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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MAY 27 1998

Christine E. Benter
Bell Laboratories, Inc.
3699 Kinsman Blvd.
Madison, WI 53704

S 537163 300/18
S 537164 305/12
S 537195 305/13

Subject: Final[®] Blox
EPA Registration No. 12455-89
Application for Amended Registration and Revised Labeling dated
November 26, 1997
Application for Amended Registration and Revised Labeling dated
December 3, 1997
Application for Amended Registration, Submission of Product
Performance Data, and Revised Labeling dated January 9, 1998

Dear Ms. Benter,

You submitted three (3) separate applications for amended registration. Your application dated November 26, 1997 included a proposed revised label and requested that the efficacy claim "Kills Warfarin Resistant Norway Rats" be changed to "Kills Warfarin Resistant Norway Rats and House Mice." Your application dated December 3, 1997 requested the addition of 3 new package sizes (all weighing less than 1 lb) and included revised labels for each new package size with proposed "qualifying statements" for the number of rats each package size could be expected to kill. Your application dated January 9, 1998 requested label amendments to add claims and directions for baiting sewers and to change your product name to Final[®] All-Weather Blox and included a proposed revised label and single-feeding efficacy studies on mice and rats using weathered bait. We have reviewed all three of your applications; the conclusions of our review are discussed below.

1. With respect to the efficacy data submitted January 9, 1998, the "three-day" rat trial using weathered bait (MRID# 444602-02) is reported to have produced 80% mortality and an overall composite acceptance score of 33.5%. The mortality figure meets our criterion for weathered baits and the acceptance score exceeds the 25% criterion for anticoagulants in multi-day tests with weathered baits. ~~However,~~ the test results also show that the

SYMBOL							
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Internet Address (URL) http://www.epa.gov							

four rats that survived exposure to the bait rejected it nearly absolutely and that 9 of 20 test-group rats ate less than a gram of bait on the first day of exposure to it and 12 ate less than 3 grams on the first day. As the laboratory employed procedures which clearly included different criteria for replenishing bait and challenge diet, we cannot be sure that the subsequent increases in bait acceptance were not due to an introduced bias.

The poor bait consumption figures on the first day suggest that many fewer than 80% of test-group subjects ate enough bait on that day alone to kill them. Therefore, any single-feeding claim made for the weathered bait would be questionable. Due to the possible acceptance bias associated with use of different criteria for replacing bait and challenge diet, we cannot put any faith in the validity of bait acceptance data after the first day of the study. As it is highly unlikely that this product would have produced 80% mortality due to the amount of toxicant ingested on the first day alone, this study is rejected. Therefore, all claims of weather-resistance, directions for use of the bait blocks in sewers, and the proposed addition of "ALL-WEATHER" to the name of the product also are rejected.

In this rat study with weathered bait, there also were deviations from protocol in temperature, humidity, animal weights, and weathering procedures to go along with the poor bait acceptance by many subjects, the four survivors, and the evidence that the criteria for replenishing bait differed from those for replenishing challenge diet. The bait-weathering environment apparently was maintained for only 14 days. It seems possible to us that the procedures used to weather the bait might have altered its palatability and its fate under warm and moist conditions. If you choose to run another study to substantiate claims of weather-resistance, the problems detected in this rat study must be resolved.

The proposed revised label submitted January 9, 1998 is not accepted for the reasons discussed above.

- 2. The "three-day" laboratory efficacy study run with house mice (MRID# 444602-01) involved the same weathered bait batch used in the rat study discussed above. Consequently, many of the criticisms made of that study apply to this one as well. The bait was well above the 25% criterion for weathered bait, and such acceptance appeared to be fairly uniform across test days and, to a lesser extent, across subgroups. However, it was clear from this trial that different criteria were used for replacing bait than were used for replacing challenge diet.

