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IRB BRANCH REVIEW - TSS

Record Number(s)

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IN 12/31/90 OUT 2/6/92

EFFICACY

FILE OR REG. NO. 35975-4

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 11/14/91

DATE OF SUBMISSION "11/7/89"

DATE SUBMISSION ACCEPTED 12/31/91

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

DATA ACCESSION NO(S) none

PRODUCT MER. NO. 14

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

COMPANY NAME Montana Department of Livestock

SUBMISSION PURPOSE amend label, provide monitoring report

CHEMICAL & FORMULATION 1.00% Sodium monofluoroacetate solution in

Livestock Protection Collar

1/5

Efficacy Review: SODIUM FLUOROACETATE (COMPOUND 1080) LIVESTOCK PROTECTION COLLAR,
35975-4
Montana Department of Livestock (MDL)
Helena, MT 59620

200.0 INTRODUCTION

200.1 Uses

A 1.00% Sodium Monofluoroacetate (Compound 1080) solution in a two-pouched rubber vessel which is attached to Velcro or elastic bands which hold the pouches in place in the throat regions of sheep and goats subject to predatory attacks by coyotes. Use of this "Restricted" product is limited to the State of Montana.

200.2 Background Information

See efficacy reviews of 9/30/86, 4/21/87, 5/21/87, 7/12/89, 10/23/89, 5/24/90, and 10/16/91, along with other information in product jacket. The current submission consists of a letter incorrectly dated 11/7/89 (it refers to EPA's letter of 10/18/91!) with which were enclosed copies of revised labeling, a new Confidential Statement of Formula (CSF), and a "monitoring" report on use of this product in calendar year 1990. The monitoring report was prepared by the Montana Department of Agriculture (MDA).

MDL recently has explored the possibility of canceling this product and having Ranchers Supply's collar (46779-1) made available for use in Montana. The label for 46779-1 would have to be modified to permit use in states other than Texas.

200.0 DATA SUMMARY

The monitoring report is three pages long and is written in question-and-answer form. According to the report, no collars were purchased in 1990, but collars purchased previously were used in Blaine, Sheridan, and Sweetgrass Counties. By the end of 1990, 28 applicators had been licensed to use collars in Montana including 17 "Private," 9 "Government," and 2 "Commercial" applicators. MDA reports no improper disposal or loss of nontarget animals associated with use of Livestock Protection Collars in Montana in 1990. Table 1. summarizes three-year data reported by MDA.

MDA summarizes collar use in Montana in the following paragraph.

"The use of LP Collars in Montana has [been] too limited to make meaningful conclusion on parameters that affect the effectiveness of the collars. The limited information seems to suggest that attempting to use too small of a target flock is less effective than [sic] using larger flocks. However, three of the coyotes taken were with target flocks of less than 10 animals."

Use of collars in Montana has been too limited to support any conclusions. It appears, however, that three coyotes out of six (or eight if the missing collars were not included as assumed punctures) coyotes taken resulted from use of small target flocks. Therefore, the only inference suggested by MDA may also be premature.

Table 1. Data reported by Montana Department of Agriculture summarizing three years of operational use of Livestock Protection Collars (35975-4) in Montana.

	1988	1989	1990	TOTAL
Collars Purchased	45	90	0	135
Applicators Purchasing Collars	6	4	0	9*
Collar-days of Use	1185	1110	630	2925
Mean Number of Days Collars Used in Field	26	41	30	32†
Number of Collars Lost in Field@	2	0	2	4
Mean Days Until Collars Lost	7	-	?	?
Number of Collars Ruptured in Field	3	0	3	3
Mean Days Until Collars Ruptured	7	-	7	7
Number of Collar Ruptures Attributed to Coyotes	3	0	1-3	4-6
Percent of Collar Ruptures Attributed to Coyotes	100	-	33-100	67-100
Dead Coyotes Found Attributed to Collars	1	0	0	1
Nontarget Deaths Attributed to Collars	0	0	0	0

* The applicator who purchased collars in 1988 and 1989 is counted only once.

† This figure represents the arithmetical average of the figures for the three years. No attempt was made to weight results according to the intensities of use in the three years.

@ Sheep wearing the collars also were lost in each case. Sheep lost with collars in 1990 were believed to have been coyote-killed as predation declined after the sheep were lost.

The CSF describes a product containing Tartrazine (yellow) dye rather than the Rhodamine B (reddish purple) dye formerly used in all Livestock Protection Collars. Rhodamine B was deleted because it was an "inert [ingredient] of concern" to EPA. The CSF fails to indicate weight, nominal concentration, or upper and lower certified limits for the water used in the formulation.

The revised labeling differs from the current accepted label (stamped 11/17/89) primarily through changes reflecting the dye substitution and the comments in EPA letter of 11/1789, in which the Agency accepted MDL's label "with comments." No separate copies of the container label appears in MDL's submission of "11/7/89". The container label present as an attachment to the technical bulletin differs from the label accepted on 11/17/89 in that it contains a statement noting that the product contains Tartrazine dye and that it claims a nominal concentration of 1.04% sodium fluoroacetate. The label accepted 11/17/89 had no dye statement and claimed a nominal concentration of 1.00%. The CSF submitted on "11/7/89" claims 1.00% active ingredient for the lower certified limit and the nominal concentration. (According to OPP's fluid policy regarding nominal concentrations, it seems to be acceptable for the label to claim 1.04% if it agreed with what is claimed in the CSF as the nominal concentration.) Whether the label includes a Tartrazine statement seems to be optional.

In the revised technical bulletin, MDL has chosen to write out agency and legal abbreviations rather than to retain the casual references which appeared in the version accepted "with comments" on 11/17/89. The revised bulletin is far less confusing.

CONCLUSIONS

1. We have reviewed the monitoring report for 1990. Thank you for submitting it.
2. Your revised Confidential Statement of Formula (CSF) lacks the following information for the ingredient XXXXXXXXXX
 - a. nominal batch weight,
 - b. nominal concentration,
 - c. upper certified limit, and
 - b. lower certified limit.

Submit a revised CSF which includes this information.

3. The proposed revised labeling did not include separate copies of the container label. The container label included as an appendix to the technical bulletin specifies a concentration (1.04%) of sodium fluoroacetate which differs from that (1.00%) claimed on the container label accepted on November 17, 1989, and from the nominal concentration on your revised CSF. The nominal concentration claimed on the label and the CSF must be the same. The nominal concentration claimed may be any concentration within the range delineated by the certified limits. Therefore, either 1.04% or 1.00% sodium fluoroacetate could be claimed.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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