FEB U 1 1995

Richard Gabriel, Product Manager Lab Products Inc. 255 West Spring Valley Avenue Maywood, N.J. 07607

Subject: Cide-Swipes P-100A

EPA Registration No. 56095-2 Letter Dated December 27, 1994

Dear Mr. Gabriel:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to include the HIV-1 claims and MOU statement, is acceptable. A stamped copy of the labeling is enclosed for your records.

However, at the next printing of your labels, include the following statement to be placed immediately above the "Special instructions against the HIV-1 (Aids Virus)".

"Kills HIV-1 on precleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

If you have any questions concerning this letter, please contact Martha Terry at (703) 305-6982.

Sincerely,

Walter C. Francis Acting Product Manager (31) Antimicrobial Program Branch Registration Division (7505C)

Enclosure

CONCURRENCES		
SYMBOL		
SURNAME		
DATE		
FPA Form 1320 1A (1/90)	Printed on Recycled Page	OFFICIAL FILE COPY

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LEAR HERE

· DISINFECTANT . . VIRUCIDE* . CLEANER

C-100A Contents: 1 Towelette (Net wgt. 9 58 cz.) (16 5 gms.)

Clde-Swipes are pre-saturated wipes containing known anti-bacterial and antiviral agents. For use in medical, dental, home, school and institutional applications.

Active ingredient Glutaraldehyde 0.24% inert ingredients** 99.76% **Does not include weight of dry towelette.

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its lebeling.

Tear open protective wrap. Allow towel to unfold by holding and gently shaking. Wipe surface and allow to remain wet for 60 seconds. Each towel cleans and disinfects a surface area 40 times ita siza.

KEEP OUT OF REACH OF CHILDREN

· CAUTION:

- May cause eye and skin Imitation on contact. In case of contact with eye or skin, flush thoroughly with water. If Irritation persists, contact a physician.
- Avoid contact with food.

CONTAINER DISPOSAL:

- Keep packaged towel in a dry area. Do not open until ready to use. Do not re-use towel. Place used towel in the trash container.
- Clde-Swipes are effective as a virucide against HIV-1 (AIDS VIrus) for a 3 minute contact time and Poliovirus Type I for a 15 minute contact time on pre-cleaned, hard, nonporous surfaces.

See back panel for Special Instructions for cleaning and Decontamination Against HIV Contaminated surfaces.

EPA Establishment No. 52831-NJ001 • EPA Registration No. 56095-2 Made by: LAB PRODUCTS, INC., Maywood, NJ 07607

BEST AVAILABLE COPY

ACCEPTED

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Under the Federal Insecticide. Fungiciale, and Rodonucide Act as amended, for the pesticide da dimination de de de la compensación de la compen EPA Reg. No.

Reg. 56095-2

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MOU COMPLIANCE PER PR NOTICE , 1994

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Special Instructions for Cleaning and Decontamination Against HIV of Surfaces or Objects Soiled With Blood or Body Fluids.

Personal Protection: When handling items soiled with blood or other body fluids, disposable latex gloves, gowns, surgical mask and eye protection are rocommended.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the disiniectant.

Contact Time: Cide-Swices™ are effective as a virucide against HIV-1 (AIDS Virus) for a three minute contact time.

Disposal of Infectious Material: Blood and other body illuios should be autoclaved and disposed according to local regulations for infectious waste disposal.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts infact mucous men.branes but which does not ordinantly penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to its sterilization or high level disinfection.

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