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IRB BRANCH REVIEW - TSS

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4/19/94
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EFFICACY

FILE OR REG. NO. 39508-2

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 4/13/94, 2/15/94, 6/21/94

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TYPE PRODUCTS(S): I, D, H, F, N, R, S ^X _____

DATA ACCESSION NO(S) 14
none

PRODUCT MGR. NO. _____

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

COMPANY NAME New Mexico Department of Agriculture

SUBMISSION PURPOSE add large-size collar with same amount (30 ml) of 1080 solution in it as small collars now have

CHEMICAL & FORMULATION 1.00% Sodium Fluoroacetate 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 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, and 10/6/93, along with other items in this product's jacket.

The current submissions include

1. a letter of 1/20/94 pertaining to potential for misuse of toxic collars;
2. a letter of 3/21/94 to which are appended five copies of a proposed revised container label and five copies of a proposed revised technical bulletin.
3. a letter of 6/15/94 with which were included copies of labeling currently used for the collars themselves and a possible alternate type of labeling for the collars. (Completion of this review was delayed so that this submission could be included. This submission was made after I telephoned NMDA to tell them that labels for collars also should be provided.)

The purpose of the second submission is for NMDA to secure EPA's approval for use of large-size Livestock Protection Collars, containing the same amount of 1080 solution as is used in the small collars, under the this product's registration. As EPA already has accepted use of the large-size collars for other registrants, the issue at hand is merely whether the labeling submitted by NMDA is acceptable.

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.

NMDA's letter of 1/20/94 was inspired by a letter of 12/21/93 from Roy McBride of Rancher's Supply, Inc., (Alpine, TX) who felt compelled to respond to comments from EPA concerning "possible 'malicious' use" of 1080 collars. McBride is the inventor and Rancher's Supply the producer of Livestock Protection Collars. NMDA reports having monitored use of 39508-2 collars within New Mexico since early 1989 (with an 18-month hiatus imposed by EPA because NMDA lacked an approved applicator certification plan). NMDA states that

"not one infraction or incident involving the misuse of this highly selective predacide has been observed."

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Frank A. DuBois, author of NMDA's letter of 1/20/94, adds that there was no use of collars in New Mexico during the 18-month suspension "although the need to use LPCs was very real."

DuBois adds that

"Serious malicious (chemical) misuse to control predators is more likely to occur using a variety of readily available chemicals as toxicants such as antifreeze, old stockpiles of strychnine, anticoagulants used for rodent control, Temik, and Carbofurdan [sic]. These chemicals are cheaper, easier to obtain, and more cost effective than purchasing LPCs and removing the toxicant to use illicitly. Our experience indicates that conscientious and responsible persons will not jeopardize the continued use of a valuable tool such as the LPC by illegally removing and using the troxicant."

While there appears to be much truth in what DuBois writes, it also must be remembered that laws and regulatory agencies are not established primarily to govern the actions of "conscientious and responsible persons." It is all of those other folks that are the problem. While we have heard many stories about illegal uses of various agents for predator control (Rancher's Supply itself having recently plead guilty to a charge of selling Carbofuran for that purpose), such reports seem to me to call for increased vigilance regarding the materials that are legal so that it may be possible to keep them available.

There have been some violations associated with toxic collar use and regulatory programs. The 1080 that Randy Graham sold when he was an agent of the Wyoming Department of Agrciculture (WDA) was illegally provided for predator control uses not removed from collars, but WDA was authorized to obtain 1080 for filling collars. Under the experimental use permit for testing toxic collars in New Mexico in the early 1980s, there was one incident in which 1080 solution was removed from collars and held in another container. At the same site, collared sheep were stolen (see efficacy review of 7/27/82 for 39508-EUP-4). A target flock also was rustled in Wyoming in 1994, although the criminals apparently were more interested in the uncollared ewes than in the collared lambs (see efficacy review of 1/13/94 for 35978-8). There also have been a number of violations reported in Texas, many of which were of the administrative type and involved the registrant or his agents. Among the more serious of the user-related infractions in Texas were the use of collars by a non-certified applicator (Texas Department of Agriculture's monitoring report for 1988) and the loaning of collars to non-certified applicators in 1989 (TDA's report for 1989 and a follow-up submission).

NMDA's also requests that EPA "consider expanding the LPC label to include bobcats" that prey upon livestock and suggests that, "at the very least," EPA should issue EUPs to McBride, APHIS, and State registrants of collars

". . . to explore the use of LPCs to include control of bobcats and other predators."

EPA has received comments from several sources regarding the bobcat claim for the 1080 toxic collar. Only APHIS has applied for a labeling amendment to allow use of collars to control Lynx rufus. No one has applied for an EUP to test this

and other non-coyote uses of the collar. If someone did, we would review the application, consider its merits, and accept it if it were sufficiently complete. We would not deliberately obstruct such an application.

The proposed revised container label corresponds to the current accepted label for 39508-2 (stamped on 3/30/92) except for the addition of directions for disposing of collars by incineration. EPA has accepted these directions for other toxic collar products. There is one cross-referencing problem on the container label (see "CONCLUSIONS").

