Ms. Karen C. Maass
3M/Personal Care Products Project
Bldg. 235-3E-06
t. Paul, MN 55144-100

Dear Ms. Maass:

. 17H-10

Subject: Deer Tick Repellency Claims: MRID 42076-01

3M Insect/Arthropod Repellent Lotion

EPA Reg. No. 58007-1

3M Ultrathon Insect Repellent

EPA Reg. No, 58007-3

Submissions: October 15, 1991

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. Five copies of the finished labeling must be submitted prior to releasing the product for shipment.

- 1. The efficacy data submitted support claims for repelling deer ticks, <u>Ixodes dammini</u>, as explained in the attached review. The following claims .owever, are misleading and inconsistent with regulation at CFR 156.10(a)(5) and must be deleted:
  - a. Greater Protection with less DEET!
  - b. Contains DEET, the most effective tick protection xxx you can wear.
- 2. On the back label (#58007-1), delete the first two paragraphs beginning -3M has developed a revolutionary insect repellent xxx. You may retain the alternate text beginning -The

Ultrathon formula was created for the U.S. Army xxx. For #58007-3, delete references to a revolutionary insect repellent, Maximum Protection and Controlled Release Technology.

- 3. Assure that these registered repellents have distinctly unique names; it appears that you are using 3M Ultrathon Insect Repellent for both, which is unacceptable FIFRA Section 2(q)(1)(c).
- 4. Modify the military label (58007-1) to include appropriate statements from PR Notice 91-4. We believe the statements from copy approved October 30, 1991, #58007-1, beginning -Use just enough repellent xxx may cause skin reactions in rare cases. would be appropriate.

Sincerely,

Richard F. Mountfort
Product Manager 10
Insecticide/Rodenticide Branch
Registration Division (H7505C)

3 % 6

## BEST AVAILABLE COPY

FRONT LABEL

3M

ULTRATHON INSECT REPELLENT

Repels Mosqui oes, Biting Flies, Ticks including Deer Ticks, Chiggers, Gnats, Fleas, and Deer Flies

CONTROLLED RELEASE FORMULA Provides Effective Protection up to 8 hours. THIS CAN IS DESIGNED TO SPRAY RIGHT SIDE UP OR UPSIDE DOWN FOR CONVENIENT APPLICATION.

ACTIVE INGREDIENTS
N,N-DIETHYL-META-TOLUAMIDE 22.56%
OTHER ISOMERS 1.19%
INERT INGREDIENTS 76.25%

ACCEPTED
with COMMENTS
in EPA Letter Dated

KEEP OUT OF REACH OF CHILDREN.

#### WARNING:

SEE ADDITIONAL PRECAUTIONS ON BACK PANEL.

NET ₩T. 6 0Z. × 170g

02 MAR 1992

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 5807-3

ADDITIONAL CLAIMS THAT MAY BE INCLUDED ON LABELING \*Repels Deer Ticks that can cause Lyme disease \*Repels Ticks that can cause Lyme disease. \*Provides Effective Protection against Deer Ticks that can cause Lyme disease. \*Provides Effective Protection against Deer Ticks. \*Contains (DEET) the most effective tick protection (tick ingredient, tick fighting ingredient, or tick repellent you can wear (on skin).

BACK LABEL

INSECT REPELLENT

3M has developed a revolutionary insect repellent with .

CONTROLLED RELEASE TECHNOLOGY. It provides a continuous shield of protection that last up to 8 hours against ... mosquitoes. Also repels ticks, including Deer ticks, biting flies, chiggers, gnats, fleas and deer flies.; This controlled Release Technology was developed for the U.S.'. Military and is for use in challenging situations reduiring long lasting protection.

THIS UNIQUE FORMULA - Creates an effective barrier that. repels mosquitoes and biting insects - Provides maximum protection hour after hour - Resists rain, sweat, water splashes.

For extra protection against from crawling ticks, apply extra spray along all openings of clothing that they may crawl under, inspect for ticks often.

BACK PANEL (Cont.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS - WARNING: For external use only. if swallowed. Causes eye irritation. Do not get in eyes or mouth. Do not apply to hands of young children. Do not apply over cuts, wounds, or irritated skin. Do not spray in enclosed areas.

