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IRB BRANCH REVIEW - TSS

Record Number(s)

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IN 2/19/88 CUT 3/21/88

EFFICACY

FILE OR REG. NO. 39508-E

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 10/30/87

DATE OF SUBMISSION 10/26/87

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DATA ACCESSION NO(S). none

PRODUCT MGR. NO. 16

PRODUCT NAME(S) SODIUM MONOFLUOROACETATE (COMPOUND 1080) IN THE LIVESTOCK PROTECTION COLLAR

COMPANY NAME New Mexico Department of Agriculture

SUBMISSION PURPOSE Registration

CHEMICAL & FORMULATION 1.04% Sodium fluoroacetate solution in Livestock
Protection Collar

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Efficacy Review: SODIUM MONOFLUOROACETATE (COMPOUND 1080) IN THE LIVESTOCK PROTECTION COLLAR, 39508-E
New Mexico Department of Agriculture
Las Cruces, NM 88003

200.0 INTRODUCTION

200.1 Uses

A 1.04% Sodium monofluoroacetate (Compound 1080) solution enclosed in a two-pouched rubber vessel which is attached to Velcro bands which hold the patches in place in the throat regions of sheep or goats subject to predatory attacks.

200.2 Background Information

This is a new registration application. It is a "me-to" with other registrations of the Livestock Protection Collar held or applied for by the Animal Plant Health Inspection Service (APHIS) of the U. S. Department of Agriculture (USDA), Montana Department of Livestock, Wyoming Department of Agriculture, and Rancher's Supply Inc. of Alpine, TX. Most of the data on which these products "rely" were developed by the U. S. Department of the Interior (USDI) before Animal Damage Control (ADC) responsibilities were transferred from USDI to APHIS. Additional Experimental Use Permits were held by the Texas Agricultural Experiment Station of Texas A & M University and by the New Mexico Department of Agriculture (NMDA).

Under NMDA's EUP, collars were applied by ranchers, whose activities were then monitored by state personnel. This program provided some idea of what could go wrong with the livestock collar. In many cases, sheep were not managed so as to direct predation to the target flocks (which included collared animals, mostly lambs) and away from the remainder of the sheep on the ranchers. Theft of collared animals and removal of 1080 from collars, presumably to use the toxic solution for other purposes, also were reported under NMDA's permit.

Despite this this history, NMDA is applying for its own Livestock Protection Collar registration. The application includes a label (for large collar only), a copy of the Technical Bulletin ("labeling" that would accompany the product in shipment), a Confidential Statement of Formula (CSF), a description of the state's proposed certification plan, a copy of the certification examination (without answer key), text describing applicable state and federal laws, a protocol for the plan for monitoring the use of the collar during the early years following its registration, and assorted administrative registration forms.

201.0 DATA SUMMARY

No new efficacy data were submitted.

The label, technical bulletin, monitoring plan, and examination closely follow those submitted by other parties. These documents will not be discussed at length in this review. Specific comments appear under "CONCLUSIONS". The training program would use product labeling and the manual and slide show prepared, at EPA's expense, by Dr. Dale Wade then of Texas A & M University, now of APHIS.

It is interesting to note that the "hands-on" portion of the training program would have students placing collars on "live sheep and goats when practical" or on "a facsimile of the head/neck portion of a sheep or goat when practical." This text begs the question of the course of action to be followed when neither of the approaches mentioned is "practical".

The certification plan was submitted with the registration package rather than through the Office of Compliance Monitoring. It is not clear to me that enforcement knows of the document's existence. Regardless of OCM's familiarity with the plan, the plan should be reviewed by the Office of General Counsel, which should also review the legal citations and paraphrasings in the various documents that make up this submission.

The quality of the applicators' examination cannot be fully assessed without knowledge of what NMDA perceives to be the correct answers.

NMDA's version of Use Restriction 8 conveys the thoughts of others' versions but with improved language. The same situation occurs with Use Restriction 15. NMDA has preserved the important text while eliminating some redundancy. Because the label does not limit use of the product to New Mexico, these restrictions are needed even though none of the critical habitats mentioned are in New Mexico.

