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February 1, 1996

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

Attention: Ms. Ruth Trager

Subject: d-Con Pellets Generation II EPA Registration No. 3282-66

Your amended application of November 8, 1995

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 apper to be inconsistent with the Regulations [40 CFR 156.10(h)] for the following reasons:

- 1. A product supported by an acute <u>oral</u> 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 <u>oral</u> 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 the proposed revised labeling submitted for this product on November 8, 1996, to read as indicated below.
 - 1. On the back panel of the label for the 12-oz outer box, organize the heading and subheadings in the "DIRECTIONS FOR USE" in the manner indicated below (and in PR Notice 94-7) and modify this entire section to read as shown below. Note that some of the text in the "USE RESTRICTIONS", "SELECTION OF TREATMENT AREAS", and "APPLICATION DIRECTIONS" sections must be changed.

DIRECTIONS FOR USE

It is 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 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 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 hoofed 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: This product may be used to control house mice, Norway rats, and roof rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON Pellets Generation II also may be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. Do not use in sewers. 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: Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or signs of rodents have been seen. Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see "IMPORTANT").

APPLICATION DIRECTIONS:

The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations.

To Control Norway and Roof Rats: Place 1-4 bait trays per placement. Space placements at intervals of 15-30 feet in infested areas. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and apply 1/4-1/2 ounce (1-2 level tablespoons) of bait at 8- to 12-foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

For Rats and Mice: Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity still is evident. If trays are not fed from for 5 consecutive days, relocate them to other

places where rodent activity exists and where placements consistent with the requirements of this label can be made. Collect and dispose of all dead animals and leftover bait properly.

To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish them as needed."

Preserve this format and content when bels are printed. Do not include any graphics with these directions.

2. On the front panel of the box label, replace

CAN KILL IN ONE FEEDING
Rats and mice will die within 4 or 5 days

with

Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days a ter feeding begins.

Make this same substitution on the left side pane. of the box label.

3. Delete from the back panel of the box label the sentence

d-CON Pellets Generation II can kill in one feeding when used as directed.

4. As written, the claim, on the left side panel of the box, 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 would be

"d-CON BAITS: KILLING RATS AND MICE IN AMERICA FOR MORE THAN 40 YEARS".

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5. Either delete the single-feeding claim from the front panel of the label for individual bait trays or modify the claim to read

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

As these trays are not to be sold individually, we question the need for this claim on the label for the bait trays.

On the back panel of the label for the bait tray, replace

See outer box for complete Directions for Use.

with the text shown immediately below.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label on the outer package before using this product. It is illegal to sell these bait trays individually."

Note that bait trays sold individually would be misbranded because they would lack complete "DIRECTIONS FOR USE" and "STORAGE AND DISPOSAL" text. As the 3-oz contents are below the minimum requirement for a single placement of "loose" anticoagulant bait used to control commensal rats, an individually-sold container of that amount could not bear claims for controlling Norway rats or roof rats.

When setting up labels for printing, make sure that logos and other not-required items do not obscure or detract from required label statements.

C. In accordance with PR Notice 93-8, change the last sentence in your "Environmental Hazards" section from "Keep out of any body of water." to "Do not apply directly to water."

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D. 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 container and any unused bait in

newspaper and discard in trash.

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,

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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\3282-66:305-5407,-6600:2/1/96

d-CON PELLETS GENERATION II EPA REG. NO. 3282-66 12 oz. BOX FRONT LABEL

(GOOD HOUSEKEEPING SEAL)

ACCEPTED
with COMMENTS
to EPA Letter Dated

d-CON® PELLETS GENERATION II WELL

KILLS RATS AND MICE

Under the Federal Insecticide, and which has being the section of the section of

4 READY-TO-USE BAIT FILLED TRAYS

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flavor attractive to rats and mice

CAN KILL IN ONE FEEDING
Rats and mice will die within 4 or 5 days

Keep out of reach of children. CAUTION: May be harmful or fatal if swallowed. Read additional precautionary statements on back panel.

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
INERT INGREDIENTS99.995%
TOTAL 100.000%

NET CONTENTS 4/3.0 OZ. (85g) NET WT. 12 OZ. (340g)

d-CON PELLETS GENERATION II EPA REG. NO. 3282-66 12 OZ. BOX BACK PANEL

d-con® PELLETS GENERATION II

KILLS RATS AND MICE

d-CON Pellets Generation II can kill in one feeding when used as directed. Kills Warfarin-Resistant Norway Rats and Warfarin-Resistant House Mice.