PRACTICAL TREATMENT: IF IN EYES: flush with plenty of water. If irritation persists, get medical attppention. IF SWALLOWED, call a physician or poison control center. Get medical help. IF ON SKIN, use of this product may cause skin reactions in rare cases. If you suspect that you or your child is reacting to this product, wash treated skin and call your local poison control center. If you go to a doctor, take this repellent with you.

PHYSICAL & CHEMICAL HAZARDS: EXTREMELY FLAMMABLE. Contents under pressure. Do not use near heat, sparks or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 F may cause bursting Keep treated surfaces away from fire or flame until dry.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. READ ALL DIRECTIONS BEFORE USING THIS PRODUCT. Hold container 6 to 8 inches from skin or clothing and spray with a slow sweeping motion. Use just enough repellent to cover exposed skin and clothing. Do not use under clothing. Avoid overexposure. Frequent reapplication and saturation is unnecessary for effectiveness. Do not spray directly on face. TO APPLY TO FACE, spray into palm of hand and spread evenly on face and neck. DO NOT APPLY TO EYES AND MOUTH. For best protection spread evenly with hand to moisten all exposed skin. WORKS ON CLOTHING TOO. Spray shirts, pants, cuffs, socks and around other openings on outer clothing. WILL NOT DAMAGE nylon, cotton or wool fabrics. MAY DAMAGE other synthetic fabrics, plastics, watch crystals, leather, painted or varnished surfaces. After returning indoors, wash treated skin with soap and water. Wash treated, clothing.

STORAGE: Store away from heat or flame in an area inaccessible to children. DISPOSAL: Do not reuse empty container. Wrap container and

put in trash. Do not puncture or incinerate.

Distributed by 3M/Personal Care Product 3M Center St. Paul, MN 55144-1000 EPA Reg. No. 58007-3 Cat. 632 EPA Est.11525-IL-01

Remember to Help Keep Our Work Clean!

02 MAR 1992

Ms. Karen C. Maass
3M/Personal Care Products Project
Bldg. 235-3E-06
St. Paul, MN 55144-100

Dear Ms. Maass:

j

Subject: Deer Tick Repellency Claims: MRID 42076-01

3M Insect/Arthropod Repellent Lotion

EPA Reg. No. 58007-1

3M Ultrathon Insect Repellent

EPA Reg. No, 58007-3

Submissions: October 15, 1991

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. Five copies of the finished labeling must be submitted prior to releasing the product for shipment.

- 1. The efficacy data submitted support claims for repelling deer ticks, <u>Ixodes dammini</u>, as explained in the attached review. The following claims however, are misleading and inconsistent with regulation at CFR 156.10(a)(5) and must be deleted:
  - a. Greater Protection with less DEET!
  - b. Contains DEET, the most effective tick protection xxx you can wear.
- 2. On the back label (#58007-1), delete the first two paragraphs beginning -3M has developed a revolutionary insect repellent xxx. You may retain the alternate text beginning -The

Ì

Ultrathon formula was created for the U.S. Army xxx. For #58007-3, delete references to a revolutionary insect repellent, Maximum Protection and Controlled Release Technology.

- 3. Assure that these registered repellents have distinctly unique names; it appears that you are using 3M Ultrathon Insect Repellent for both, which is unacceptable FIFRA Section 2(q)(1)(c).
- 4. Modify the military label (58007-1) to include appropriate statements from PR Notice 91-4. We believe the statements from copy approved October 30, 1991, #58007-1, beginning -Use just enough repellent xxx may cause skin reactions in rare cases. would be appropriate.

Sincerely,

Richard F. Mountfort
Product Manager 10
Insecticide/Rodenticide Branch
Registration Division (H7505C)

FRONT LABEL

3M

ULTRATHON INSECT REPELLENT

Repels Mosquitoes, Biting Flies, Ticks including Deer Ticks, Chiggers, Gnats, Fleas, and Deer Flies

CONTROLLED RELEASE FORMULA Provides Effective Protection up to 8 hours. THIS CAN IS DESIGNED TO SPRAY RIGHT SIDE UP OR UPSIDE DOWN FOR CONVENIENT APPLICATION.

