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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
401 "M" St., S.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
x Registration
___ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
12455-91	October 16, 1997

Term of Issuance: Conditional

Name of Pesticide Product:
FINAL® RODENTICIDE READY-TO-USE PLACE PAC

Name and Address of Registrant (include ZIP Code):
Bell Laboratories, Inc.
3699 Kinsman Blvd.
Madison, WI 53704
Attn: Steven G. Oaks, Ph.D.

16.4/12

55192 53182
52149 53183
52552 53187
56096 53170

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4. **Please note that the Reregistration Eligibility Decision (RED) for Brodifacoum will be issued shortly and you should receive a copy of the RED and the generic and product-specific Data Call-Ins (DCIs). Your technical product and all registered end-use products are subject to the requirements of the Brodifacoum RED and DCIs and you must submit acceptable responses within the timeframe(s) provided in the RED. If you do not receive copies of the RED and both DCIs, please contact Frank Rubis (SRRD/Reregistration Branch I) at (703) 308-8184.**

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Signature of Approving Official	Date
Peg Perreault	10/16/97

EPA Form 8570-6

P. Perreault C:\Bell\12455-91.OR

2. You submitted the following acute toxicity studies to support your application for registration of **FINAL® RODENTICIDE READY-TO-USE PLACE PACS**: Guideline 81-1, acute toxicity (MRID 441634-04); 81-2, acute dermal toxicity (MRID 441634-05); 81-4, eye irritation (MRID 441634-05); and 81-5, dermal irritation (MRID 441634-06). These studies have been reviewed and are considered acceptable. However, you did not submit acute inhalation (81-3) or dermal sensitization (81-6) studies for this product; these studies are considered data gaps. **Within 30 days of receipt of this letter you must indicate, in writing, how you intend to address these data gaps.**

3. Your Confidential Statement of Formula (CSF) for this product, dated June 10, 1996, is conditionally acceptable from the standpoint of efficacy. Your proposed lower certified limit for Brodifacoum is equal to the nominal concentration, please check the proposed lower certified limit. With respect to efficacy, it is acceptable for the lower certified limit to match the nominal (which was once our general policy), or for the lower certified limit to be as low as 0.0045%.

4. With respect to the efficacy data you submitted to support label claims for this product we have the following comments:

   a. We have concluded that the basic claims for controlling commensal rodents which you have proposed for this product can be accepted conditionally based upon the efficacy data accepted for your similarly formulated loose-bait product, 12455-ON, your placepack-penetration study for rats (MRID# 442729-01), and upon your representation that the placepack material used for 12455-OR is identical to that used for your registered Bromadiolone placepack products. The conditions of this acceptance are listed below.

      i. Within one year of the date of conditional registration, you must submit a report of a laboratory placepack-penetration study (Protocol 1.218) in which house mice are used as test subjects.

      ii. The label's single-feeding claim will be limited to Norway rats.

      As the single-feeding claim accepted for house mice for 12455-ON was based upon rather marginal data, we are not fully confident that such claims would apply to the placepack product 12455-OR. Therefore, we have concluded that we will not accept the mouse single-feeding claim for this product until the mouse placepack-penetration data have been submitted, reviewed, and determined to indicate that the bait is likely to perform as well in placepacks as it does when presented without a wrapper. Because we expect that the bait in placepacks eventually will be eaten by house mice, and because the sole placepack size for this product would contain less than an ounce of bait, we have decided not to require users to open the 25-g placepacks applied to control house mice.

b. We honor your request of August 29, 1997, to have the 25-g placepack size be the one considered for this product. Because we have conditionally accepted the claim that house mice will penetrate such placepacks, we **consider the labeling submitted on August 27, 1997, for the 25-g placepacks and their outer containers to be the relevant labeling for this product.**

c. The word "**FINAL**" may be used in the name of this product only if it is clearly indicated to be a brand name. Although the surest way to accomplish this qualification would be to add the word "**BRAND**" after "**FINAL**", you may use the registered trademark symbol "®" after "**FINAL**" provided

i. that the symbol "®" appears after "**FINAL**" each time that it is used on the label; and

ii. that, in all instances of its use, the symbol "®" is clearly legible and at least one third as high as the text used for the word "**FINAL**".

d. The labeling "ACCEPTED with COMMENTS" is suitable for packaging arrangements of at least 16 placepacks. The 25-g placepacks may not be sold individually unless all claims and directions pertaining to the control of commensal rats are deleted from the label. Rat claims may appear on labeling for packaging arrangements of 4 to 15 placepacks, provided that an appropriate qualifying statement is added to the outer container's label to the effect that the amount of bait provided could not be expected to kill more than a specified limited number of rats. Qualifying statements for any packaging arrangements which need them must be proposed as amendments and accepted by EPA before such packaging arrangements may be used.

No packaging arrangements which pertain to individual or multiples of 50-g placepacks may be used for this product at this time.

e. Specific labeling changes that must be made are indicated under 5. below.

5. Before you release your product for shipment, the proposed labeling submitted on **August 27, 1997**, for the 25-g size of placepack must be modified as indicated below. **These changes must be made both to the label for the placepack and to the label for the outer container.**

a. Revise the EPA Registration Number to read, "EPA Reg. No. 12455-91.

b. Delete "and house mice" from the single-feeding claim.

c. In the "**USE RESTRICTIONS:**" subsection of the "**DIRECTIONS FOR USE**", replace the non-sentence "May also be used in alleys" with the sentence

> "This product also may be used in alleys."

d. In the first sentence of the "**APPLICATION DIRECTIONS:**" for "**RATS:**", insert "intervals of" between "usually at" and "15 to 30 feet".

e. Change the third sentence of the "**APPLICATION DIRECTIONS:**" for "**HOUSE MICE:**" to read

> "Two pacs may be applied at points of extremely high mouse activity."

