differs only with respect to the description of the product, product name, dilution volume, the how-supplied statement, and the specific manufacturer's information.

The proposed strengths do not pose questions of safety or effectiveness because the uses, doses and route of administration of the proposed products are the same as those of the listed drug. The only difference between the proposed products and the approved product is strength (total drug content). The proposed doses are reflected in the approved labeling of the listed drug. For the above reasons, the undersigned requests that the Commissioner approve this petition and find that an application for Amiodarone Hydrochloride Injection, 300 mg / 6 mL and 450 mg / 9 mL is suitable for submission as an ANDA.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact Statement

According to 21 CFR 10.30(b), the petitioner will, upon request by the Commissioner, submit economic impact information.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner, which are unfavorable to the Petition.

Sincerely,


Gordon R. Johnston
Associate 

GRJ/pk/m

Attachment 1 – Draft Labeling
Attachment 2 – Labeling for Cordarone® Intravenous

cc: G. Davis, OGD
L. Lachman

F02K2317