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IRB BRANCH REVIEW - TSS

Record Number(s)

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IN 2/4/97 OUT 2/4/97

EFFICACY

FILE OR REG. NO. 39508-2

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 5/13/96

DATE OF SUBMISSION 5/1/96

DATE SUBMISSION ACCEPTED 2/4/97

TYPE PRODUCT(S): I, D, H, F, N, R, X 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 supply monitoring information and final printed labeling

CHEMICAL & FORMULATION 1.00% Sodium Fluoroacetate in solution enclosed
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 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, 4/30/91, 10/16/91, 3/30/92, 10/6/93, 6/27/94, and 4/5/96, along with other items in this product's two-volume registration jacket.

The current submissions consists of a letter of 5/1/95 to which are appended two copies each of a final printed container label and a final printed technical bulletin. The cover letter adds

"Also enclosed is the monitoring data for the LPCs used in the private LPC applicator program for calendar years 1991 through 1995, inclusive."

201.0 DATA SUMMARY

No efficacy data were submitted. The Animal and Plant Health Inspection Service (APHIS/USDA) has submitted data supporting the efficacy of large-size collars containing 30 ml of 1080 solution. APHIS made these data available to NMDA.

Attached as APPENDIX 1 of this review is NMDA's entire report of 5 years of "monitoring data". This document lists only whether there was legal collar use and, if so, the numbers of coyotes (presumably?) taken by this program. Such information is grossly inadequate. Prior to registration of this product, the importance of the monitoring program and its need to capture a variety of information other than target species believed to have been taken was explained to NMDA (e.g., EPA's letter of 4/11/88). NMDA must do a better job of monitoring and reporting information on collar use in New Mexico.

The final printed container labeling appears, upon scanning, to be accurate. The required textual changes were made to the technical bulletin, but no copy of the container label was inserted into the technical bulletin in the place ("Appendix A") where the container label is promised. I was able to insert a copy of the container label into the copy of the final printed technical bulletin that we will keep on file, but NMDA must be told of this omission and not to distribute any bulletins which lack an "Appendix A". EPA's letter of 4/5/96 specifically required the insertion of the newly accepted container label as "Appendix A". NMDA did not submit a copy of the label for the individual collars themselves, although EPA's letter of 4/5/96 specifically stated that NMDA was to submit "two copies of all final printed labeling".

202.0 CONCLUSIONS

The monitoring information supplied for the calendar years 1991 through 1995 is inadequate to the point of being essentially useless. At most, this information might be telling us how many target animals were taken by 1080 toxic collars in the New Mexico Private Applicator Livestock Protection Collar Program during those 5 years. There is no information on the number of applicators certified, the number of applicators who used collars, the number of collars sold or transferred to applicators, the number of days each applicator used collars, the number of collars punctured, the likely causes of such punctures, the number of collars lost, the number of collars found to be defective, the numbers of nontarget species found dead in or near pastures where collars were used, the number and nature of violations detected upon inspection of sites where collars are used or stored, or the other bits of information which were to be collected under your monitoring program. As there is essentially no narrative accompanying the table that was provided, we are not even sure exactly what entries such as "5 coyotes" mean. Does such an entry mean that 5 dye-marked coyotes were found dead in pastures where collars were used, that there were 5 incidents of collar punctures which were attributed to coyotes, or something else?

If your monitoring program is not capturing all of the information that it should (review content of the approved plan and our letter of April 11, 1988), make sure that such information is captured for all future years. If your program has captured such information, prepare and submit a narrative report supported by tables which summarize all information collected regarding collar sales and use from the onset of collar registration in New Mexico through the end of 1996. We have not considered suspending the requirement to submit annual monitoring reports for any Livestock Protection Collar registrant until we have reviewed detailed reports which cover at least 4 years of reasonably intense use. Only then can we make any generalizations concerning the degree of compliance of users and the adequacy of the surveillance and monitoring program.

We have scanned the final printed labeling submitted on May 1, 1996, for completeness and have found that no copy of final printed labeling for individual collars was submitted and that there was no copy of the newly accepted container label inserted as "Appendix A" in the technical bulletin. As we have inserted a copy of the container label into the copy of the final printed technical bulletin that we are keeping on file, you do not have to submit a new final printed technical bulletin. You must make sure, however, that each copy of the technical bulletin distributed to users contains a copy of the container label. You also must submit a copy of the final printed label that is used for the individual collars.

William W. Jacobs
Biologist
Insecticide-Rodenticide Branch
February 4, 1997

APPENDIX 1

New Mexico Private Applicator Livestock Protection Collar Program

	<u>January</u>	<u>April</u>	<u>July</u>	<u>October</u>
1991	No Use*	No Use*	No Use*	No Use*
1992	No Use*	No Use*	0	2 coyotes
1993	0	0	7 coyotes	0
1994	0	1 coyote	0	3 coyotes
1995	0	0	4 coyotes	5 coyotes

* No Use of Livestock Protection Collars due to voluntary, temporary suspension while the state certification plan was being revised.