

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

March 7, 2016

Micah Reynolds Wisconsin Pharmacal Company LLC 1 Pharmacal Way Jackson, WI 53037

Subject: Label Amendment – Add Claims against Mosquitoes That May Carry Zika Virus Product Name: INSECT GUARD "25-S" AEROSOL EPA Registration Number: 79533-6 Application Date: February 12, 2016 Decision Number: 514060

Dear Mr. Reynolds:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Maggie Rudick by phone at 703-347-0257, or via email at <u>rudick.maggie@epa.gov</u>.

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Sincerely,

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Jennifer Urbanski Saunders, Product Manager 4 Invertebrate & Vertebrate Branch 1 (IVB1) Registration Division (7505P) Office of Pesticide Programs

Enclosure

(Front Panel)

Insect Guard "25-S" Aerosol

Alternate Brand Names: Coleman® High & Dry[™] Insect Repellent Coleman® Insect Repellent 25% DEET Coleman® Insect Repellent High & Dry[™] 25% DEET Coleman® 25% DEET Insect Repellent Dry Spray

ACTIVE INGREDIENT: DEET	25.0%
OTHER INGREDIENTS:	<u>75.0%</u>
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN WARNING SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS (PRECAUTIONS) [SEE ADDITIONAL PRECAUTIONS ON BACK PANEL]

Net (Wt/Contents:) __ oz (__ g)

Batch Code [Lot Number] _____

[] Indicates optional text

ACCEPTED

Mar 07, 2016 Under the Federal Insecticide, Fungicide

and Rodenticide Act as amended, for the

EPA Reg. No. 79533-6

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **READ AND FOLLOW ALL DIRECTIONS AND PRECAUTIONS ON THIS PRODUCT LABEL.** Apply this product only as specified on this label.

Shake Well Before Each Use. Hold container 6 to 8 inches from exposed skin and/or clothing with a slow, sweeping motion. DO NOT spray in enclosed areas. Avoid breathing a spray product, and DO NOT use it near food. Repellents should be applied only to exposed skin and/or clothing (as directed on this product label). DO NOT use under clothing. Never use repellents over cuts, wounds or irritated skin. Use of this product may cause skin reactions in rare occasions. If 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, take this repellent product with you. Use just enough of this product to cover exposed skin and/or clothing. Heavy application and saturation is unnecessary for effectiveness. For maximum protection, spread evenly with hand to moisten all exposed skin. If biting insects do not respond to a thin film of repellent, apply a bit more. DO NOT allow children to handle this product, and DO NOT apply to children's hands. When using on children, apply product to your own hands and then put it on the child. DO NOT use on infants. DO NOT apply more than 3 times per day to children ages twelve (12) and under. After returning indoors, wash treated skin with soap and water or bathe. This is particularly important when repellents are used repeatedly in a day or on consecutive days. DO NOT apply on or near acetate, rayon, Spandex or other synthetic fabrics (other than nylon), furniture, plastics (such as eyeglasses and watch crystals), leather and painted or varnished surfaces (Including automobiles).

To Apply to Face: When using sprays, do not spray directly into face, spray on hands first and then apply to face. DO NOT apply near eyes and mouth, and apply sparingly around ears. Wipe palms after applying.

When Applying to Clothing: DO NOT use under clothing. To apply to clothing, spray shirts, pants, socks and hats. For chiggers and ticks, also spray cuffs, socks and around openings in outer clothing. Wash treated clothing before wearing it again. Will not damage cotton, wool or nylon. DO NOT apply on or near acetate, rayon, Spandex or other synthetic fabrics (other than nylon). DO NOT apply on or near leather.

STORAGE AND DISPOSAL

STORAGE: Keep this product in its tightly closed original container when not in use. Store in a cool, dry (preferably locked) area, that is inaccessible to children and animals, and away from heat and open flame. **CONTAINER HANDLING: Do Not Puncture or Incinerate!** Non-refillable container. Do not reuse or refill this container. **If empty**: Place in trash or offer for recycling if available. **If partly filled**: Call your local solid waste agency [or 1-800-CLEANUP] for disposal instructions.

PRECAUTIONARY STATEMENTS HAZARD TO HUMANS AND DOMESTIC ANIMALS WARNING

Causes substantial but temporary eye injury. Harmful if swallowed. Avoid contact with eyes and lips. DO NOT get in eyes. DO NOT apply to children's hands. DO NOT use on infants. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye
- Call a poison control center or doctor for treatment advice

If swallowed:

- Call poison control center or doctor immediately for treatment advice
- Have a 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 doctor
- Do not give anything by mouth to an unconscious person

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies, or pesticide incidents), call toll free 1-XXX-XXX-XXXX, 24 hours a day, seven days a week.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

NOTE. The First Aid statement's grid format will be used if market label space permits. Otherwise a paragraph format will be used.

