)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 14 1992

5423591

5418754

5419062 345

Ms. Victoria Dunnum Bell Laboratories, Inc. 3699 Kinsman Boulevard Madison, WI 53704

Dear Ms. Dunnum:

Contrac Rodenticide Ready To Use Place Pac 5423546 Subject:

EPA Registration No. 12455-76

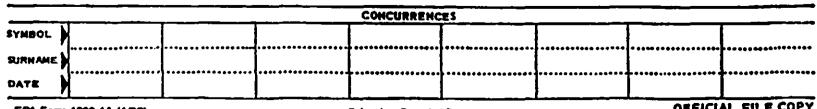
Your Letters Dated April 29, May 22, and

August 10 and 12, 1992

The Agency has reviewed the submission referred to above and has the following comments:

With your letter of April 29, 1992, you provided proposed 1. labels for 0.88-oz placepacks, outer packages that would contain 200 0.88-g placepacks, an outer packages that would contain six 1-1/2-oz placepacks. We have concluded that these various labels and packaging arrangements are not acceptable as proposed under this registration.

The labels which pertain to 0.88-oz placepacks differ significantly from your current label in the application directions for controlling commensal rats. Although we feel that the 0.88-oz size is somewhat small for controlling rats, this size of placepack would be acceptable if it were to be the only placepack size sold under registration number 12455-76. In the same amendment application, however, you also propose to continue to sell the product in 1-1/2-oz placepacks. Depending upon whether the larger or smaller placepacks were used, applying the same numbers of packs would lead to vastly different amounts of bait being placed. proposed solution to this problem is to adjust the application directions for rats to the size of the pack being used. We could permit this if you had separate registrations for the two distinct package sizes, but do not allow major substantive changes in application directions under one registration number for rodenticide baits.



For the mouse claims, the application directions proposed for the 0.88-oz placepack are identical to those already being used for the 1-1/2-oz pack. Therefore, the 0.88-oz size of pack could be used for this product if it were sold with a label from which all claims for controlling rats had been deleted. Some of the changes which would be needed for a "mouse-only" label are listed below.

- on the front panel,
 - (1) "KILLS RATS AND MICE" would have to be changed to "KILLS MICE";
 - (2) "KILLS WARFARIN RESISTANT NORWAY RATS" would have to be deleted; and
 - (3) "Norway rats and" would have to be deleted from, the "h" in "house" would have to be capitalized, and "rodents" would have to be changed to "mice" in the "one-feeding" claim.
- b. In the "DIRECTIONS FOR USE,"
 - (1) "Norway rats, roof rats, and" would have to be deleted from the phrase which immediately follows "USE RESTRICTIONS:";
 - (2) "rats or" would have to be deleted from the first sentence of "SELECTION OF TREATMENT AREAS:";
 - (3) "APPLICATION DIRECTIONS" for "RATS" would have to be deleted; and
 - (4) The subheading "RATS/MICE:," but not the text which follows it, would have to be deleted from the "APPLICATION DIRECTIONS."

The label for the "SIX-PACK" of 1-1/2-oz placepacks is unacceptable. As you are aware, we do not knowingly accept packaging for rat and mouse baits when the amount of b single placement for controlling rats at the highest rate prescribed on the label unless an appropriate statement is added to the label to qualify the "KILLS RATS" claim. The label which you have proposed for the "SIX-PACK" bears the qualifying statement

"The place pacs in this bag contain enough bait (9 oz.) to kill three to nine rats."

We suspect that this statement was derived by extrapolation from a comment in our letter of September 24, 1991, to the effect that the smallest quantity in which 1-1/2-oz placepacks bearing rat claims could be sold would be two and that a two-pack would have to have

an outer package which bore a statement such as

"The placepacks in this package contain enough bait to control one to three rats."

We are not sure that such extrapolation is warranted or accurate. The basis for the statement for the 3-oz amount was that if there were more than three rats present, 3 oz of bait probably would not be enough to kill them, figuring how much the rats would be likely to eat in one day's feeding and the extremes of how bait might be divided among rats.

We have no reason to believe that rodents that are not individually caged are likely to share limited amounts of bait evenly. How many rats a given amount of bait can kill depends not only upon the toxicity of the bait but also on where baits are placed, how much bait each rat that feeds leaves for the next rat, etc., and the extent to which the rats permit the bait to be shared. Placepacks often are removed from their placement locations and cached in burrows. Bait in caches may be less generally available to all rats infesting an area than baits placed in bait stations or other man-chosen locations.

