

8-9-94

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

<u>Active Ingredients(s)</u>	<u>%</u>
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.

- 200.0      **Introduction:**
- 200.1      **Uses:**  
See attached proposed label dated 7-20-94.
- 200.2      **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.
- 200.3      **Factors Affecting Amount/Type of Data Required:**  
None
- 201.0      **Data Summary**  
None
- 201.1      **Abstract of Test Reports:**  
None
- 201.2      **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)
- 201.3      **Data Summaries**  
None
- 201.4      **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 35255-5305; 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.