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February 1, 1996

Reckitt & Colman Inc.
225 Summit Ave.
Montvale, NJ 07645-1575

Attention: Ms. Ruth Trager

Subject: d-Con Mouse-Prufe II
EPA Registration No. 3282-65
Your amended application of November 8, 1995

We consider this product to be a ready-to-use bait station that is not tamper-resistant. The likelihood that such a product could or would be used appropriately in a tamper-resistant bait station seems to us to be extremely small. Although PR Notice 94-7 does not cover this point as well as it should have, our policy toward ready-to-use bait stations claimed to control is to label them according to the degree of bait protection that they provide.

Products such as MOUSE PRUFE II provide essentially no bait protection and, consequently, are labeled to prohibit placements in any areas that are accessible to young children, pets, domestic animals, or nontarget wildlife potentially at risk. As the bait station portion of this product is made of cardboard, MOUSE PRUFE II may not be used outdoors. Note that these use limitations are covered by text in the "USE RESTRICTIONS" portion of the "DIRECTIONS FOR USE" on this product's current accepted labeling.

We recently have become concerned that the prohibitions on some of the "older" labels for non-protective, ready-to-use rodenticide bait stations are not as strong or as clear as they need to be. Your recent television advertisements which show d-Con baits being applied unprotected in areas which would appear to be accessible to small children and pets who lived in or visited the premises have underscored this concern about MOUSE PRUFE II specifically. We have concluded that the "DIRECTIONS FOR USE" on this product's label must be amended to read as indicated immediately below.

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The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable provided that you make the following changes and submit one (1) copy to us before your ship product:

- A. In your precautionary statements, we have required, in the past, the following text:

CAUTION

May be harmful or fatal if swallowed.

However, the second precautionary statement would appear to be inconsistent with the Regulations [40 CFR 156.10(h)] for the following reasons:

1. A product supported by an acute oral toxicity study in Category III requires the signal word, "CAUTION" and the precautionary statement: "May be harmful if swallowed."
2. A product supported by an acute oral toxicity study in Category II requires the signal word, "WARNING" and the precautionary statement: "May be fatal if swallowed."

According to our files, the acute oral toxicity study supporting this 0.005% Brodifacoum product is in Toxicity Category III. Therefore, in order to make the labeling for this product consistent with the regulations, you should modify the above precautionary statements as follows:

CAUTION

May be harmful if swallowed.

- B. Modify your use directions as follows:

DIRECTIONS FOR USE

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

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USE RESTRICTIONS:

THIS IS NOT A TAMPER-PROOF OR TAMPER-RESISTANT BAIT STATION. DO NOT USE THIS PRODUCT IN AREAS ACCESSIBLE TO CHILDREN, PETS, DOMESTIC ANIMALS, OR NONTARGET WILDLIFE. DO NOT USE THIS PRODUCT OUTDOORS.

This product may be used to control house mice in homes, industrial, commercial, agricultural and public buildings. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Wedges of MOUSE PRUFE II may be placed along walls, in corners, and in concealed places where mice are active and where nontarget mammals and birds will not be exposed to the bait.

APPLICATION DIRECTIONS: Place wedge in horizontal position. Pull tab, lift and twist off. Space wedges at intervals of 8 to 12 feet if mouse activity is not highly localized and placements can be made in areas not accessible to children and nontarget animals. Replace wedges as their contents are consumed. Two wedges may be needed at points of extremely high mouse activity. [Use preceding sentence on labels for 1.5-oz box but not for 3.0-oz box.] Wedges not touched after three days should be moved to new locations appropriate for bait placements if mouse activity persists. Maintain a supply of fresh bait for at least 15 days. Collect and dispose of all dead animals and leftover bait properly."

- C. Revise the following promotional claims which appear on the proposed revised labels submitted on November 8, 1995. Claims not mentioned here may be regarded as acceptable as proposed.

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1. As written, the claim, on the left side of the front panel, which reads

"Solving
America's
Rodent
Problems
For Over
40 Years"

is false and misleading. This product has not been registered for 40 years. What seems to be true is that d-CON baits have been used to control commensal rodents for more than 40 years. Therefore, an acceptable claim for this product would be

"d-CON Baits:
Killing
Mice In
America
For Over
40 Years".

2. Delete the "EASY TO USE" claim from the right side of the front panel. This claim seems to us to be misleading. Although placing and opening the wedges themselves would not appear to be extremely difficult activities, following the entire "DIRECTIONS FOR USE" also requires users to determine where suitable bait locations would be, to monitor bait consumption, and to collect and dispose of dead rodents and unconsumed bait. In determining where wedges may be placed, users must find locations not accessible to young children and nontarget animals which also are appropriate for intercepting house mice. When all of a user's responsibilities are considered, product use does not seem to us to be so easy. There also is a danger that this type of claim might influence some users to be a bit careless in their use of the product.
- D. Some of the promotional claims which appear on your current accepted labels for this product were not included in the proposed revised labeling submitted for this product on November 8, 1995. As it is possible that some of these claims were not omitted intentionally, we indicate which of these claims we no longer consider to be appropriate.