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 hoofed livestock, raccoons, bears, or 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 Norway Rats, Roof Rats and House Mice in and around homes, industrial, commercial, agricultural and public buildings. d-CON Pellets Generation I may also be used in and around transport vehicles (ships, trains, aircraft) and related port or terminal buildings. Do not use in sewers. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food.

SELECTION OF TREATMENT AREAS: Place trays in or near points where you have seen rat or mice signs such as droppings, runways, burrows, or gnawing marks. Once areas requiring baiting have been identified proceed as follows:

APPLICATION DIRECTIONS:

1. Place one ready-to-use bait tray in each potential feeding location. Place trays in dark, out-of-the-way locations, where rodents are likely to find them.

For Norway and Roof Rats: Start with one tray per location. Add trays, up to a maximum of four per location, if you determine that there is high rat activity at the location.

For House Mice: Use only one tray per location.

2. For best results, leave trays undisturbed for at least two days after placement. However, if contents have been scattered or mostly consumed sooner, replace trays. Clean up spilled bait. Check bait every two days, replacing trays as needed or until signs of rodent activity cease. Trays not fed from for five consecutive days may be relocated as needed. When there are no longer any signs of rodent activity, dispose of trays properly.

For complete control, continue baiting for at least 15 days. If you are in an area where there is a danger of reinfestation from adjoining property, permanent bait stations should be maintained. Stations should be checked periodically.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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 AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. 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 K, are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K, is antidotal at doses of 10 to 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 K, is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K, should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS:

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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 AND DISPOSAL:

Store in original container in areas inaccessible to small children and pets. Bait that cannot be used according to label instructions must be disposed of according to applicable federal, state or local procedures.

d-CON PELLETS GENERATION II EPA REG. NO. 3282-66 12 OZ. BOX RIGHT SIDE PANEL

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d-CON®
PELLETS GENERATION II

KILLS RATS AND MICE

Kills
Warfarin-Resistant
Norway Rats and
Warfarin-Resistant
House Mice

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 abnormal use conditions, or under conditions not reasonably foreseeable to Seller, and Fuyer 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 I'D BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

EPA Reg. No. 3282-66 EPA Est. No. 3282-OH-1; 475-MS-1; 2393-WI-1

> SATISFACTION GUARANTEED OR YOUR MONEY BACK

d-con pellets generation II EPA REG. NO. 3282-66 12 OZ. BOX LEFT SIDE PANEL

d-CON®
PELLETS GENERATION II

KILLS RATS AND MICE

CAN KILL IN ONE FEEDING

Rats and Mice will die within 4 or 5 days

MADE IN THE USA

SOLVING AMERICA'S RODENT PROBLEMS FOR OVER 40 YEARS

SATISFACTION GUARANTEED OR YOUR MONEY BACK

Distributed by:
Household Products Division
Reckitt & Colman Inc.
Montvale, NJ 07645

d-con pellets generation II EPA REG. NO. 3282-66 3 OZ. BAIT TRAY - FRONT PANEL

d-CON® PELLETS GENERATION II

KILLS RATS AND MICE

Ready-To-Use Bait Tray

Kills Warfarin-Resistant Norway Rats and Warfarin-Resistant House Mice

CAN KILL IN ONE FEEDING
Rats and mice will die within 4 or 5 days

Keep out of reach of children. CAUTION: May be harmful or fatal if swallowed. Read additional precautionary statements on back panel.

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
INERT INGREDIENTS99.995%
TOTAL 100.000%

NET WT. 3 OZ. BAIT TRAY (85g)

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d-CON PELLETS GENERATION II EPA REG. NO. 3282-66 3 OZ. BAIT TRAY - BACK PANEL

d-CON® PELLETS GENERATION II

KILLS RATS AND MICE

Kills Warfarin-Resistant Norway Rats and Warfarin-Resistant House Mice

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND 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 AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. 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 K, are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K, is antidotal at doses of 10 to 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 K, is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K, should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

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.

See outer box for complete Directions for Use. Household Products Division Reckitt & Colman Inc., Montvale, NJ 07645 EPA Reg. No. 3282-66 EPA Est. No. 3282-OH-1; 475-MS-1; 2393-WI-1