The proposed revised technical bulletin includes items from the current label for APHIS's collar (56228-22, accepted 7/19/93) and some of NMDA's own ideas (such as abbreviating "Livestock Protection Collar" as "LPC" and not referring, at appropriate places in the text, to the illustrations which appear in the manual). The proposed revised bulletin can be "ACCEPTED with COMMENTS."

The current "label" for the collar consists of the following information stamped in India ink onto the collar's straps: the code name ("1080") of the active ingredient, the registration number, the serial number, and bilingual signal words ("DANGER - PELIGRO"). Although the registrant's full name and address is missing, this information would be known to certified applicators and to most of their employees. I suggest that we accept this label now so that the large-size collars can be made available to New Mexico's certified collar applicators.

The "alternate" labeling system consists of a "laminated" printed label that be attached at the point where the straps cross on the underside of the collar. This label bears printed text which is generally superior to that on the "label" now used but lacks a place for the product's EPA registration number.

202.0 CONCLUSIONS

Submission of March 31, 1994

The proposed revised label for the collar container is acceptable, except for an incorrect citation in the "ENDANGERED SPECIES CONSIDERATIONS" section. Change

"See Technical Bulletin (for restriction No. 15) for"

to

"See USE RESTRICTION O. in Section II. of the Technical Bulletin for"

The proposed revised technical bulletin is acceptable, provided that the specific changes listed below are made.

1. On the 14th "DO" ("store collars properly . . ."), change "p. 15" to "p. 16."
2. In 7th sentence of Section I.2.b. (page 7), change "fronts" to "front."
3. In USE RESTRICTION F. (Section II.F.), change "(H7505C)" to "(7505C)."
The mail code has been changed slightly.

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4. In USE RESTRICTION J. (Section II.J.), change

"(English/Spanish or other second language appropriate for the region)"

to

"(English/Spanish)."

Your current technical bulletin states "(English/Spanish)." Although we could be mistaken, we suspect that these two languages would be appropriate throughout New Mexico. Please let us know if this is not the case.

5. In USE RESTRICTION O. (Section II.O.), change "FWS" to "U.S. Fish & Wildlife Service."
6. Alter the positions of the photographs so that the picture with the lower number is in the upper half of each page. Position labels for pictures (e.g., "Photo 16") parallel to and either above or below the pictures to which they refer.

Submission of June 15, 1994

The text currently being used on your collars is being accepted at this time so that large-size collars can be made available to your certified Livestock Protection Collar applicators. However, we find this "label" to be short on precautionary information and lacking the registrant's name and address.

The copies of the laminated labels which you provided with your letter of June 15, 1994, do provide your name and location plus additional precautionary statements but currently lack a place for the registration number. We feel that the amount of information provided on the laminated label is superior to that currently being provided and that the registration number could be added to the label rather easily. Our only reservations with the laminated label are concerned with possible irritation to livestock and conceivable deterrence of coyotes from completing throat attacks. We suspect that collars would be punctured by the time any coyotes would encounter the plastic, however.

Letter of January 20, 1994

In this letter, you raise issues concerning use of Livestock Protection Collars to control bobcats and on the potential for misuse.

Whether bobcat claims ultimately will be accepted for Livestock Protection Collars sold in the United States is an open issue. We have and will continue to consider applications pertaining to this use.

Although it does not seem to be a major problem at this time, misuse of Livestock Protection Collars has taken place in the U.S. Among the incidents that have been reported are transfers of collars to and use by non-certified persons, and removal of 1080 solution from collars (under 39508-EUP-4). In at least two cases, collared sheep were rustled.

We recognize that "conscientious and responsible persons" in the livestock industry have a vested interest in the continued availability of the collars. We also are aware however, that not all human beings meet this description and that it is basically because of those who are not so "conscientious and responsible" that laws, regulatory agencies, and enforcement authorities are established by democratic societies. We view the collar as the most selective tool available for controlling coyotes that prey upon sheep and goats and the only tool that catches "offending animals" in the act. EPA has expended great effort (including information-gathering and Subpart D hearings, countless numbers of submission reviews, and several site visits) toward assessing the risks and benefits of Livestock Protection Collars. These efforts have culminated in the initial and continued registration of collars for use in the U.S. These registrations are highly restricted, but these restrictions are designed in large part to minimize incidents that would trigger petitions for cancellation of this use.

For many years, we have heard stories of illegal uses of various agents for controlling predators and are aware of several relatively recent instances in which violators were prosecuted. As the enforcement agents in your Department may attest, it is very difficult to "be everywhere," catching all offenders and casting a long deterrent shadow, over extensive land areas. Consequently, it is likely that this illegal activity will continue unless concerted coordinated efforts are made to eliminate it. Much of this activity seems to occur in areas (e.g., open rangelands) where collars cannot be used legally or appropriately. It is hard for us to muster sympathy for any producers who could use collars legally but who employ various illegal measures nevertheless.

William W. Jacobs
Biologist
Insecticide-Rodenticide Branch
June 27, 1994

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