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1. The meaning of the claim "ADVANCED FORMULA", which appears in several places on the label for the outer box, is unclear to us and, we suspect, would be misleading to others. The same can be said for the "IMPROVED ANTICOAGULANT FORMULA" claim which has been used on wedge labels. Delete these claims from all places where they appear.

2. Wherever they appear, single feeding claims such as

"CAN KILL IN ONE FEEDING* . . .
 *Mice will die within 4 or 5 days"

must be deleted or replaced with

"Mice may consume a lethal dose in one feeding with first dead mice appearing 4 or 5 days after feeding begins."

Note that at the time of product reregistration, efficacy data from choice tests with only one day of exposure to toxic bait will be required to support retention or addition of single-feeding claims to labels for rodenticide baits.

E. Revise your "STORAGE AND DISPOSAL" statement as follows:

STORAGE AND DISPOSAL

Storage: Store only in original container, in a dry place inaccessible to children and pets.

Disposal: Do not reuse empty container. Securely wrap in newspaper and discard in trash.

Within 90 days of the date of this letter, submit proposed revised labels with use directions organized in the format shown above. When labels are printed, organize the main heading "DIRECTIONS FOR USE" and the subheadings "USE RESTRICTIONS", "SELECTION OF TREATMENT AREAS", and "APPLICATION DIRECTIONS" in the manner indicated above. Make sure that logos and other not-required items do not obscure or detract from required label statements.

When you submit revised labels, include a separate label for the outer container of the pack of four 1.5-oz wedges. Information which pertains only to the 4-pack should appear only on the label proposed for it. One draft label may stand for both sizes of wedge, but that label must clearly indicate that the "Two wedges may be needed" sentence applies only to the 1.5-oz wedge. When labels are printed for wedges, the "Two wedges may be needed" sentence may be used only for the 1.4-oz wedge.

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 the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

Sincerely yours,



Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7504C)

Enclosures: 1. Stamped Label
2. A-79 Enclosure

Peacock WP#8:A:Brodifac\3282-65:305-5407,-6600:2/1/96

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d-CON MOUSE-PRUFE II
EPA Reg. No. 3282-65
FRONT LABEL

d-CON®
MOUSE-PRUFE II™

Solving
America's
Rodent
Problems
For Over
40 Years

KILLS
MICE

APPROVED
BY EPA
in EPA Label Order

EASY
TO
USE

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this product is registered under the name of d-CON MOUSE-PRUFE II™. EPA Reg. No. 3282-65.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....	0.005%
INERT INGREDIENTS.....	.99.995%
TOTAL	100.00%

Keep out of reach of children.

CAUTION:

May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

NET WT. 1.5 OZ. (43 g)
3 OZ. (85 g)
6 OZ. (170 g)

NET CONTENTS 4/1.5 oz.
VALUE PACK Multiple Baits for the many places mice feed
4 PACK OF MOUSE PRUFE II

d-CON MOUSE-PRUFE II
EPA Reg. No. 3282-65
BACK LABEL

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help to prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by dogs and by children under six years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hooved livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: For control of House Mice in homes, industrial, commercial, agricultural and public buildings. Do not place bait in areas where there is a possibility of contaminating food, water or surfaces that come in direct contact with either.

SELECTION OF TREATMENT AREAS: Place wedges of Mouse Prufe II along walls, in corners, and in concealed places where mice are active and where nontarget mammals and birds will not be exposed to the bait.

APPLICATION DIRECTIONS: Place wedge in horizontal position. Pull tab, lift and twist off. Place Mouse-Prufe II at points of mouse activity. Replace containers as they are consumed. Two or more containers should be used where there is extremely high mouse activity. Replace packs as they are consumed. Packs not touched after 3 days should be moved to new location where mouse activity is high. Maintain an uninterrupted supply of fresh bait for 15 days or until signs of mouse activity cease.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS & DOMESTIC ANIMALS:

Caution: May be harmful or fatal if swallowed. Keep away from humans, domestic animals and pets. Wash hands after handling bait. **If Bait is Eaten by Humans, Call a Physician at once:** For 24-hour emergency assistance, call your local Poison Control Center. **If Bait is Eaten by Animals or Pets:** Call your local veterinarian. **Note to Physician or Veterinarian:** This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K₁ are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). **For Human Cases:** Vitamin K₁ is antidotal at doses of 10-20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. **For Animal Cases:** Vitamin K₁ is antidotal at 5mg/kg intramuscularly. Oral Vitamin K₁ should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times).

Environmental Hazards: This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Keep out of any body of water.

Storage & Disposal: Store away from children and pets. Wrap empty or used container and put in trash.

NOTICE TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under conditions not reasonably foreseeable to Seller, and Buyer and User assumes the risk of any such use. Seller disclaims all other warranties, expressed or implied, including any warranty of fitness or merchantability. Seller shall not be liable for consequential, special or indirect damages resulting from the use or handling of this product and Seller's sole liability and Buyer's and User's exclusive remedy shall be limited to the refund of the purchase price.

Satisfaction guaranteed or your money back.

EPA Reg. No. 3282-65

EPA Est. No. 3282-OH-1; 475-MS-1; 2393-WI-1

Distributed by:

Household Products Division

Reckitt & Colman Inc., Montvale, NJ 07645