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RECORD NO.

SHAUGHNESSEY NO.

100
REVIEW NO.

EEB REVIEW

DATE: IN 2-2-90 OUT 3/13/90

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PETITION OR EXP. NO

DATE OF SUBMISSION: 12-5-90

DATE RECEIVED BY EFED: 1-25-90

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RD ACTION CODE/ TYPE OF REVIEW: 354

TYPE PRODUCT(S): Predicide

ACCESSION NUMBER(S):

PRODUCT MANAGER: Miller (16)

PRODUCT NAME(S): 1080 Livestock Protection Collar

COMPANY NAME: USDA/APHIS

PURPOSE OF SUBMISSION: Reconsider requiring tests on assessing hazards to eagles and skunks.

SHAUGHNESSEY NO.	CHEMICAL AND FORMULATION	%A.I.

MRID # 415371-01

ECOLOGICAL EFFECTS BRANCH

Chemical Name: Sodium monofluoroacetate (Compound 1080)

100.0 Purpose of Submission

The United States Department of Agriculture/ Animal and Plant Health Inspection Service (USDA/APHIS) requests that the Agency reconsider its evaluation of two studies for assessing the hazards from the use of the Livestock Protection Collar (LPC) to skunks and golden eagles. The USDA/APHIS acknowledges that there were, in fact, deficiencies in the conduct of the original studies, but contends that they were minor in nature (i.e., they simply failed to properly archive raw data) and that the "results remain scientifically valid". Accordingly, the USDA/APHIS has requested that the Agency reconsider its position and accept the studies as core data for purposes of registration (See attachment 1).

100.1 Background

On November 24, 1986, the EEB completed a review of a laboratory audit, conducted at the Denver Wildlife Research Center (DWRC) on the ecological effects and secondary poisoning of Compound 1080 and Brodifacoum, respectively (See review completed by R. Felthousen in EEB files). The audit took place between July 14-16, 1986, and was conducted by an interagency inspection team at the request of the Office of Compliance and Monitoring (OCM), Office of Pesticides and Toxic Substances. The studies were audited through review of available raw data and reports, interviews with senior study personnel and visits to the laboratory areas where the studies were conducted.

The studies involving Compound 1080 were identified by the Ecological Effects Branch (EEB) as data requirements to support the Federal Registration of the 30 ml LPC. The studies in question were:

1) "Estimated Doses of Sodium Fluoroacetate Delivered to Coyotes by Toxic Collars" and,

2) "Primary Hazard of the 1080 Toxic Collars to Skunks and Golden Eagles".

As stated in Section 104.0- Conclusions- of EEB's 11/24/86 review, the EEB did not prepare a data evaluation report for any of the studies but instead relied heavily on those study deficiencies, conclusions and recommendations reported in the audit report in

making its decision on the adequacy of the data to support a registration. The EEB concluded, based upon these findings, that the Compound 1080 studies were not adequate to support the registration.

101.0 Discussion

The USDA/APHIS contends that the study discrepancies were minor and did not affect the scientific validity of the reported results. The following discussion will address this claim, relative to the study determining primary hazard to skunks and golden eagles.

Skunk Portion of Study

In the EEB review of 11/24/86, it was noted that there were discrepancies with both the biological and chemical aspects of the study. The biological audit revealed that there were missing data whereas the chemical audit noted that there were raw data missing on substance identification and purity; residue analysis and dosage preparation. The EEB has previously noted that if these data were made available, this portion of the study may be adequate to support registration. However, the EEB is unaware that any of these missing data were ever reported. Therefore, the issue now becomes whether the study can be scientifically validated given the available data. The EEB believes that since there are no data upon which to confirm what dosage was used and/or what residues actually occurred, there is no way to verify or scientifically repeat the results of the study. As such, the EEB must conclude that the study is invalid and does not satisfy the data requirement.

Eagle Portion of Study

Study deficiencies identified in the biological audit included incorrect tables, missing data and incomplete records. The chemical audit cited no raw data records, missing data on test substance, no data documenting test solution and lack of supporting data and traceability of reference standards. The audit team recommended that the raw data be re-analyzed and the data tables corrected. Corrections should be made only if there were the raw data to document fact that the original data submissions were incorrect. Otherwise, reported data cannot be supported by raw data and should be dropped from the report. Again, given the fact that there is no way to confirm the reported data and scientifically validate the study results, the EEB must conclude that the study is invalid and does not satisfy the data requirement.

The EEB also notes that this portion of the study also had problems with sample size. Apparently, only two of

the five eagles tested actually consumed sheep flesh from the neck area of the animal. Obviously, no effects would be expected to occur to those eagles that were not exposed to 1080. This greatly reduces the utility of the study for providing any useful information on the potential hazard of sheep carcasses to non-target raptors under actual field-use conditions.

The EEB also is concerned with the researchers explanations relative to the sub-lethal symptoms (i.e., tremors) exhibited by those eagles that actually fed on the neck area. It's important to note that the purpose of conducting these studies is to determine whether or not non-targets are being adversely affected by 1080. The EEB believes that, while mortality is obviously the most significant effect, other symptoms of exposure, such as tremors, are also important toxicological end-points that must be monitored and reported. This is especially the case for assessing hazard under field conditions where animals are subject to stress from a variety of biotic and abiotic factors that are not present under laboratory conditions.

102.0 Conclusions

The EEB has reviewed the USDA/APHIS request that the Agency reconsider its data evaluation of two studies to support the registration of the 30 ml toxic collar. The EEB believes that the data deficiencies identified in the audit are such that the studies cannot be scientifically validated. Therefore, the EEB concludes that the data requirements for registration are still outstanding.

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