EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -I

ANTIMICROBIAL PROGRAM BRANCH

IN 7-25-94 OUT 8-9-94

Reviewed by Michael Nieves Date 8-9-94

EPA Reg. No. or File Symbol 49403-23

EPA Petition or EUP No. None

Date Division Received 7-20-94

Type Product Hospital Disinfectant

MRID No(s) 433083-01

Product Manager R. Douglas (PM 32)

Product Name Ocide Hospital Cleaner-Disinfectant

Company Name NIPA Labs, Inc.

Submission Purpose The submission is an application to change
the HIV dilution rate from 1:128 to 1:256
with supporting efficacy data and proposed
labeling.

Type Formulation Liquid

Active Ingredients(s) %

Ortho-Benzyl-Para-Chlorophenol 10.10
Ortho-Phenylphenol 4.90
Para-Tertiary-Amylphenol 2.50
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Product Name Ocide Hospital Cleaner-Disinfectant

Company Name NIPA Labs, Inc.
Introduction:

Uses:

See attached proposed label dated 7-20-94.

Background Information:

The submission is an application to change the HIV dilution rate from 1:128 to 1:256 with supporting efficacy data and proposed labeling.

Factors Affecting Amount/Type of Data Required:

None

Data Summary

None

Abstract of Test Reports:

None

Brief Description of Tests:

"Virucidal Efficacy Of NIPA Laboratories, Inc.'s Super Ocide Hospital Cleaner-Disinfectant Against The Human Immunodeficiency Virus" by Bonnie J. Bowdon of Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35255-5305; dated May 11, 1993. (MRID No. 433083-01)

Data Summaries

None

Other Summarized Results:

See Recommendations under 202.0.
202.0 **Recommendations**

202.1 **Efficacy Supported By The Data:**

"Virucidal Efficacy Of NIPA Laboratories, Inc.’s Super Ocide Hospital Cleaner-Disinfectant Against The Human Immunodeficiency Virus" by Bonnie J. Bowdon of Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35224-3305; dated May 11, 1993. (MRID No. 433083-01)

The submitted efficacy data (MRID No. 433083-01) appear adequate to support effectiveness of the product as a virucide when used on hard non-porous surfaces against HIV (AIDS Virus) when diluted with 424.2 ppm AOAC hard water to make a 1:256 dilution in the presence of 5% blood serum for a contact time of ten minutes at 23°C.

203.0 **Labeling:**

The proposed labeling does not contain the proper dilution rate of 1:256. Under the heading: Directions for Use Against HIV-1 (AIDS Virus), change the dilution rate from 1:128 to 1:256.