3862-102

-7/22/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001

> OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

July 22, 2008

Ms. Kim Inman, Regulatory Chemist ABC Compounding Co., Inc. P.O. Box 16247 Atlanta, GA 30321-0247

Subject: Revised Labeling in Response to PR Notice 2007-4 Insect Repellent, EPA Reg. No. 3862-102 Your Submission Dated May 9, 2008

Dear Ms. Inman:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with the following provision(s):

Directions for Use section comment(s):

1. In the 3<sup>rd</sup> sentence of the paragraph starting with "**For application to exposed skin**," replace the word "and" with the word "an."

Storage and Disposal Statement section comment(s):

2. In the "**PESTICIDE STORAGE**:" subsection, replace the word "and" with the words "in an area that is."

To be eligible for reregistration, aerosol and pump spray formulations must be packaged in containers utilizing a concave trigger to help aim product or other comparable mechanism that will ensure that the product will not be inadvertently sprayed in the eyes.

The Agency is in the process of developing and improving the current Efficacy Assessment Guidelines for repellent products. The Agency intends to defer the determination of any related efficacy data requirements supporting the claims that may appear on this label until these Efficacy Assessment Guidelines are complete. When the guidelines are finalized, the Agency expects to issue a Data Call-In to address the revised guidelines to all registrants with registrations for personal repellent products that have not previously submitted efficacy data sufficiently consistent with the revised guidelines.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

If you have any questions about this label review, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at <u>Rodia.Carmen@epa.gov</u>.

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Richard J. Gebken Product Manager (10) Insecticide Branch Registration Division (7505P)

Enclosure: Copy of label stamped "Accepted with Comments"

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS WARNING Causes substantial but remporary eye filogy. Hemful if size lowed. Do not get

Causes substantial but temporary eye bijury, Hernfuld swa towed. Do not get in eyes. Use of this product may cause side needoors in rare cases. Wash realed obliving before wearing in again. Wash herads before earling, drinking, chewing gun, using tabacco or using the totlet. PHYSICAL OR CHEMICAL MAZARDS:

FLAMMABLE, Contents under pressure, Keep away from heat, sparks and open flame. Do not purchare or increase container Exposure to remperatures above 150 P may cause buryling. DIHECTIONS FOR USE:

It is a visibilition of Fockeral law to use inits product in a manner inconsistent with its labeling. READ AND FOLLOW ALL DIRECTIONS AND PRECAUTIONS ON THIS

BEAD AND FOLLOW ALL DIRECTIONS AND PRECAUTIONS ON THIS PRODUCT LABEL.

For Dutcloar Use Only: Do not speay in enclosed areas. Never use repetients over cuts, wounds, subbuind or initiated stin. Do not apply near eyes and mouth, and apply sparingly around easy. Do not abow chickers to handle this product, and do not apply to children's hands. When using on children, apply to your own hands and then put it cm the child. Apply only to exposed skin action colling (as directed on the undert date). Do not use under colling, Use just enough repetient to cover exposed skin. Heavy application and saturation is untelessary for effectiveness it billing insects do not respond to a thin this of applient, apply a child mark there returning indoors, wesh freaked skin with scap, and water or balte. This is particularly important when repetients are used repeatedly in a day or on consocutive days. Also, wash treated coloring for access, it you suspect a reaction to this product, discontinue use, wash treated skin, and call your local poison control center. If you go to a doctor that this product with you.

For application to exposed skin to repet most whoes bring lifes, grats, and least hold unit 4.6 inches from the skin of arms or legs while applying with a skow sweeping motion, unit surface is slightly moistened. Now with hard to insure and even distribution. To apply to face and neck, spray in path of hand in short bursts and spread on the skin sparingly avoiding eyes. For application, to outer surfaces of citaling to repet mosquitces, bring the surface of citaling to repet mosquitces. bring

For application to outer surfaces of clothing to repei mosquitces, biting lifes, chiggers, fleas, and ticks: Spray outer surfaces of clothing, especially socks, shoe lops, pant legs, and varistband.

Do not apply to synthetic labrics such as acetate, rayon or spandex. May damage furniture linishes, leather, plastics, painted and varnished surfaces including watch mystals, and automobiles.

## STORAGE AND DISPOSAL Do Not Puncture Or Incinerate!

PESINCIDE STORAGE: Store in a cool cry place away from heat or open frame and inaccassible to children. PESTICDE DISPOSAL: Non-reliable crotainer Do not reuse or reliativis container. Offer for recycling if available fit Partly Filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.

Manufactured by: EP/ ABC Compounding Co., Inc. EPA Ri Atlania, GA 30321-0247

EPA EST. 9143-TX-1 EPA REG. NO. 3852-102 8457208SA\_0804

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## ACCEPTED with COMMENTS In EPA Letter Dated

THE PROFESSION OF THE PROFESSION

FIRST AID

minutes, men continue rinsino.

for 15-20 minutes.

treatment advice.

advice.

person.

- Hold eye open and rinse slowly and gently with water

Remove contact lenses, if present, after the first five

Call a poison control center or doctor for treatment.

Call a poison control center or doctor immediately for

Have person sip a glass of water if able to swallow.

Do not induce vomiting unless told to do so by a

poison control center or a coctor.

HOT LINE NUMBER

In case of emergency call bit free 1-800-535-5053. Have the product container or lacel with you when calling a poison control center or doctor or

F IN EYES:

SWALLOWED:

noing for treatment

Tuly 22, 2008 Under the Federal Insecticide. Fungicide, and Rodenticide Act. as amended, for the pesticide registered under EPA Reg. No. 3962-102