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IRB BRANCH REVIEW - TSS

Record Number(s)

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IN 10/3/91 CUT 10/16/91

EFFICACY

FILE OR REG. NO. 39508-2

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 7/31/91

DATE OF SUBMISSION 7/25/91

DATE SUBMISSION ACCEPTED 10/3/91

TYPE PRODUCTS(S): I, D, H, F, N, Rx S _____

DATA ACCESSION NO(S). none

PRODUCT MGR. NO. 14

PRODUCT NAME(S) SODIUM FLUOROACETATE (COMPOUND 1080) LIVESTOCK PROTECTION COLLAR

COMPANY NAME New Mexico Department of Agriculture

SUBMISSION PURPOSE amend technical bulletin (and formulation and label for container)

CHEMICAL & FORMULATION 1.00% Sodium fluoroacetate (Compound 1080) solution in Livestock Protection Collar

Efficacy Review: SODIUM FLUOROACETATE (COMPOUND 1080) LIVESTOCK PROTECTION COLLAR,
39508-2
New Mexico Department of Agriculture
Las Cruces, NM 88003

200.0 INTRODUCTION

200.1 Use

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, 12/1/89, 10/22/90, and 4/30/91, along with other information in product jacket. The current submission consists of a letter of 7/25/91 to which are appended a single copy of a proposed revised technical bulletin and copies of the three pages of the bulletin upon which NMDA claims to have made changes in response to EPA's letter of 11/19/90.

EPA's letter of 11/19/90 indicated that NMDA had to revise the labeling for this product before it, and the attendant formulation change could be accepted.

201.0 DATA SUMMARY

No efficacy data were submitted.

In the cover letter, Ronald J. White of NMDA promises that future monitoring reports will include "narrative regarding monitoring procedures and a discussion of results" and that data tables in future reports "will be made durable with a water resistant ink."

The separately offered, revised pages of the technical bulletin include all changes stipulated in EPA's letter of 11/19/91. Upon comparing the technical bulletin submitted on 7/25/91 with that discussed in EPA's letter of 7/19/91. however, it is apparent that some minor editorial changes also were included in the newer version. As a result, the first three "DON'T"s appear twice in the newer version and certain text on page 8 was omitted.

202.0 CONCLUSIONS

Although the changes prescribed to the technical bulleting that were prescribed in our letter of November 19, 1990, were made to the bulletin submitted on July 25, 1991, the revised technical bulletin cannot be accepted for the reasons listed below:

1. Only one copy of the revised bulletin was submitted. Five copies of all proposed revised labeling are needed.
2. The revised bulletin did not include figures, figure captions, and other attachments such a copy of the container label and the warning sign.

3. In revising the bulletin to make the changes stipulated in our letter of November 19, 1990, some additional changes were introduced. These changes include:

- a. repetition of the first three "DON'T"s (at the bottom of page 3 and at the top of page 4);
- b. changing "punctured" to "puncture" in sentence "Inspect each animal's . . ." in fourth paragraph on page 8 (change it back to "punctured");
- c. deletion from the fourth paragraph on page 8 of the sentences

"If dye is seen, catch the animal and check the collar.
Replace any damaged or leaking collar.";

The text deleted under "c." above must be restored on the amended technical bulletin.

Submit five copies of a complete and appropriately revise technical bulletin. The version of the container label that was submitted on August 31, 1990, should be inserted in the appropriate location in the revised technical bulletin.

William W. Jacobs
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Insecticide-Rodenticide Branch
October 16, 1991