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APPLICATION NUMBER:

50-517/S-038

PHARMACOLOGY REVIEW

REVIEW AND EVALUATION OF PHARMACOLOGY/TOXICOLOGY DATA
Division of Anti-infective Drug Products, HFD-520

NDA number: 50-517 (SLR-038)

Reviewer Name: Kenneth Seethaler, R.Ph., Ph.D., D.A.B.T.

KEY WORDS: Cefoxitin, Mefoxin

Date of submission: January 6, 2000

Review completion date: February 10, 2000

Submission format: Labeling supplement

Scientific literature reviewed: Yes () No (x)

Information to sponsor: Yes (x) No ()

Drug:

Generic name: Cefoxitin for Injection

Trade name: Mefoxin

Sponsor: Merck Research Laboratories

P. O. Box 4

West Point, PA 19486

Contact person: Virginia Snyder

Manager, Regulatory Affairs

Phone 610-397-7984

INTRODUCTION

In the "Carcinogenesis, Mutagenesis, Impairment of Fertility" section of this label, animal doses are expressed as mg/kg, _____

This section of the label also contains the following statement: "Long-term studies in animals have not been performed with cefoxitin to evaluate carcinogenic or mutagenic potential."

The "Overdosage" section of this label lists three LD₅₀ values, _____

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/s/

Kenneth Seethaler
4/3/02 09:39:39 AM
PHARMACOLOGIST

Robert Osterberg
4/3/02 09:45:02 AM
PHARMACOLOGIST

Lillian Gavrilovich
4/3/02 03:02:36 PM
MEDICAL OFFICER

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