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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 9, 2007

Mr. Timothy H. Dickens, Ph.D.
Registered Agent
Associated Registrations
c/o Scientific Coordination, Inc.
4629 Cherry Valley Drive
Rockville, MD 20853-1110

**Subject: EXPEDITED REVIEW -- Amended Labeling, Addition of Various Insect-Borne Diseases
DEET PLUS® COMPOSITE SPRAY II INSECT REPELLENT, EPA Registration No. 54287-13
Your Submission Dated September 19, 2006**

Dear Mr. Dickens:

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 provisions:

Marketing Claims section comment(s), page 1 of 3:

1. Delete the "Alcohol Free" portion of the 1st optional marketing claim. ¹
2. Revise all references to "R-326," "R326" and "MGK Repellent 326" to read as follows: "MGK® 326"
3. Modify the 5th line to read as follows:
"Includes MGK® 326 to repel biting flies"
4. Modify the 6th line to read as follows:
"Repels Ticks, Mosquitoes & Biting Flies~Contains DEET Plus MGK® 326"
5. Delete the existing 6th line. This may not be used as an alternate trade name. ²
6. Modify the 8th line to read as follows:
"Specially formulated with DEET to repel mosquitoes and ticks, and MGK® 326 to repel flies"

¹ Statements or claims that express the absence of certain ingredients are misleading statements prohibited by the Agency's labeling regulation. These claims are examples of a true statement used in such a way as to give a false and misleading impression to the purchaser. Even though a claim expressing the absence of an ingredient is true, it could be misleading if it is used in a way to falsely suggest to the potential purchaser that the product is in some way less risky, better or more desirable than a product containing the ingredient in question. Further, a product must not claim that it does not contain an ingredient if it never contained the substance in the first place.

² For more detailed information, please refer to Chapter 12, Section II(6) of EPA's Label Review Manual.

Marketing Claims section comment(s), page 1 of 3 (continued):

- 7. Delete the following insect-borne diseases from the 11th optional marketing claim, as follows: (1) Japanese encephalitis; (2) Murray Valley encephalitis; (3) Ross River Fever; (4) Barmah Forest Disease; (5) Yellow Fever; and (6) Rift Valley Fever. These insect-borne diseases currently do not occur within the continental United States and/or its territories.

Ingredient Statement section comment(s), page 1 of 3:

- 8. Relocate the CAS number listed for DEET as a footnote on the first page of the label.
- 9. Delete the word "INERT" from the ingredient legend. ³

Precautionary Statements, Hazards to Humans and Domestic Animals section comment(s), page 2 of 3:

"For human use product packaged as a liquid (rub-on):" subsection:

- 10. Insert the following text after the existing 5th sentence: "If you suspect a reaction to this product, discontinue use, take off contaminated clothing, wash treated skin, and call your local poison control center or doctor for treatment advice. If you go to a doctor, take this product with you." ⁴

"For human and equine use product packaged with pump spray:" subsection:

- 11. Insert the following text after the existing 5th sentence: "Do not apply near eyes and mouth. Apply sparingly around ears."
- 12. Insert the following text after the existing 7th sentence: "If you suspect a reaction to this product, discontinue use, take off contaminated clothing, wash treated skin, and call your local poison control center or doctor for treatment advice. If you go to a doctor, take this product with you. This product is for use on equine only. Do not use on cats or dogs." ⁴

First Aid section comment(s), page 2 of 3:

- 13. Delete the 3rd row from this table that starts with "If you suspect a reaction to this product." For a more detailed explanation, please refer to the footnote #2 below and the comments on items #9 and #10 above.

Directions for Use section comment(s), page 3 of 3:

"For equine use product packaged in a pump spray:" subsection:

- 14. Insert the following text after the existing 17th sentence: "Not for use on humans."

