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IRB BRANCH REVIEW - TSS

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10/28/88 11/19/88

IN _____ CUT _____

EFFICACY

13808-T

FILE OR REG. NO. _____

PETITION OR EXP. PERMIT NO. _____

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DATA ACCESSION NO(S). none

PRODUCT MGR. NO. 16

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

COMPANY NAME South Dakota Department of Agriculture

SUBMISSION PURPOSE registration

CHEMICAL & FORMULATION 1.04% Sodium fluoroacetate solution in Livestock

Protection Collar

1/4

Efficacy Review: SODIUM FLUOROACETATE (COMPOUND 1080) LIVESTOCK PROTECTION COLLAR,
13808-T
South Dakota Department of Agriculture
Pierre, SD 57501

200.0 INTRODUCTION

200.1 Use

A 1.04% Sodium Monofluoroacetate (Compound 1080) solution enclosed in a two-pouched rubber vessel which is attached to Velcro or elastic bands to 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 review of 8/29/88. In the current submission, SDDA has provided revised labeling (including the container label, a technical bulletin, and a labeled, unfilled collar example), a revised Confidential Statement of Formula (CSF), a revised "monitoring plan" for gaining feedback on the use of the collar.

201.0 DATA SUMMARY

The revisions to the container label and technical bulletin have addressed the items noted in prior reviews and in EPA's letter of 9/18/88. A few new problems have arisen (see "CONCLUSIONS"). The most notable of these are:

- 1) A decision by SDDA to permit users to dispose of collars rather than requiring users to return damaged collars to SDDA in Pierre. This change has led to a merging of the Use Restrictions formerly numbered 13 and 14 into a somewhat expanded number 13. The new restriction 13 is now in conflict with text on the container label which directs users to return damaged collars to SDDA.
- 2) Insertion of lengthy Endangered Species language in a new Use Restriction 15. The new text lists counties in many states where there are Endangered Species considerations and mentions the black-footed ferret as one species that needs protection. That South Dakota is not one of the states mentioned is very surprising as this product has been proposed for use only in South Dakota and as South Dakota is one of the few (perhaps only two) states where black-footed ferrets have been sighted within the last 15 years.

The text required by EPA was added to the straps of one of the two collar examples submitted. However, the labeling appears to be for Montana's product, not South Dakota's. Some of the text is located near the free ends of the straps. As the User Instructions in the Technical Bulletin permit applicators to cut off the ends of straps that are too long for the animals selected to wear particular collars, it is important that any text that might be clipped off be repeated elsewhere on the same strap. In the labeled example provided, text found near the free end was repeated closer to the collar bladders.

The revisions requested for the "Monitoring Plan" have been made.

202.0 CONCLUSIONS

The following comments apply to the revised Technical Bulletin

1. References to pages where particular items are discussed must remain accurate through all editions of the Technical Bulletin. Note that referencing by section and subsection is less labile with respect to minor changes in the document, although such changes might affect pagination.
2. In the first line of the second paragraph of section "I.A." (page 5), change "behavior" to "behaviors".
3. In section "I.D.1.d" (page 7), note that the reference to "Appendix B" has no meaning as there is nothing in the organization of the revised version of the Technical Bulletin to suggest that there are any appendices. You may refer to the location of the sample warning sign by page number or you may construct a format which uses appendices. If appendices are to be used, they must appear last in the document, after the photos and their captions. The table of contents must be amended as needed to preserve accuracy.
4. In the next-to-last paragraph of section "I.D.2." (Page 8), the "Appendix B" problem appears again.
5. The proposed merging of former Use Restrictions 13 and 14 into a new Use Restriction 13 is acceptable. We note that you now direct users to dispose of badly damaged collars themselves. All labeling must be consistent on this point.
6. The new Use Restriction 15 does not address Endangered Species considerations in South Dakota, the only state where this product is to be used legally. As South Dakota is one of the few states where black-footed ferrets have been seen within the last two decades, we believe that the labeling needs some text addressing potential hazards to this species (as well as to any other Threatened or Endangered species potentially at risk in South Dakota). Possible ways to approach this problem would be to develop a list of counties or areas within specific counties where collars may not be used without approval of an appropriate wildlife agency (e.g., U.S. Fish & Wildlife Service and/or the South Dakota agency responsible for Threatened or Endangered Species), to state that collars may not be used in any location within an appropriate buffer radius (e.g., one mile) of a prairie dog town, or to require a ferret survey of any prairie dog towns within such a specified radius of the fenced pasture site where the collars are intended to be used. As you are in closer touch with prevailing situations in your state, we suggest that you propose language for Use Restriction 15 to address the ferret hazard in South Dakota. EPA will evaluate your proposed text and determine whether it can be accepted as written or with modifications.

7. In the caption for photograph 14, change "files" to "flies".

The following comments apply to the revised container label:

1. The label text in the section on "COLLAR DISPOSAL" conflicts with the revised version of Use Restriction 13, which directs users to dispose of damaged collars themselves instead of returning such collars to the South Dakota Department of Agriculture. Modify the label language so as to be consistent with the Technical Bulletin. Such text might read

"COLLAR DISPOSAL: Damaged, irreparable and/or leaking collars must be disposed of by deep burial. Follow the procedures described above and in Use Restriction 13 in the Technical Bulletin."

2. The second paragraph under "ENDANGERED SPECIES CONSIDERATIONS" is accurate for the currently proposed version of Use Restriction 15. As you have been required to modify Use Restriction 15, you must also modify your label text accordingly.

The labeled collar submitted appeared to be that for the State of Montana. Your collars must bear your registration number and serial numbers assigned by the South Dakota Department of Agriculture. On the labeled example submitted, some of the text is located near the free ends of the straps. As the User Instructions in the Technical Bulletin permit applicators to cut off the ends of straps that are too long for the animals selected to wear particular collars, it is important that any text that might be clipped off be repeated elsewhere on the same strap. In the labeled example provided, the text found near the free ends was repeated closer to the collar bladders. This practice should be followed for all collars.

The revised monitoring plan is acceptable.

William W. Jacobs,
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Insecticide-Rodenticide Branch
November 19, 1988

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