ACTIVE INGREDIENTS
N,N-DIETHYL-META-TOLUAMIDE 22.56%
OTHER ISOMERS 1.19%
INERT INGREDIENTS 76.25%

ACCEPTED
with COMMENTS
in EPA Letter Dated

KEEP OUT OF REACH OF CHILDREN.

#### WARNING:

SEE ADDITIONAL PRECAUTIONS ON BACK PANEL.

NET WT. 6 0Z. \* 170g

02 MAR 1992

Under the Federal Insecticide, Fungicide, and Roduct cide Act as amonded, for the pesticide registered under EPAReg. No.

ADDITIONAL CLAIMS THAT MAY BE INCLUDED ON LABELING \*Repels Deer Ticks that can cause Lyme disease \*Repels Ticks that can cause Lyme disease. \*Provides Effecti e Protection against Deer Ticks that can cause Lyme disease. \*Provides Effective Protection against Deer Ticks. \*Contains (DEST) the most effective tick protection (tick ingredient, tick fighting ingredient, or tick repellent you can wear (on skin).

BACK LABEL

)

BEST AVAILABLE COPY

INSECT REPELLENT

3M has developed a revolutionary insect repellent with

CONTROLLED RELEASE TECHNOLOGY. It provides a continuous shield of protection that last up to 8 hours against mosquitoes. Also repels ticks, including Deer ticks, biting flies, chiggers, gnats, fleas and deer flies. This CONTROLLED RELEASE TECHNOLOGY was developed for the U.S. Military and is for use in challenging situations requiring long lasting protection.

THIS UNIQUE FORMULA - Creates an effective barrier that repels mosquitões and biting insects - Provides maximum protection hour after hour - Resists rain, sweat, water plashes.

For extra protection against from crawling ticks, apply extra spray along all openings of clothing that they may crawl under, inspect for ticks often.

# BEST AVAILABLE COPT

BACK PANEL (Cont.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS - WARNING: For external use only. Harmful if swallowed. Causes eye irritation. Do not get in eyes or mouth. Do not apply to hands of young children. Do not apply over cuts, wounds, or irritated skin. Do not spray in enclosed areas.

PRACTICAL TREATMENT: IF IN EYES: flush with plenty of water. If irritation persists, get medical attppention. IF SWALLOWED, call a physician or poison control center. Get medical help. IF ON SKIN, use of this product may cause skin reactions in rare cases. If you suspect that you or your child is reacting to this product, wash treated skin and call your local poison control center. If you go to a doctor, take this repellent with you.

PHYSICAL & CHEMICAL HAZARDS: EXTREMELY FLAMMABLE. Contents under pressure. Do not use near heat, sparks or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 F may cause bursting. Keep treated surfaces away from fire or flame until dry.

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. READ ALL DIRECTIONS BEFORE USING THIS PRODUCT. Hold container 6 to 8 inches from skin or clothing and spray with a slow sweeping motion. Use just enough repellent to cover exposed skin and clothing. Do not use under clothing. Avoid overexposure. Frequent reapplication and saturation is unnecessary for effectiveness. Do not spray directly on face. TO APPLY TO FACE, spray into palm of hand and spread evenly on face and neck. DO NOT APPLY TO EYES AND MOUTH. For best protection spread evenly with hand to moisten all exposed skin. WORKS ON CLOTHING TOO. Spray shirts, pants, cuffs, socks and around other openings on outer clothing. WILL NOT DAMAGE nylon, cotton or wool fabrics. MAY DAMAGE other synthetic fabrics, plastics, watch crystals, leather, painted or varnished surfaces. After returning indoors. wash treated skin with soap and water. Wash treated clothing.

STORAGE: Store away from heat or flame in an area inaccessible to children.

DISPOSAL: Do not reuse empty container. Wrap container and put in trash. Do not puncture or incinerate.

Distributed by 3M/Personal Care Product 3M Center
St. Paul, MN 55144-1000 EPA Reg. No. 58007-3
Cat. 632 EPA Est.11525-IL-01
Remember to Help Keep Our Work Clean!