202.0 CONCLUSIONS

1. On page 2 of "FEDERAL PESTICIDE LEGISLATION", insert "that" between "however," and "the" on 8th line of 5th paragraph.
2. On tenth listed item of "CRITERIA FOR APPLICATORS OF COMPOUND 1080 LIVESTOCK PROTECTION COLLARS", insert "damaged collars" between "of" and "properly".
3. Only small collars may be registered at this time. Delete all references to large collars on your labeling at this time, unless you prefer to have your application held until such time, if any, that large collar are accepted for registration and use. Alternatively, you may add statements as needed in the technical bulletin to the effect that it is illegal to use large collars at this time.
4. The following comments refer to the technical bulletin:
 - a. "DO's"
 - (1) Delete references to large collars in 3rd "DO" or delete 3rd "DO" entirely.
 - (2) In 12th "DO", change "see page 14" to "see pages 13 and 14".
 - (3) In 13th "DO", change "take collars off" to "remove collars from target flock animals".

b. "USER INSTRUCTIONS"

- (1) In first line of 2nd paragraph on page 5, change "behavior" to "behaviors".

c. "USE RESTRICTIONS"

- (1) In next-to-last line of 2nd paragraph of Use Restriction 2, change "laying" to "lying".

5. The applicators' examination cannot be assessed fully without an answer key. The questions generally seem to be sound and appropriate, provided that NMDA's and EPA's ideas regarding the correct answers correspond. Question #6 is problematical because the principal lethal effects of 1080 may vary somewhat from species to species. It appears that neither "A" or "B" could be considered to be correct.
6. In Objective "A" of the proposed "Monitoring Plan", change "Insure that" to "Determine whether". As it is now written, it appears that the monitoring program would be used to bring people into compliance, rather than to determine whether they are in compliance. While it is appropriate to direct users toward compliance, the major time for such direction is during the training phase of the certification process. The monitoring program is to be used to determine how many certified applicators deviated from requirements, in what areas they deviated, how they reacted to being informed of violations, and the extent to which their actions were changed in the future. Incidents of flagrant violations (such as occurred under your Experimental Use Permit) or repeated violations should be noted, along with the consequent actions taken by your Department. It is very important to determine the extent to which users comply with requirements when they are not closely watched or put on the spot.

The monitoring program needs a form for state personnel to use to summarize numerical results obtained from ranchers' records. There should be a convenient way to tally numbers of collars used, numbers of days collars are in the field, fates of collars (e.g., numbers apparently punctured by coyotes, numbers lost, numbers punctured in other ways, numbers remaining intact, etc.), nontarget deaths in "treated" pastures and speculated causes of deaths, and other pertinent information. The "Inspection Report" submitted appears to be fine for general bookkeeping and for noting violations, but more numerical information is needed to summarize the extent and success of collar use.

7. Submit an example of the collar to be used in New Mexico, showing the label that goes with the collar and the method of attaching the serial number.

William W. Jacobs
 Biologist
 IRB/TSS
 March 21, 1988

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IRB/TSS PRECAUTIONARY LABEL REVIEW

PM: 16

OUT: 03-29-88

EPA REG NO: 39508-E

COM: NAC

IN PLR: 03-23-88

DUE: 05-23-88

PRODUCT NAME: SODIUM FLUOROACETATE
LIVESTOCK PROTECTION COLLAR

AC: 160

RN: 207549

COMPANY NAME: NEW MEXICO
DEPT., OF AGRICULTURE
LAS CRUCES, NM. 88003

FORMULATION: SODIUM FLUOROACETATE 1.04%
INERT INGREDIENTS 98.96%

INTRODUCTION

New product registration.

USES

For use on sheep and goats to kill depredating coyotes. The collar is an rubber bladder containing a solution of sodium fluoroacetate (1080), with neck straps for attachment to a sheep or goat.

SUBMITTED DATA

Product label, technical bulletin, individual collar labeling, and warning sign.

CONCLUSIONS

1. PRODUCT LABEL COMMENTS:

- a) Is this product only for the state of New Mexico?, If so the Restricted Use statement needs to say so.
- b) Only the label for the large collar was submitted for review, comments are for the small collar also.
- c) Add: "Collars are not recommended for animals under 25 pounds".
- d) Endangered Species statement needs to be rewritten based on OES identification of threatened species in the state of NM.

e) Product label advises the use of syrup of ipecac and in the technical bulletin suggest that this material is provided with the collars. Number 17 needs to be rewritten to clarify this.

f) Under Note to Physician, please add below TREATMENT statement.

"CAUTION: The use of parenteral monacetin is hazardous. Technical grade material contains glycerin which, in adequate dosage, may cause hemolysis, hypotension, convulsions, and paralysis. If a non-sterile solution is injected, the monacetin should be cultured to guide the administration of antibiotics if sepsis develops".
(USEPA, RECOGNITION AND MANAGEMENT OF PESTICIDE POISONINGS 3RD ED.)

e) We recommend adding to the individual collar wording and to the warning sign, "FATAL IF SWALLOWED".

[NOTE TO PM: We had someone look at the label language who is fluent in spanish, he recommended that the comma be change to an period (see first line of text) that confusion arises in the grammatical interpretation of a comma.]

DONA WILLIAMS
PL/TSS

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