³ For more detailed information, please refer to PR Notice 97-6.
⁴ PR Notice 2001-1 is very specific about which sections are applicable for the various routes of exposure. The "If you suspect....." comment is not a part of this PR Notice, but is specifically addressed as a requirement in the DEET Reregistration Eligibility Decision (RED) document, dated April 1998, page 40 of 118, and should be placed in the Precautionary Statements, Hazards to Humans and Domestic Animals section and NOT in the First Aid section.

Storage and Disposal section comment(s), page 3 of 3:

15 Replace the existing "Disposal" section with the following:

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool and dry area. Keep out of reach of children.

Pesticide Disposal: If empty: Do not reuse this container. 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. Never place unused product down any indoor or outdoor drain.

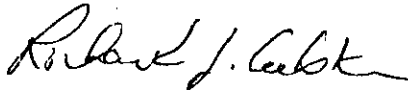
Container Disposal: Triple rinse (or equivalent). Then offer for recycling, or puncture and dispose of in a sanitary landfill, or incineration, etc., or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

The optional marketing claim "Repels mosquitoes that may carry West Nile virus" requires in part the submission of product-specific efficacy data. In accordance with the Agency's January 5, 2004 letter, this data requirement remains applicable. Once the efficacy performance guidelines for repellents are in place, you will be notified of all efficacy data requirements.

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

A stamped copy is attached for your records. Please submit two (2) final printed copies of the referenced label, incorporating the above changes, before releasing the product for shipment. If you have any questions regarding the label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely yours,



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

Attachment

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DEET PLUS® COMPOSITE SPRAY II INSECT REPELLENT

~ OPTIONAL LANGUAGE ~

~~Alcohol Free~~ Liquid~Rub-On~Roll-On~Pump Spray

Repels Mosquitoes, Chiggers, Ticks, Black Flies, Deer Flies, Gnats, Stable Flies and Fleas
(on Exposed Skin Surfaces)

Repels Black Flies, Chiggers, Deer Flies, Fleas, Gnats, Mosquitoes, Stable Flies and Ticks on Horses
Includes R-326 Black Fly Repellent~Repels Biting Flies

Repels Ticks, Mosquitoes & Biting Flies~Contains DEET Plus Fly Repellent
DEET 17.5%~Family Insect Repellent

Specially formulated with DEET to repel mosquitoes and ticks, and R326 to repel flies.

Repels mosquitoes that may carry West Nile Virus

Repels mosquitoes that may carry (St. Louis) (Eastern equine) (Western equine) (Lacrosse)
(Japanese) (Cache Valley) (Venezuelan equine) (Murray Valley) encephalitis and (Ross River Fever) (Barnah-
~~Forest Disease) (Dengue Fever) (Yellow Fever) (Rift Valley Fever)~~

ACTIVE INGREDIENTS:

DEET (CAS No. 134-62-3).....	17.5%
*N-octyl bicycloheptene dicarboximide	5.0%
**Di-n-propyl isocinchomeronate	2.5%
INERT (OTHER) INGREDIENTS:	75.0%
TOTAL:	100.0%

*MGK-264, Insecticide Synergist, **MGK Repellent 326
MGK® - Reg'd TM McLaughlin Gormley King Co.

KEEP OUT OF REACH OF CHILDREN
CAUTION
See Back Panel for Additional Precautionary Statements

NET CONTENTS _____ fl. oz.

[] Optional/Alternate text

ACCEPTED
with COMMENTS
In EPA Letter Dated
May 9, 2007
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
54287-13

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**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

{For human use product packaged as a liquid (rub-on):}

CAUTION: Causes eye irritation. Harmful if swallowed. Instruct older children in the proper use of this product. Do not apply over cuts, wounds or irritated skin. Use of this product may cause skin reactions in rare cases.

{For human and equine use product packaged in pump spray:}

CAUTION: Causes eye irritation. Harmful if swallowed. Instruct older children in the proper use of this product. If used on the face, spray on hands first and then apply sparingly and avoid the eyes. Do not spray directly onto face, lips or into eyes. Do not spray in enclosed areas. Do not apply over cuts, wounds or irritated skin. Use of this product may cause skin reactions in rare cases.

