EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - I

ANTIMICROBIAL PROGRAM BRANCH

IN 09/21/93 OUT 02/10/94

Reviewed by Srinivas Gowda Date 02/10/94

EPA Reg. No. or File Symbol 46781-3

EPA Petition or EUP No. None

Date Division Received 08-27-93

Type Product Hospital Disinfectant/Sterilant

MRID No (s) 429028-01

Product Manager PM 31 (Lee)

Product Name MetriCide Plus 14

Company Name Metrex Research Corporation

Submission Purpose Amendment to add 99.8% TB kill claim in 10 minutes/100% kill claim in 45 min. at 25°C with efficacy data and revised label

Type Formulation Liquid

Active Ingredient (s): %

Glutaraldehyde.....3.2

200.0 **Introduction:**

200.1 **Uses(s)**

See attached proposed label.

200.2 **Background Information:**

The submission received 08-27-93, is an amendment to add new tuberculocidal claim (99.8% TB kill claim in 10 minutes/100% kill claim in 45 min. at 25°C) with efficacy data and revised label.

201.0 **Data Summary**

201.2 **Brief Description of Test:**

"Quantitative Tuberculocidal Test (Survival Curve and D-Value Calculation)" by Aliene Borgus, MicroBio Test, Inc. (MBT), 14280 Sullyfield Circle, #200, Chantilly, Virginia 22021, dated 12-09-92 (MRID No. 429028-01).

201.2 **Data Summaries**

See 202.0.

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202.0 **Recommendations**

202.2 **Efficacy Not Supported by the Data:**

"Quantitative Tuberculocidal Test (Survival Curve and D-Value Calculation)" by Aliene Borgus, MicroBio Test, Inc. (MBT), 14280 Sullyfield Circle, #200, Chantilly, Virginia 22021, dated 12-09-92 (MRID No. 429028-01).

The submitted Quantitative Tuberculocidal Test data are not acceptable because:

1. Product failed to meet the EPA's performance standard which is 100% kill of a 10^6 colony forming units/ml in suspension.

2. Data were not developed on 14 day reused solution to support 14 day reuse claim.

3. No validation data were submitted as required by EPA's TB Data Call-In Notice for glutaraldehyde products.

4. Data were derived from only three studies instead of required four independent studies.

5. Two unauthorized modifications were employed: Culture was not grown/prepared as specified in the method and culture was grown in 7H9 media instead of Modified Proskauer-Beck Medium.

6. Data were not developed on Metricide Plus 14.

7. (*)

203.0 **Labeling:**

The proposed amendment is not acceptable because testing performed was not according to the EPA Guidelines requirements and EPA's TB Data Call-In Notice.

(*) Any future label amendments must be submitted to FDA for data approval and label claim language (for clearance under 510(k)). the 510(k) clearance letter then must be submitted to EPA for final label approval.

B. Vanturyn, Head
EETMS
2/23/94

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