)

If the 43-g placepacks in your "SIX-PACK" were removed and cached by rats, it would be hard to predict how many animals they would kill. One rat might cache all six packs and feed from none of them. One rat might cache all six and feed from some or all of them before dying. Other rats might or might not find and feed on the remaining bait, which could lose palatability over time. Six rats might cache one pack each. Maybe each rat would be killed. Maybe some would not eat the bait at all. Perhaps the bait in some caches would be fed upon by more than one rat. How many rats exposed to the baits cached in these ways actually would die could vary greatly from one control effort to another.

We feel is that qualifying statements on labels for packages which offer limited amounts of bait should be conservative in reflecting what one could reasonably expect to kill with 9 oz of 0.005% Bromadiolone bait. If you decide to market a "SIX-PACK" of 1-1/2-oz. placepacks, the qualifying statement should read

"The place pace in this bag contain enough bait (9 oz.) to kill two to five rats."

If you decide to produce a 0.88-oz mouse-only pack of sell 1-1/2-oz packs in a six pack, submit amended proposed labels for our review. If you propose a new label for the "SIX-PACK," we suggest that you reduce the

amount of space on the front panel that is devoted to the product name, the claim "KILLS RATS AND MICE," and the statement of contents, especially "SIX PACK." Such reductions would provide ample space on the front panel for the precautionary statements which appear on the center panels of your other labels for this product. Moving the precautionary statements to the front panel also would permit a larger type size to be used for the "DIRECTIONS FOR USE" and other text on the back panel. This change also would provide space for properly centering the heading "DIRECTIONS FOR USE" so that it is apparent to readers that everything from the "It is a violation" statement through the end of the "RATS/MICE" paragraph is part of the "DIRECTIONS FOR USE" section.

2. The rat and mouse efficacy studies submitted on May 22, 1992, are acceptable and, under our current criteria, would support the "single-feeding" claim that you have retained on the label submitted on May 22, 1992. The rat study was assigned the MRID# 423269-02. The mouse study was assigned the MRID# 423269-01. These efficacy data are not applicable to the formulation that was proposed for this product on August 10, 1992.

)

The rat and mouse efficacy studies submitted on August 10, 1992, are applicable to the formulation described in the Confidential Statement of Formula (CSF) for your product 12455-69, dated August 6, 1992. These data also appear, by reference, to be relevant to the CSF for 12455-76 dated August 7, 1992. These efficacy studies are acceptable and would support a true "single-day'sfeeding" claim. The rat study was assigned the MRID# The mouse study was assigned the MRID# 424360-02. These efficacy data are applicable to the 424360-01. formulation that was proposed for this product on August 10, 1992. We assume that the formulation described by the CSF for 1245-69 dated 8/6/92 describes the only formulation that you intend to use for this product in the future. Except for certain types of dye substitutions, we do not permit "alternate formulations" for rodenticide baits.

As long as the material used in the placepacks for this product does not differ from that of the packs used in the placepack-penetration study for the current formulation (lacking Bitrex) for this product, new placepack penetration studies are not required.

We believe that data from laboratory efficacy studies involving only one day of exposure to toxic bait, which occurs in a standard choice situation, provide better support for a "single-feeding" claim than do the data that we have been accepting from 3-day tests. Even on

the one-day test, however, rodents have opportunities to feed many times. Therefore, a claim which stated that the product kills in one feeding would is not be absolutely correct. What the product has been shown to do is to kill after one day's feeding.

Because rodents do not die soon after eating lethal doses of anticoagulant baits, it is misleading to permit single-feeding or one-day's-feeding claims without adding a qualifying statement which informs potential users when the first rodent deaths are likely to occur. We do not believe that any claims which imply quick results are justified for anticoagulants.

Despite these considerations, we feel that this bait's having exceeded the 90% mortality criterion in rat and mouse tests which involved only one day of bait exposure is a very significant event. Therefore, we have attempted to develop language which could be added to the label for your product to allow it's single-feeding claim to be somewhat different from those made for other products for which the claims are based upon the results of tests which included three days of exposure to toxic bait. Below, we provide examples of statements that would be acceptable to us.

"This product has been shown to kill Norway rats and house mice after one day of feeding. As Bromadiolone is a slow-acting poison, rodent deaths should not be expected to occur until 3-5 days after treatment begins."

