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**APPLICATION NUMBER: NDA 20377/S002**

**ADMINISTRATIVE DOCUMENTS**

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DEC 10 1997

**RHPM Review of Final Printed Labeling  
NDA 20-377/S-002**

**Sponsor:** Wyeth-Ayerst Laboratories  
**Product:** Cordarone (amiodarone HCl) I.V.  
**Submission Date:** October 1, 1997  
**Receipt Date:** October 2, 1997  
**Type of Submission:** Final Printed Labeling

**Background:** Supplement 002, submitted July 12, 1996, provided for draft labeling revised under **Dosage and Administration** recommending that glass evacuated bottles not be used for admixing Cordarone I.V. as incompatibility with a buffer in the container may cause precipitation. The labeling further provided for the addition of a **SURGERY** subsection under **Precautions** as well as the addition of a **Precautions/ DRUG INTERACTIONS/Potential drug class interactions** with Cordarone subsection to add the words "Volatile Anesthetic Agents: (see "Precautions, SURGERY")."

An amendment submitted August 1, 1996 refers to an Agency letter dated March 15, 1996 requesting Wyeth-Ayerst to incorporate text to address the issue of evacuated bottles and formation of a precipitate. This amendment provided additional information in support of the text proposed by Wyeth-Ayerst in S-002 regarding use of evacuated bottles versus that proposed by the Agency in the March 15, 1996 letter.

An approvable letter issued for this supplement on April 18, 1997 requesting final printed labeling identical in content to the draft labeling included with the July 12, 1996 submission.

**Evaluation:** When compared with the July 12, 1996 draft labeling submitted with S-002, the following changes were noted:

- 1) Under **Adverse Reactions**, a sentence has been added that states:

In postmarketing surveillance, toxic epidermal necrolysis also has been reported with amiodarone therapy.

**Comments/Recommendations:** A June 19, 1997 letter from the Division requested revision of the Cordarone IV labeling to add the adverse event term "toxic epidermal necrolysis."

An approval letter should issue for this supplement.

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Diana Willard  
Regulatory Health Project Manager

cc: original file  
HFD-110  
HFD-110/DWillard  
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