

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
50-807

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE

**DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF DRUG SAFETY
(DMETS; HFD-420)**

DATE RECEIVED: March 8, 2006	DESIRED COMPLETION DATE: April 3, 2006	ODS CONSULT #: 06-0094
DATE OF DOCUMENT: July 15, 2005	PDUFA DATE: May 19, 2006	

TO: Robert Justice, MD
Director, Division of Drug Oncology Products
HFD-150

THROUGH: Linda Kim-Jung, PharmD., Team Leader
Denise Toyer, PharmD, Deputy Director
Carol Holquist, RPh., Director
Division of Medication Errors and Technical Support, HFD-420

FROM: Linda M. Wisniewski, RN, Safety Evaluator
Division of Medication Errors and Technical Support, HFD-420

PRODUCT NAME: Epirubicin Hydrochloride for Injection 50 mg and 200 mg NDA# 50-807	NDA SPONSOR: Mayne Pharma., Inc.
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SAFETY EVALUATOR: Linda M. Wisniewski, RN

RECOMMENDATIONS:

DMETS recommends implementation of the label and labeling revisions outlined in section II of this review that might lead to safer use of the product. We would be willing to revisit these issues if the Division receives another draft of the labeling from the manufacturer.

DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Diane Smith, project manager, at 301-796-0538.

Division of Medication Errors and Technical Support (DMETS)
Office of Drug Safety
HFD-420; PKLN Rm. 6-34
Center for Drug Evaluation and Research

LABEL AND LABELING REVIEW

DATE OF REVIEW: March 15, 2006

NDA#: 50-807

NAME OF DRUG: Epirubicin Hydrochloride for Injection
50 mg and 200 mg

NDA HOLDER: Mayne Pharma, Inc.

I. INTRODUCTION:

This consult was written in response to a request from the Division of Drug Oncology Products for assessment of the labels and labeling for Epirubicin Hydrochloride for Injection. The sponsor provided draft container labels, carton and package insert labeling for review and comment. The reference listed drug for this 505b2 application is Ellence, NDA 50-778.

PRODUCT INFORMATION

Epirubicin Hydrochloride for Injection is an anthracycline cytotoxic agent, intended for intravenous administration. Epirubicin Hydrochloride for Injection is supplied as a sterile, orange-red, lyophilized powder in single-dose vials containing 50 mg or 200 mg of epirubicin. It is indicated as a component of adjuvant therapy in patients with evidence of axillary node tumor involvement following resection of primary breast cancer. Starting doses range from 100 mg/m² to 120 mg/m² and subsequent doses range from 60 mg/m² to 100 mg/m². Epirubicin HCl for Injection is given in repeated three to four week cycles.

II. LABELING, PACKAGING, AND SAFETY RELATED ISSUES:

In the review of the container labels, carton and insert labeling of Epirubicin Hydrochloride for Injection, DMETS has attempted to focus on safety issues relating to possible medication errors. DMETS has identified the following areas of possible improvement, which might minimize potential user error.

A. GENERAL COMMENT

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B. CONTAINER LABEL (50 mg and 200 mg)

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C. CARTON LABELING (50 mg and 200 mg)

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D. INSERT LABELING

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No comments.

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/s/

Linda Wisniewski
4/12/2006 12:58:21 PM
DRUG SAFETY OFFICE REVIEWER

Linda Kim-Jung
4/12/2006 01:12:19 PM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
4/12/2006 01:49:35 PM
DRUG SAFETY OFFICE REVIEWER
Also signing for Carol Holquist, Director DMETS, in her
absence