

4-5-96

IRB BRANCH REVIEW - TSS

Record Number(s)
D224898

IN 4/4/96 4/5/96
GUP

EFFICACY

FILE OR REG. NO. 39508-2

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 6/1/95

DATE OF SUBMISSION 5/24/95

DATE SUBMISSION ACCEPTED 4/5/96

TYPE PRODUCTS(S): I, D, H, E, N, R^x, S

DATA ACCESSION NO(S) no new efficacy data

PRODUCT MER. NO. 14

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

COMPANY NAME New Mexico Department of Agriculture

SUBMISSION PURPOSE amend labeling

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, 10/6/93, and 6/27/94, along with other items in this product's two-volume registration jacket.

The current submissions consists of a letter of 5/24/95 to which are appended five copies of a proposed revised container label and five copies of a proposed revised technical bulletin. The cover letter claims no changes other than those prescribed by EPA (presumably in our letter of 6/27/94) but refers to the new labeling as "revised". As neither our letter of 6/27/94 nor NMDA's letter of 5/24/95 mentions "final printed labeling", I have elected to treat the submission as proposed amended labeling and to review it accordingly.

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.

The only changes made to the proposed revised container label submitted on 5/24/95 are a modification to the "ENDANGERED SPECIES CONSIDERATIONS" section that we prescribed in our letter of 6/27/94 and an acceptable alteration in the way in which the manufacturer and registrant are identified near the bottom of the center panel.

Two organizational changes appear in the proposed revised technical bulletin. Photos and photo captions now are presented in one appendix rather than in two, with the captions appearing below the pictures. This change is appropriate. The copies of the collar and container labels which appear in the current technical bulletin are missing from the proposed revised version submitted on 5/24/95. The container label (at least) belongs in the bulletin.

202.0 CONCLUSIONS

The proposed revised labeling submitted on May 24, 1995, is acceptable, although the technical bulletin technical bulletin must be modified as indicated below.

1. Change "3 foot" to "3 feet" in the second sentence of the first paragraph of "a." under "Disposal of damaged collars and other contaminated materials" (page 10)

2. Change "properly positions" to "properly positioned" in the last sentence of item "f." under "Mistakes in Targeting" (page 12).
3. At the bottom of page 16, list "Photos and Photo Captions" together and in appendix "C." and delete reference to an appendix "D."
4. Insert a copy of the newly accepted container label in the technical bulletin and identify this container label as "Appendix A".

William W. Jacobs
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Insecticide-Rodenticide Branch
April 5, 1996