IRB BRANCH REVIEW - TSS

Record Number(s)
D155381
S381611

IN 9/7/90 CUT 10/22/90
EFFICACY

PETITION OR EXP. PERMIT NO. DATE DIV. RECEIVED 9/6/90 DATE OF SUBMISSION 8/31/90 DATE SUBMISSION ACCEPTED 9/7/90	
DATE OF SUBMISSION 8/31/90	
DATE SUBMISSION ACCEPTED 9/7/90	
TYPE PRODUCTS(S): I, D, H, F, N, R, S	
DATA ACCESSION NO(S). none	
PRODUCT MGR. NO. 16	•
PRODUCT NAME(S) SODIUM FLUOROACETATE (COMPOUND 1080) IN THE LIVESTOCK PROTECTION (COLLAR
COMPANY NAME New Mexico Department of Agriculture	
SUPMISSION PURPCSE Clear up past problems	
1.00% Sodium fluoroacetate solution in Livestock CHEMICAL & FORMULATION	
Protection Collar	

Efficacy_Review: SODIUM FLUOROACETATE (COMPOUND 1080) IN THE LIVESTOCK PROTECTION

COLLAR, 39508-E

New Mexico Department of Agriculture

Las Cruces, NM 88003

200.0 INTRODUCTION

200.1 <u>Use</u>

A 1.00% Sodium Monofluoroacetate (Compound 1080) solution enclosed in a two-pouched rubber vessel which is attached to Velcro bands which hold the pouches in place in the throat regions of sheep or goats subject to predatory attacks by coyotes.

200.2 Background Information

See efficacy reviews of 3/21/88, 10/21/88, 3/6/89, and 12/1/89, along with other information in product jacket. The current submission consists of a letter of 8/31/90 to which are appended

- a. copies of letters exchanged by NMDA and EPA over the past two years:
- b. copies of revised labeling; and
- c. a hand-written "spread sheet" regarding collar use in New Mexico in calendar year 1989.

201.0 DATA SUMMARY

No efficacy data were submitted.

The "spread sheet" indicates that 180 collars were sold to nine parties in New Mexico in 1989. Of these, 159 were used on eight livestock operations for a total of 4169 collar-days. No collars were reported to have been lost. Ten were reported to have been punctured by coyotes. No collars were reported to have been ruptured by other causes. On each of the six ranches where collars were reported to have been punctured by coyotes, predation was said to have ceased following collar puncture. The only adverse incident reported that involved nontarget species was the capture of a sheep in a trap.

If the results summarized in the table are "the whole truth," the collar program in New Mexico in 1989 can be described as "successful."

Of the past correspondences provided by NMDA, the following do not appear in the product jacket for 39508-2:

- a. NMDA's letter of 1/19/90; and
- b. NMDA's application amendment of 10/20/89, which included a formulation change to replace Rhodamine B dye with Tartrazine.

In this review, I leave the issue of blame for missing information aside and comment only on the revised labeling.

The "DIRECTIONS FOR USE" portion of the revised container label is acceptable.

The technical bulletin has some errors in it. It also lacks figures, figure captions, and copies of the container label and the bilingual warning signs.

202.0 CONCLUSIONS

The "spread sheet" for collar use in New Mexico for calendar year 1989 suggest a successful program for that year. Be sure to submit complete monitoring reports for each year of collar use.

The "DIRECTIONS FOR USE" portion of the revised container label is acceptable.

Make sure that appendices (container label and bilingual warning signs) are included with each copy of the technical bulletin that is shipped with collars. Also make sure that figures and figure captions are included in each copy of the technical bulletin that is shipped with collars.

You must make the changes listed below to your technical bulletin (based on the copy submitted with your letter of August 31, 1990).

- 1. On page 3, delete "and 15" from the ninth "DO" ("report any suspected poisoning . . .").
- 2. On page 8, first paragraph,
 - a. change "there" to "their" in fourth line, and
 - b. insert "that" between "satisfied" and "the" in the seventh line.
- 3. On page 8, fourth paragraph,
 - a. change "One" to "Once" in first line, and
 - b. change "orange" to "yellow" in the sixth line.
- 4. On page 8, last paragraph, change "60 day" to "60-day" in second line.
- 5. On page 9, fourth paragraph, change "may by" to "made by" in fourth
- 5. On page 9, sixth paragraph, change "double bag" to "double-bag" in third line.

William W. Jacobs Principal Specialist: Rodenticides Insecticide-Rodenticide Branch October 22, 1990

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IRB BRANCH REVIEW - TSS

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William W. Jacobs Principal Specialist: Rodenticides Insecticide-Rodenticide Branch October 22, 1990

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