Because the user's options are limited to placing one pack or two, and because there are no instructions for opening packs, the sentence indicated above is adequate for a 25-g placepack product.

f. On the front panels of your labeling, directly under the word "**CAUTION,**" insert the following "**STATEMENT OF PRACTICAL TREATMENT.**":

"STATEMENT OF PRACTICAL TREATMENT

If Swallowed: Call physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.
If on Skin: Wash with plenty of soap and water. Get medical attention if symptoms persist.
If in Eyes: Flush eyes with plenty of water. Call a physician if irritation persists."

Note: If you cannot fit the above specified Statements of Practical Treatment on the placepack label, you must place the "**PRECAUTIONARY STATEMENTS**" and "**NOTE TO PHYSICIAN**", revised as indicated under g., h., i., and j. below., on the front panel of the placepack label and add the sentence **"FOR SPECIFIC STATEMENTS OF PRACTICAL TREATMENT, REFER TO THE OUTER CONTAINER LABEL FOR THIS PRODUCT."**

g. The "**NOTE TO PHYSICIAN**" section that appears on the front panel of your proposed labeling should be inserted just below the last Statement of Practical Treatment, but should be clearly distinguished from the Statements of Practical Treatment. In addition, the first sentence of the "**NOTE TO PHYSICIAN**" section should read "If swallowed, this material may reduce the clotting ability of the blood and cause bleeding." On your proposed label this sentence is part of the "**PRECAUTIONARY STATEMENTS**" and

should be moved to the "**NOTE TO PHYSICIAN**" section.

h. Below the "**NOTE TO PHYSICIAN**" section, add an emergency telephone number to call for specialized medical advice.

i. On your proposed labeling, the "**PRECAUTIONARY STATEMENTS**" appear on the front panels, these may be moved to either side panel (except if the Statement of Practical Treatment do not fit on the placepack label, as indicated under f. above). In addition, the statement "**HAZARD TO HUMANS AND DOMESTIC ANIMALS**" should be left-justified so it is clear that this is a subheading subordinate to the heading "**PRECAUTIONARY STATEMENTS.**" Also, delete the "S" in "**HAZARDS.**" The paragraph under "**PRECAUTIONARY STATEMENTS**" must also be left-justified and must be revised to read as follows:

"**CAUTION:** May be harmful or fatal if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling bait.

j. Amend the "**ENVIRONMENTAL HAZARDS**" statement, as required by PR Notice 93-3, by deleting the sentence "Keep out of lakes, streams, or ponds" and replacing it with the following:

"For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark."

k. On the **outer carton label only**, the "**STORAGE AND DISPOSAL**" statement must be modified as indicated in PR Notice 83-3. Specifically, the statement "Do not contaminate water, food, or feed by storage or disposal" must be added directly under the heading "**STORAGE AND DISPOSAL**" and separate statements for "**PESTICIDE DISPOSAL**" and "**CONTAINER DISPOSAL**" must be added. These statements must include directions for both household use and commercial use as follows:

"**PESTICIDE DISPOSAL: Household use** - Securely wrap original container in several layers of newspaper and discard in trash.
Commercial use - Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility.

CONTAINER DISPOSAL: Household use - Do not reuse empty container. Discard container in trash.
Commercial use - Completely empty container. Then dispose of empty container in sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke."

6. Submit two copies of your revised final printed labeling before you release the product for shipment.

If the above specified 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.

Stamped copies of the labeling are enclosed for your records. If you have any questions regarding this notice, please call me at (703) 305-5417 or (703) 305-5404.

Sincerely yours,

Peg Perreault
Product Management Team 4
Insecticide-Rodenticide Branch
Registration Division (7505C)

12455-OR 25g
Cutter pkg.

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, and similar manmade structures. FINAL Place Pacs may also be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. May also be used in alleys. 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.

See right side panel for additional DIRECTIONS FOR USE.

Final®

RODENTICIDE

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: 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%
* Contains Denatonium Benzoate TOTAL	100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Keep away from humans, domestic animals and pets. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling. If swallowed, call a physician at once.

NOTE TO PHYSICIAN: If ingested, administer Vitamin K_1 intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as necessary 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 lakes, streams or ponds.

Net Contents: 200 x 0.88 oz (25 GRAMS)

Mfg. by:
Bell Laboratories, Inc.
Madison, WI 53704 U.S.A.

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

DIRECTIONS FOR USE (continued from left side panel)

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 4 to 16 pacs (usually at 15 to 30 feet) per placement. Maintain an uninterrupted supply of fresh bait for at least 10 days or until there no longer are signs of fresh rat activity.
HOUSE MICE: Apply one pac per placement. Space placements at 8- to 12-foot intervals. Larger placements, up to two unopened pacs, may be made at points of extremely high mouse activity. Maintain an uninterrupted supply of fresh bait for at least 15 days or until there no longer are signs of fresh rat activity.
RATS/MICE: Replace contaminated or spoiled bait immediately. 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 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 trash.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
Oct. 16, 1997

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.: 12455-91

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