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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:
12455-89	October 16, 1997

Term of Issuance: Conditional

Name of Pesticide Product: **FINAL® BLOX®**

Name and Address of Registrant (include ZIP Code):

Bell Laboratories, Inc.
3699 Kinsman Blvd.
Madison, WI 53704
Attn: Steven G. Oaks, Ph.D.

16/18 519579 525939 521492 521526 531016 525546 531566 531566

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.**

continued on p.2

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

EPA Form 8570-6

P. Perreault C:\BELL\12455-89.REG

2. You submitted the following acute toxicity studies to support your application for registration of **FINAL® BLOX®**: Guideline 81-1, acute toxicity (MRID 441635-04); 81-2, acute dermal toxicity (MRID 441635-05); 81-4, eye irritation (MRID 441635-05); and 81-5, dermal irritation (MRID 441635-06). 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 November 13, 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 examined the information provided regarding the weathering of bait used in the rat efficacy study reported under MRID# 442623-01. The weathering information provided appears to be unrelated to that particular efficacy study.

   b. We have reviewed the report of the 3-day, house-mouse efficacy study (MRID# 443311-01) in which weathered bait was used. Although bait take was almost non-existent on the first day of exposure, the bait reportedly eventually was well accepted and sufficiently lethal to test-group mice. Times to death were rather protracted for a bait containing Brodifacoum. As the weathering of the test bait was concluded nearly two months before the bioassay began, the suitability of this trial as an efficacy test of weathered bait is questionable.

   c. As we have not accepted either of the efficacy studies submitted to support claims that this product would be effective in wet or damp areas, we have suspended consideration of all pending labeling in which any claims of weather-resistance, "**ALL-WEATHER**", or suitability for use in wet or damp sites (e.g., sewers) are proposed.

   d. 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**".

e. The proposed single-feeding claim is acceptable.

f. Specific labeling changes that must be made to the "**DIRECTIONS FOR USE SECTION**" are indicated below under 5.e.

5. On your proposed labeling submitted August 29, 1997 make the labeling changes listed below before you release the product for shipment.

a. Revise the EPA Registration Number to read, "EPA Reg. No. 12455-89.

b. On the front panel of your label under the word "**CAUTION,**" delete the paragraph beginning with "May be harmful..." and ending with "call a physician at once." Replace this paragraph with the following "**STATEMENT OF PRACTICAL TREATMENT,**" directly under the word "**CAUTION**":

"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."

c. The "**NOTE TO PHYSICIAN**" section that appears on the right panel of your proposed label should be moved to a position 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.

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

e. On the left panel, the "**DIRECTIONS FOR USE**" portion of the "**FINAL® BLOX®**" label proposed on August 29, 1997, is generally acceptable, but the changes noted below must be made.

i. In the "**USE RESTRICTIONS:**", replace the non-sentence "May also

be used in alleys" with the sentence

"This product [or '**FINAL® BLOX®**'] also may be used in alleys."

ii. From the "**APPLICATION DIRECTIONS:**" for "**RATS:**", delete the claim

"Approximately 3 blocks will kill one to three rats."

This claim is ambiguous and, even if substantiated, would be of marginal predictive value.

All containers of this product must provide sufficient amounts of bait for a single placement for controlling all species claimed on the label at the lowest rates claimed for those species. This means that, if you still intend to produce a package containing four blocks, all claims and directions related to the control of commensal rats must be deleted from the label for that package. Labels for packages which contain at least 5 but fewer than 22 blocks may bear claims and directions for controlling commensal rats if the labels also bear appropriate qualifying statements which indicate that there are limits to the numbers of rats that the product could be expected to control. As we have noted in past letters regarding certain of your products which contain active ingredients other than Brodifacoum, such statements must be expressed as limitations on the usefulness of the amount of bait in the package rather than as predictions of the number of rats that the quantity of bait provided can be expected to kill.

f. On the right panel of your proposed label, 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.

g. 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."

h. The "**STORAGE AND DISPOSAL**" statement must be modified as indicated in PR Notice 83-3. Specifically, the **PESTICIDE DISPOSAL**" and "**CONTAINER DISPOSAL**" sections must be amended to 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 container. Discard container in trash.
Commercial use - Completely empty pail. Then dispose of empty pail 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.

A stamped copy of the labeling is 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)

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 BLOX 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 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.

deleted "and sewers"

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these areas 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. Remove as much alternative food as possible.

(Continued at the top of the right panel.)

Final® Blox®

→ deleted "ALL-WEATHER"

deleted → directions for sewers

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 to five days after treatment begins.

ACTIVE INGREDIENTS: 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	100.000%

*Contains Denatonium Benzoate

KEEP OUT OF REACH OF CHILDREN

CAUTION

May be harmful or fatal if swallowed or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wash hands after handling bait. If swallowed, call a physician at once.

(SEE RIGHT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS.)

NET WEIGHT: 18 lbs. (8.18 kg)

Mfg. by:
Bell Laboratories, Inc.
Madison, WI 54704

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

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. 12455-89

DIRECTIONS FOR USE (Continued from left panel.)

APPLICATION DIRECTIONS:

Each bait block in this container weighs nearly 3/4 ounce (20 grams)

RATS: Place 5 to 22 FINAL BLOX (usually at intervals of 15 to 30 feet) per placement. Maintain an uninterrupted supply of fresh bait for at least 10 days or until signs of rat activity cease. Approximately 3 blocks will kill one to three rats.

MICE: Place 1 block per placement. Space placements at 8- to 12- foot intervals. Two FINAL BLOX may be needed at points of very high mouse activity. Maintain an uninterrupted supply of fresh bait for at least 15 days or until signs of mouse activity cease.

RATS AND 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.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

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.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

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

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Completely empty pail. Then dispose of empty pail in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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