FIRST AID

If Swallowed	<ul style="list-style-type: none"> • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person. • Call a poison control center or doctor immediately for treatment advice.
If In Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, continue rinsing the eye. • Call a poison control center or doctor for treatment advice.
If you suspect a reaction to this product	 <ul style="list-style-type: none"> • Discontinue use. • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
<p>Have product container with you when calling for help or going for treatment. Questions ??? : 800-940-4464 , Weekdays from 9-5 EST.</p>	

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

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.

{For human use product packaged as a liquid (rub-on):}

Use just enough repellent to cover exposed skin and/or clothing. Avoid over-application of this product. Do not use under clothing. Do not apply near eyes and mouth. Apply sparingly around ears. Do not apply to children's hands. When using on children, apply to your own hands and then put it on the child. Do not allow children to handle this product. Do not apply more than 3 times per day to children ages twelve (12) and under. Frequent reapplication and saturation is unnecessary for effectiveness. For ticks and chiggers, also apply to shoe tops, socks and around openings in clothing. After returning indoors, wash treated skin with soap and water. Wash treated clothing before wearing it again. Avoid contact with plastics such as eyeglass frames, fabric such as acetate and rayon, and leather such as watchbands. [Will not damage cotton, wool, or nylon.][Do not apply on or near acetate, rayon, spandex, or other synthetics, furniture, plastics, watch crystals, leather and painted or varnished surfaces including automobiles.]

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{For human use product packaged in a pump spray:}

Use just enough repellent to cover exposed skin and/or clothing. Avoid over-application of this product. Do not use under clothing. Do not spray directly on face. To apply to face, spray on hands and rub on. Do not apply near eyes and mouth. Apply sparingly around ears. Do not apply to children's hands. When using on children, apply to your own hands and then put it on the child. Do not allow children to handle this product. Do not apply more than 3 times per day to children ages twelve (12) and under. Frequent reapplication and saturation is unnecessary for effectiveness. For ticks and chiggers, also apply to shoe tops, socks and around openings in clothing. After returning indoors, wash treated skin with soap and water. Wash treated clothing before wearing it again. Avoid contact with plastics such as eyeglass frames, fabric such as acetate and rayon, and leather such as watchbands. [Will not damage cotton, wool, or nylon.][Do not apply on or near acetate, rayon, spandex, or other synthetics, furniture, plastics, watch crystals, leather and painted or varnished surfaces including automobiles.]

{For equine use product packaged in a pump spray:}

To repel the insects listed on the front panel, hold sprayer 6 to 12 inches from animal and spray on the areas where insects are observed. To apply to face, spray on a clean cloth and rub on. Apply in early morning or at dusk for best results. Repeat every 24 hours or as directed by a veterinarian. Frequent reapplication and saturation is unnecessary for effectiveness. Do not apply other insecticides or repellents when using this product. Do not spray in enclosed areas. Do not apply under wraps or bandages. Do not apply near eyes and mouth. Apply sparingly around ears. Do not spray directly on face. Wash thoroughly with soap and water after handling. Wash contaminated clothing before reuse. Avoid contact with plastics, such as eyeglass frames, fabric, such as acetate and rayon, and leather. [Will not damage cotton, wool, or nylon.][Do not apply on or near acetate, rayon, spandex, or other synthetics, furniture, plastics, watch crystals, leather and painted or varnished surfaces including automobiles.] Do not use on horses intended for slaughter.

DISPOSAL

If empty: Do not reuse this container. 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. Never place unused product down any indoor or outdoor drain.

ASSOCIATED REGISTRATIONS

P.O. Box 188
Safety Harbor, FL 34695

EPA REG. NO.: 54287-13

EPA EST. NO.: 54287-FL-1

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