We will withhold a final decision on this study pending a detailed explanation written by the individual who conducted the test of the procedures used to offer baits to the animals. This write-up must include descriptions and tare

weights of containers used for bait and challenge diet, the criteria used to determine whether to replacing or replenish bait and challenge diet, the ways in which bait and challenge diet were stored and handled prior to use in the test, and any special procedures that might have been employed because the bait used in this study was in block form.

3. With respect to your application for amended registration dated December 3, 1997, the "qualifying statements" for rats proposed for the labels for the packs of six, eight, and ten 20-oz bait blocks are acceptable. However, other problems were noted in our review of the proposed labels submitted December 3, 1997. Please revise your labels as indicated below.

- a. The major problem with the labels submitted on December 3, 1997, is that the first panel of the "DIRECTIONS FOR USE", which contains the bait protection statements, the "USE RESTRICTIONS", and other important text is so narrow and so compressed that it is difficult to read and certainly is less conspicuous than the second panel of the "DIRECTIONS FOR USE", which includes the "APPLICATION DIRECTIONS". A likely result is that some readers will completely miss all of the requirements for responsible use of the product and go right to the information about how much to use. Considering the broad-spectrum toxicity of the active ingredient, the requirements for proper use of this type of product are not to be taken lightly.

Note that it is an unlawful act to sell a pesticide that is misbranded. Such an unlawful act may subject a product to a stop sale and removal order. One way in which a product may be misbranded is if

"any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use". [FIFRA, §2(q)(1)(E)]

Keep this in mind when formatting labels and selecting containers for products. With folded-over and bag labels, make sure that seams and sealings do not obscure required label text.

- b. We also note that the symbol "©", which appears after the word "FINAL" in the name of the product, is illegible in the text of the

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"DIRECTIONS FOR USE" on the labels for the small-sized containers.

- c. Delete center-panel claim "*Guaranteed**" or modify it so that the asterisked text offered to explain the guarantee appears on the same panel of the label and is in a similar type size.
4. With respect to your application for amended registration dated November 26, 1997, from the standpoint of efficacy we have no objection to the proposed expansion of the efficacy claim "Kills Warfarin Resistant Norway Rats" to "Kills Warfarin Resistant Norway Rats and House Mice". The proposed revised label submitted November 26, 1998 is acceptable from the standpoint of efficacy. A stamped copy of the label is enclosed for your records.

Please submit one copy of your final printed label 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.

We note that, of your 3 applications for amended registration discussed above, only the application and proposed revised label dated November 26, 1997 is considered acceptable at this time. Further consideration will be given to your other two applications upon submission of the additional data and information requested above and proposed labeling, revised as indicated above. If you have any questions about this letter, please call me at (703) 305-5417 or (703) 305-5404.

Sincerely yours,



Peg Perreault
Chemical Manager, Team 4
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure (1)

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, 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. This product 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.

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.

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(Continued at the top of the right panel.)

Final® Blox®

KILLS RATS AND MICE

Kills Warfarin Resistant Norway Rats and House Mice
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

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 TO PHYSICIAN

If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. If ingested, administer Vitamin K, intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times.

For specialized medical advice, call Bell Laboratories at 1-800-323-6626 or call the National Pesticide Telecommunications Network at 1-800-856-7376.

(SEE RIGHT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS.)

NET WEIGHT: 9 lbs. (4.1 kg)

Mfg. by:



Bell Laboratories, Inc. In EPA Letter Dated:
Madison, WI 53704 U.S.A.

EPA REG. NO. 12455-89

EPA EST. NO. 12455-WI-1

DIRECTIONS FOR USE (Continued from left side 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.

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

HAZARD TO HUMANS AND DOMESTIC ANIMALS

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.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds, and wildlife. This product can pose a secondary hazard to birds of prey and mammals. 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.

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 onsite or at an approved waste disposal facility.

CONTAINER DISPOSAL: Completely empty container. Then **ACCEPTED** container in sanitary landfill or by incineration, or, if allowed by state or local authorities, by burning. If burned, stay out of smoke.

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Money Back Guarantee

May 27, 1998
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
12455-89

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