PHYSICAL OR CHEMICAL HAZARDS

Flammable Contents under pressure. Keep away from heat, sparks or open flame. Do not puncture or incinerate container. Exposure to temperatures above 120°F may cause bursting.

Distributed by:

Wisconsin Pharmacal Co., LLC 1 Pharmacal Way, Jackson, WI 53037 U.S.A.

EPA Reg. No. 79533-6 **EPA Est. No.**

Optional Marketing Claims

Performance Claims

- 1. Up to 8 hours of mosquito protection
- 2. Repels mosquitoes that may carry (transmit) (St. Louis) (Western equine) encephalitis and (Dengue Fever) [for up to 8 hours]
- 3. Repels ticks that may carry (transmit) (Lyme disease) (Rocky Mountain Spotted Fever) (Tick Paralysis) (Ehrlichiosis) (Powassan Encephalitis) [for up to 8 hours]
- 4. Protection [you can count on for up to 8 hours][from mosquitoes that may carry (transmit) (Zika virus) (Dengue Fever) (Chikungunya virus) West Nile Virus]
- 5. Provides up to 8 hours of protection from mosquitoes and biting flies, gnats, sand flies, stable flies, black flies. Also repels ticks, chiggers and fleas from treated skin.
- 6. Lasts up to 8 hours
- 7. Repels Mosquitoes [for up to 8 hours]
- 8. Mosquito Repellent
- 9. Repels mosquitoes that may carry (transmit) (Zika) (Dengue Fever) (and) ((Chikungunya) West Nile) virus
- 10. Repels Mosquitoes, Chiggers, Ticks, Biting Flies, Black Flies, Deerflies, Stable Flies, Sand Flies, Gnats, No-See-Ums, and Fleas on Exposed Skin Surfaces [for up to 8 hours]
- 11. Long Lasting Protection
- 12. Use on skin and clothing for maximum protection
- 13. Repels mosquitoes that may carry (West Nile) (Dengue Fever) (and) (Zika) (Chikungunya) Virus [for up to 8 hours]
- 14. Coverage time up to 8 hours
- 15. Effective, dependable protection

Formulation-Related Claims

- Contains DEET
- Contains 25% DEET
- (25% DEET)(Coleman®)(High & Dry[™])(Powder)(Formula)
- (High & Dry[™])(DEET)(insect repellent)(formula)
- Dry formula
- (High & Dry[™]) DEET formula (from Coleman®)
- (High & Dry[™]) DEET formula (by Coleman®)
- (High &) Dry insect protection
- (High &) Dry (powder)(repellent)(aerosol)
- (High &) Dry (formula)
- Powder dry (formula)
- (25% DEET) (High & Dry[™])(powder)(formula)(protection)

Product Form, Delivery, Dry Time Claims

- (Dry)(powder)(spray)(repellent)(Coleman®)(High & Dry™)
- Quick drying powder formula
- (Now) Quick Dry(ing)(High & Dry[™])(formula)
- Fast dry(ing)
- Dries fast
- (High & Dry[™])(fast dry)(repellent)

- Aerosol Spray
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Sensory Perception Claims – Touch/Feel

[Note to reviewer: Touch/feel descriptor or combinations of descriptors may be used as standalone statements or inserted into additional statements below]

Touch/Feel descriptors

Fresh	Not Greasy	Non-Greasy	
Light	Non-Oily	Not Wet	
Comfortable	Pleasant	Powder Dry	
Not Sticky	Touchable	Great	
Extra Dry			
	Light Comfortable Not Sticky	Light Non-Oily Comfortable Pleasant Not Sticky Touchable	

- Specially formulated to feel [insert touch/feel descriptor] on your skin
- (High & Dry[™]) powder formula (that) dries quickly and leaves skin feeling [insert touch/feel descriptor]
- Feels [insert touch/feel descriptor] (on) (on your skin)
- Leaves a pleasant feeling (on skin)
- [Insert touch/feel descriptor] feel (formula)
- [Insert touch/feel descriptor] touch (formula)
- [Insert touch/feel descriptor] formula
- [Insert touch/feel descriptor] skin feel
- (Insect repellent that) leaves (your) skin feeling [insert touch/feel descriptor]
- (Light feel) (Light weight) (strong) (effective) (proven) protection
- Dry (shield) (repellent) (spray)
- Smart (shield) (repellent) (spray)
- Quick dry(ing)
- Fast dry(ing)
- Dries fast
- Dry skin feel
- Not Oily or Greasy

Sensory perception claims - Lack of scent

- Unscented
- Fragrance free
- No fragrance
- No unpleasant odor