IRB PRODUCT PERFORMANCE REVIEW

PM: 18 04-13-92

2724-UEA
RF372 Collar
Zoecon Industries
Dallas, TX
Hauppauge, NY 11788

D: 169172
MRID: U.A.

FORMULATION

Methoprene 1.00%

[redacted]

INTRODUCTION

Application for new registration. This is the first time methoprene has been used [redacted] collar. Methoprene is an IGR highly effective against fleas at very low dosages. While ovicidal methoprene has no effect on either adult fleas or on pupae. Methoprene sprays have been shown to last for up to 1 year when applied to carpets. Topical preparations have been shown to last for several weeks when applied to dogs. The effectiveness of the active has therefore been established. However it must be noted that methoprene is quite unstable in the presence of U.V. light. Submitted data must also indicate that the collar will release sufficient active ingredient for the duration period claimed. See prior review of 8.26.91.

USES

Label claims are for flea control on dogs and puppies only. The initial label did not adequately describe the inability of methoprene to control existing or emerging adult insects. For this reason a second label was faxxed in on 3/26/92. This is the label used for the following review. The predominant claim is for the prevention of egg hatch for 4 months.

[redacted]

SUBMITTED DATA

MRID 418591-00. Interim efficacy report from Young Veterinary Research, Modesto CA 95356. No study number.

6 treated and 6 placebo animals, individually housed. 8-10 hours of outdoor exposure daily. Washing/wetting not reported. Animals collared prior to the initial infestation. 100 C. felis per dog infested weekly through day 28, and biweekly thereafter. Flea eggs collected four days after inoculation, by holding the animal in a 3 X 5 metal cage for 14-16 hours overnight. Four 25 egg samples from each dog were incubated in petri dishes for 3-4 days. The remaining eggs were also kept in the incubator for observation. Interim results indicate that the collar can ellicit ovicidal/developmental toxicity.

Day	Percent Live Larvae Treated	Placebo
4	0.3	61.2
11	0	59.0
18	1.3	63.2
25	1.3	64.5
32	0.3	61.2
46	0	34.5
60	0	35.8
74	0	33.7
88	0	25.8
102	0	50.7
116	0	42.0
130	0	45.0

CONCLUSIONS

1. In order to fully evaluate the submitted study, the Appendixes referred to in the interim report must be submitted. Also, we need answers to the following questions:

a. Did the outdoor runs provide full exposure to sunlight? If not, what is the average percentage of shade during the outdoor period of exposure?

b. The housing description states individual housing and 12 outdoor runs for the 12 animals. However the discussion mentions companion animals in the runs. Are these statements conflicting, or is there some explanation.

c. The discussion section mentions repair of the collars with hog rings. Which collars were repaired, and when? Are these in addition to the collars which were replaced?

d. Were adult fleas also counted? Were adult fleas removed or allowed to accumulate on the animals during the course of the study?

e. Were the animals exposed to any rainfall or wetting during the course of the study?

f. What were the results from the half-pint cartons?

g. It is noted that all of the broken collars reported were methoprene, and not placebos. Please explain. Thus far, 4/6 (67%) of the subject collars broke at an average of 45 days. This results in a concern over the physical integrity of the collar over time. Please address this concern.

2. The submitted study will not support the existing label claims as it does not evaluate the ability of the collar to protect the animal from reinfestation by adult fleas:

Long lasting protection
Kills (controls) fleas for (4 months)

3. There is some concern over the dip in the percentage of live larvae for the placebo animals. Hopefully, the placebo group will continue to recover during the remainder of the study.

Phil Hutton