"This product can kill Norway rats and house mice as a result of one day of feeding on it. Rodent deaths should not be expected to occur until 3-5 days after treatment begins."

"Norway rats and house mice may consume a lethal dose in only one day of feeding on this bait. As Bromadiolone is a slow-acting poison, rodent deaths are not expected to occur until 3-5 days after treatment begins."

If you decide to use one of these statements, or if you elect to propose a statement of your own, you must submit proposed revised labeling which bears the statement which you would prefer to use. If we were to find the revised label to be acceptable, you would be able to use it from then on.

4. The text of the proposed revised labels submitted on May 22, 1992, is acceptable. The relatively small starburst in which "WITH BITREX" appears on these labels does not detract significantly from the precautionary statements

ve ed

and the "DIRECTIONS FOR USE."

We concur with your assessment that the actual protective value of Bitrex in rodenticide baits is questionable. Our policy has been to permit this ingredient to be added to baits -- as long as the baits can be shown to remain sufficiently palatable to target species -- on the theory that the bittering agent might "help" and apparently is not "hurting" product performance significantly. The second part of our policy has been to require that label and advertising statements regarding the presence of Bitrex in the product be limited to relatively inconspicuous factual declarations that the ingredient is in the bait (i.e., no safety claims).

What we prefer to see on labels is an asterisk following "INERT INGREDIENTS" in the ingredients statement which refers the reader to a sentence, in relatively fine print, such as

"This product contains Bitrex."

We are aware of at least one instance in which our Bitrex policy and good faith have been abused in the advertising for a rodenticide bait. We intend to rectify this situation. In the meantime, we hope that such problematical advertising does not lead to an "everybody's-doing it" situation in which other companies abuse the policy in their promotional campaigns in order to keep pace.

A copy of the stamped labeling is enclosed for your records. Submit one copy of the final printed labeling before releasing the product for shipment bearing the amended labeling.

Sincerely yours,

Robert A. Forrest Product Manager (14) Insecticide-Rodenticide Branch Registration Division (H7505C)

Enclosure: Stamped label

}

10/14/92:ERICKSON:DISK4:12455-76.LBL

ACCEPTED with COMMENTS in EPA Letter Dated

OCT 14 1992

Under the Federal Insecticide, Fungicide, and Resignificide Act as amended, for the posticide registered under EPA Reg. No. 12455-76

READY TO USE PLACE PAC

KILLS RATS AND MICE

KILLS WARFARIN RESISTANT NORWAY RATS

Norway rats and house mice may consume a lethal dose in one feeding with first dead rodents appearing four or five days after treatment begins.

ACTIVE INGREDIENT: Bromadictore; 3434F-Bromo-(1,1) button/644/8-3-hydroxy-1-phenylpropyll-4-hydroxy-24-1-burzopyran-2-one......
INERT INGREDIENTS 0.005% 99.995% TOTAL 100.000%

KEEP OUT OF REACH OF CHILDREN CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Keep array bor humans, detents, ahmals and pass. If smallured, the met ability of the blees and cause bleefing. Amed careact with eyes or deticing, and mater after handling. If smallured, call a physician at sects. NOTE TO PHYSIC AM. If improved, administer Visiona K, intramenable

Net Contents 1 1/2 OZ. (43 GM) Bell Laboratories, Inc.

EPA EST NO 12455-WI-I EPA REG NO 12455-78

public buildings. Contrac Place Pacs may also be y also do used in affigs. De nel use in sement.

with COMMENTS in FPA Letter Dates:

OCT 14 1992

Under the Endered Insecticide, Fungedae, and Rodenticide Act as amended, for the pecticide registered under EPA Rog. No. 12455-76

DIRECTIONS FOR USE

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

READTHIS 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:

 Store product not in use in a location out of reach of children and pats.
 Apply beit in locations out of reach of children, pets,

2. Apply beit in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant beit 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 beit compartments and obtaining beit. If beit can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger beit stations are needed in areas open to hoofed livestock, raccoons, bears, or other potentially destructive animals, or in areas prone to vandalism.

Dispose of product container, and unused, spoiled, and unconsumed beit as specified on this label.

