IRB PRODUCT PERFORMANCE REVIEW

PM: 17

05-18-89

2724-UEU,UEA
Zoecon RF 372 Collar, RF 327 Collar
Zoecon Corporation
Dallas, TX. 75234

IN:
DUE: --------
AC: ---
RN: 222108
221949
MRID: 406131-01

FORMULATION

Methoprene 01.000% 2.00%

Collars for Cats, Dogs Respectively

INTRODUCTION

Application for new registration. New use patterns not previously registered. Methoprene is an insect growth regulator with no demonstrated adulticidal activity. It has shown excellent persistence indoors at low concentrations. Methoprene apparently degrades rapidly in the presence of ultraviolet light. Methoprene is registered in space treatments and surface treatments for the control of immature life stages of fleas.

USES

See proposed label. Topical animal treatment. Label claims include the following:

Birth control for fleas
Prevents the growth of immature life stages of fleas
Eggs deposited on and larve crawling on treated animal will not develop into adults.
Kills (controls) flea eggs.
Prevents (stops) infestation in your home from eggs laid on pets
Stops infestation at the source
Kills fleas before they mature in adults
Kills todays flea eggs and prevents tommorrows fleas.
Effectively breaks the flea life cycle
Aids in the control of flea bite dermatitis by killing, controlling, preventing new adult fleas
Stops flea infestation at the source.
Reduces flea egg production
Prevents flea egg development
Prevents larval flea hatch

SUBMITTED DATA

MRID 40613101.

Van Gundy, Doug. Zoecon Corporation. 3/1/88. 2 cats per treatment, no controls reported. Control animals were mentioned in the percentage calculations but the number of controls, individual animal data and other details of the experiment were not provided. Animals collared, then inoculated with 50 C. felis per animal. The cages were swept for 4 days after each inoculation and the % emergence was estimated by observing 25 eggs from each treatment in petri dishes.

No outdoor exposure was provided. No studies on dogs were submitted. The 0.6% collar showed greater than 90% reduction for 16 weeks. The 1.0 collar showed the same results for up to 24 weeks.

CONCLUSIONS

1. The submitted data are not valid to evaluate the proposed label claims. The number of controls, individual animal data and details of the conduct of the study were not reported. The number of animals per treatment are insufficient to make substantive conclusions. No statistical analysis is possible with only two animals. Details concerning the animal sex, wt. and hairlength must be reported. A minimum number of animals must be greater than 40 lbs.

2. Even if this laboratory assay was found to be acceptable, such data are not sufficient to support label claims. To support a new active in a flea collar, studies providing the animals with normal activity and exposure (i.e. housing with outdoor runs) are required. Unless the label is modified to add a wetting statement, the animals should either be exposed to the rain or be wetted on at least a weekly basis (usually the animals are saturated when the runs are hosed down).

3. A minimum of 4 animals per group must be tested. Actually many labs use 6 as a minimum to provide addtional confidence in the data derived and to keep a statistically relevant number of test subjects should something happen to an animal over the course of the study. (These studies traditionally extend over several months).

4. Data derived from testing both dogs and cats are required.

5. As label claims imply flea control, in addition to the larval assays, the number of fleas that appear on the animal must be counted at 24 hours after each infestation and again at either 48 or 72 hours after each infestation. Pupal emergence must also be evaluated unless this instar is excluded. Otherwise, the label must specify that the product will have no effect on existing adult fleas or on new fleas which may infest the animal. Label claims will have to be restricted to reduction of the immature stages of the insect.

6. Data regarding differences in egg deposition between treated and contol animals must be evaluated to support label claims regarding egg production.

7. Claims regarding stopage of flea infestation in the home must be evaluated in a study which monitors the numbers of adult fleas from a single infestion.

8. Data to support label statments that flea larvae crawl on and infest pets must be submitted.

9. Because of the unique nature of the product, and the extensive nature of the proposed label claims, it is strongly suggested that the applicant submit protocols to the Agency prior to the initiation of testing. It is most likely that a series of different studies will be required to support all of the proposed labelling.

Phil Hutton
PM 17