

6-27-97

IRB BRANCH REVIEW - TSS

Record Number(s)

D236938

IN 6/27/97 CUT 6/27/97

EFFICACY

FILE OR REG. NO. 39503-2

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 3/11/97

DATE OF SUBMISSION 3/3/97--

DATE SUBMISSION ACCEPTED 6/27/97

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

DATA ACCESSION NO(S) none

PRODUCT MGR. NO. 14

PRODUCT NAME(S) SODIUM FLUOROACETATE LIVESTOCK PROTECTION COLLAR

COMPANY NAME New Mexico Department of Agriculture

SUBMISSION PURPOSE Obtain information on monitoring plan, discuss labels for individual collars

CHEMICAL & FORMULATION 1.00% Sodium fluoroacetate solution in Livestock Protection Collar

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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, 6/27/94, 4/5/96, and 2/4/97, along with other items in this product's two-volume registration jacket.

The current submission consists of a letter of 3/3/97 in which NMDA's Frank DuBois (1) admits that NMDA's monitoring report for 1995 was "basic and does not provide the elements of detail previously provided"; (2) states that NMDA staff in the toxic-collar program have been told "to use extreme care in gathering and reporting all current and future data"; (3) asks EPA to provide copies of our letter of "April 4, 1988" as well as the "approved plan" for monitoring collar use; and (4) states, regarding NMDA's failure to include copies of the labels used on individual collars with the final printed labeling submitted on 5/1/96, that

"The nature of the product precludes labeling the individual LPCs, and we have no record of this being a suggested change as part of the LPCs registration or as a requirement. Please provide clarification on this point."

Our letter of 2/4/97 actually referred to a letter of "April 11, 1988" rather than 4/4/88. Our letter of 4/11/88 dealt at length with proposed labeling, certification and training materials, and the monitoring plan. An amended monitoring plan was accepted via the original letter of acceptance of this product for registration as a pesticide in the U.S. That letter, which was dated "11/4/88", describes the textual information which must appear on each collar. I interpret that letter as requiring labeling for individual collars, which could have included text hand-written on proximal parts of the straps instead of a printed label. This issue also was discussed in the efficacy review of 10/21/88.

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. Data submitted in 1979 and in the 1980's support claims of effectiveness made for small-size collars. These data also are available to NMDA.

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I have copied EPA's letters of 4/11/88 and 11/4/88 and will send them to NMDA. It would be surprising if NMDA lacked a copy of the acceptance letter, but the claim that that Department was not aware of the need to label individual collars suggests that they might be missing the original acceptance letter. I also will send NMDA a copy of its own letter of 10/26/87, to which our letter of 4/11/88 responded. In that letter, Mr. DuBois' predecessor William P. Stephens lists "Pesticide Label (small collar)" and "Pesticide Label (large collar)" among 13 categories of items enclosed with the letter. With his letter of September 7, 1988 (to which our letter of 11/4/88 responded), Mr. DuBois included a typed label for individual collars.

202.0 CONCLUSIONS

We are encouraged to learn that you intend to do a better job of monitoring and reporting information on Livestock Protection Collar use in New Mexico and will be happy to assist you in those endeavors.

As requested, I am enclosing a copy of our letter of April 11, 1988 (not April 4), in which we commented at some length on the monitoring plan as it originally was proposed. I also am including a copy of Mr. Stephens' letter of October 26, 1987, to which our letter of April 11, 1988, replied. You may note that Mr. Stephens reports having submitted labels for small- and large-size collars.

I also am enclosing a copy of the monitoring plan which we accepted with comments on November 4, 1988, when this product initially was accepted for registration. I also am including that acceptance letter and the labeling that was stamped at that time.

Our letter of November 4, 1988, addresses the content of labeling for individual collars in item "2.d." (page 3). As the labeling for this product was "ACCEPTED with COMMENTS" with reference to our letter of November 4, 1988, you were required to make all labeling changes prescribed in that letter, including labeling individual collars properly.

That the typed label for individual collars (copy enclosed) which you submitted with your letter of September 7, 1988, was not stamped may have been an oversight; and/or it may have been due to the discussions about the way in which the required text would be affixed to or written on the collar. If you are hand-labeling collar straps, you should submit photocopies of a collar with properly-labeled straps legibly copied. While we cannot stamp collar straps, we could stamp such a photocopy. If you are not putting the required text on your collars, that situation must be remedied immediately, either through writing on collars in indelible ink or affixing an appropriate label to them. Either way, submit 3 copies of the label for individual collars.

William W. Jacobs
 Biologist
 Insecticide-Rodenticide Branch
 June 27, 1997

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