USE RESTRICTIONS:

For control of Norway rats, Roof rats and House mice.
URBAN AREAS: May be used in and around the periphery of homes, industrial, commercial and public buildings. CONTRAC Place Pacs may also be used in and around transport vehicles (ships, trains, aircraft) and related port or terminal buildings. May also be used in alleys. Do not use in sewers.
NON-URBAN AREAS: May be used inside of homes and agricultural buildings.

See right side panel for additional DIRECTIONS FOR USE.

Contrac

RODENTICIDE

READY TO USE PLACE PAC KILLS RATS AND MICE

KILLS WARFARIN RESISTANT NORWAY RATS
Norway rats and house mice may consume a lethal doze in one teeding with first dead
roden's appearing four or five days after treatment begins.

TOTAL 100.000%

KEEP OUT OF REACH OF CHILDREN CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Keep away from humans, donestic arimals and eats. If swallowed, this material may notice the clatting shifty of the blood and cause bleeding. Ancid contact with eye, or clothing. Wash thoroughly with seep and water after handling. If swallowed, call a

NOTE TO PHYSICIAN: Il rejected, administer Ysamin K, intramescularly or erally as indicated in biolychorycoursann or archoses. Repeat as recessary based on morellering of professorial times.

ENMICHMENT AL MAZANDS: This product is tonic to fish and widdle. Keep out of labors, shours or punch.

Net Contents: 40 x 1 1/2 OZ.

Mfg. by:

EPA EST, NO. 12455-WI-1 EPA REG. NO. 12435-75

Bell Laboratories, Inc.

DIRECTIONS FOR USE (continued from left)

Do not place bait in areas where there is a contaminating food or surfaces that come in d with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS:

Determine areas where rats or mice will most if consume the bait. Generally, these are sto gnawed openings, in or beside burrows, in concealed places, between toors and walls, owhere rodents or their signs liave been seen, from rain or snow. Romove as much alternations to the constitution of the constitut

APPLICATION DIRECTIONS:

RATS: Apply 2 to 10 Place Pacs per placem an uninterrupted supply of fresh bait for at lee HOUSE MICE: Place 1 Place Pac at 8 to 12 I Mountain an uninterrupted supply of fresh bait i

days.

RATS/MICE: Replace contaminated or spoiled ately. Collect and dispose of all dead animals beit properly. To prevent reinfestation, limit rodent food, water, and harborage as much a reinfestation does occur, repeal treatment. Y tinuous source of infestation is present, established stations and replenish as needed.

STORAGE AND DISPOSAL

STORAGE: Store only in original container, inaccessible to children and pets.

DISPOSAL: Do not reuse empty container. S original container in several layers of newspt card in trash.



DIRECTIONS FOR USE

It is a violation of Federal lew 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.

MPORTANT: 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 beit in locations out of reach of children, pets, domestic animals and nontarnet wildlife or in tampe.
- 2. Apply best in locations out of reach of children, pets, domestic animals and nontarget wildtife, or in tamper-resistant beit 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 beit compariments and obtaining beit. If best 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.
- Dispose of product container, and unused, spoiled, and unconsumed beit as specified on this label.

USE RESTRICTIONS:

For control of Norway rats, Roof rats and House mice.
URBAN AREAS: May be used in and around the peripher; of homes, industrial, commercial and public buildings. CONTRAC Place Pacs may also be used in and around transport vehicles (ships, trains, aircraft) and related port or terminal buildings. May also be used in alleys. Do not use in sewers.
NON-URBAN AREAS: May be used inside of homes and apricultural buildings.

See right side panel for additional DIRECTIONS FOR USE.

Contrac®

RODENTICIDE

READY TO USE PLACE PAC KILLS RATS AND MICE

KILLS WARFARIN RESISTANT NORWAY RATS Norway rats and house nice may consume a lethal dose in one feeding with first dead rodents appearing hour or five days after treatment begins.

ACTIVE INGREDIENT: Bromadolone; 3-[3-(4-Brune[1,1*-biphery]-4-yh-3-bydrey:1-pherylpropy]-4-bydrey:24-1-benzepyran-2-ere 0.005%
INERT INGREDIENTS 99.995%

TOTAL 100.000%

KEEP OUT OF REACH OF CHILDREN CAUTION

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANNUALS

Keep pury from homers, denestic artirals and puts. If professed, this material more reduce the clothing ability of the blood and cause blooding. Avoid cented with eyes or clothing. Which theretify with soop and water after handling. If professed, call a theories of a new parts.

physician at error.

NOTE TO PHYSICIAN: Il impested, administer V_manna III, intramercularly or erably as indicated in biolychomycoumain evenducas. Repeat as necessary based on membering of producents in lines.

EPMPCOMENTAL HAZAVIDS: This product is took to figh and widdle. Keep out of labor, streams or pands.

Net Contents: 75 x 1 1/2 OZ.

EPA EST. NO. 12455-WH1 EPA REG. NO. 12456-76



DIRECTIONS FOR USE (continued from left side penel)

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 their signs have been seen. Protect but from rain or snow. Remove as much alternative food as possible.

APPLICATION DIRECTIONS:

RATS: Apply 2 to 10 Place Pacs per placement, Maintain an uninterrupted supply of fresh beit for at least 10 days. HOUSE MICE: Place 1 Place Pac at 8 to 12 foot intervals. Maintain an uninterrupted supply of fresh beit for at least 15 days.

tasts. RATS/MICE: Replace contaminated or spoiled beit immediately. Collect and dispose of all deed animals and fellower beit 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 beit stations and replanish as needed.

STORAGE AND DISPOSAL

STORAGE: Store only in original container, in a dry area inaccessible to children and pets.

DISPOSAL: Do not reuse empty container. Securely wrap original container in several leyers of newspaper and discard in trash.

ACCEPTED with COMMENTS in EPA Letter Dated:

UUT 14 1592

Under the Faster I Insecticide, Fungicide, and Rostenticide Act as amended, for the particide registered under EPA Roy, No. 12455-76



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 beit in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tampernesistant best 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 beit compartments and obtaining beit. If beit can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger beit stations are needed in areas open to hoofed livestock, raccooms, bears, or other potentially destructive animals, or in areas prone to vandalism.
- 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. URBAN AREAS: May be used in and around the periphery of homes, industrial, commercial and public buildings. CONTRAC Place Pacs may also be used in and around transport vehicles (ships, trains, aircraft) and related port or terminal buildings. May also be used in alleys. Do not use in sewers. NON-URBAN AREAS: May be used inside of homes and acricultural buildings.

See right side panel for additional DIRECTIONS FOR USE.

Contrac®

RODENTICIDE

READY TO USE PLACE PAC KILLS RATS AND MICE

KILLS WARFARIN RESISTANT NORWAY RATS
Norway rats and house nice may consume a lethal dose in one feeding with first dead
roderts appearing hour or live days after treatment begins.

TOTAL 100.000%

KEEP OUT OF REACH OF CHILDREN CAUTION

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Keep away from humans, domestic aromats and pels. Il prolivered, this material may notice the clotting ability of the blood and cause bleeding. Avoid centact with eyes or cloiding. Wash theroughly with soap and mater aler handling. Il smallowed, call a

physician at erce.

NOTE TO PHYSICIAN: If ingested, administer Vitamin IX, intramuscularly or erally as indicated in biolychecycumann eventures. Repeat as necessary based on monitoring of mediumbin times.

of producerbin times.

EXMANDED TAL MAZAROS: This product is text to fish and wildlife. Keep out of labor, streams or ponds.

Net Contents: 120 x 1 1/2 OZ.

EPA EST NO 12455-WI-1 EPA REG NO 12455-78

Bell Laboratories, Inc.

(R) DIRECTIONS FOR USE (continued from left side penel)

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 their signs have been seen. Protect bait from rain or snow. Remove as much alternative food as possible.

APPLICATION DIRECTIONS:

RATS: Apply 2 to 10 Place Pacs per placement. Maintain an uninterrupted supply of fresh bait for at least 10 days. HOUSE MICE: Place 1 Place Pac at 8 to 12 foot intervals. Maintain an uninterrupted supply of fresh bait for at least 15 days.

RATS/MICE: Replace contaminated or spoiled bait immediately. Collect and dispose of all deed 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 replonish as needed.

STORAGE AND DISPOSAL

STORAGE: Store only in original container, in a dry area inaccessible to children and pets.

DISPOSAL: Do not reuse empty container, Securely wrap original container in several layers of newspaper and discard in tresh.

ACCEPTED
with COMMENTS
in EPA Letter Datest

OCT 1 4 1992

Mig. by:

Under the passes of sectorde, Fungicide, the teams ade Act to amended, but the pesticide registered under EPA Rec. No. 12455-76

