IRB PRODUCT PERFORMANCE REVIEW

PM: 18

08-26-91

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

MRID: 418591-00
DP: D167509

FORMULATION

S-Methoprene.....1.00%

[redacted]

INTRODUCTION

Application for registration. Methoprene is well known as an IGR for fleas, but has no adulticidal properties. Jacket and CSF not provided.

USES

Label claims as follows:

Long lasting protection
Kills flea eggs
Ovicidal
Kills eggs before they hatch
Prevents flea eggs from hatching for 4 months
Prevents(stops) flea eggs from hatching for 4 months
Kills (controls) fleas for (4 months)

No statements regarding wetting or speed of action.

[redacted]

SUBMITTED DATA

1. No MRID assigned. A previously submitted two animal study was reviewed and found to be inadequate. Submitted data from Dr. Robert Young, Young Veterinary Research, Modesto CA 95356. This is an interim report in that the collar was still performing at a high level of efficacy at the time the report was submitted. We note no GLP page or other 86-5 requirements in the submitted data. Studies on dogs only. 6 Test and 6 control animals. No positive controls (no other ovicidal collars are registered). Housing was indoors, in 4x10 chainlink runs, with sheet metal separating the pens. Daily water flush for cleaning and all pens disinfected 2x weekly. Animals were given 8-10 hours of outside activity per day in outside runs, with partial mesh sunscreens (as required by animal care regulations). Based upon conversations with the study director, animals received about 4 hours of direct sunlight, 4 hours of partial sunlight, and 2 hours of full shade per day. Animals were infested with 100 Ctenocephalides felis initially and and then weekly for the first 4 weeks. After this, infestations were accomplished every other week. There is a 200 flea per animal maximum load for this study.

72 hours after inoculation, dogs are placed in smaller individual cages for overnight collection of flea eggs in pans beneath the cages. From this collection, 100 eggs are randomly separated and incubated to determine % successful eclosion. Results:

	Percent Adult Emergence		
Day	Placebo	Methoprene 1.0%	% Reduction
4	61.2	0.3	99.5
11	59.0	0	100
18	63.2	1.3	97.9
25	64.5	1.3	97.9
32	61.2	0.3	99.5
46	34.5	0.3	99.0
60	35.8	0	100
74	33.7	0	100
88	25.8	0	100
102	50.7	0	100
116	42.0	0	100
130	45.0	0	100

CONCLUSIONS

1. The submitted data are adequate to support label claims. While there was a significant dip in the emergence of the placebo animals at several data points, the emergence was still at 40-50% after 130 days. Given 100% reduction in emergence for eggs collected from the treated animals, the data are sufficient to conclude that the collars are performing adequately.

Some collar breakage occurred as treated animals were apparently allowed to exercise together and collars were broken during play. This does not seem to be related to matrix integrity or collar age.

The label has been adequately modified to indicate that the collar will not control adult fleas. There is no indication that the animals were washed during the four month study and a washing statement is therefore required on the label.

2. While the study method appears adequate to measure the performance of the collar with respect to the proposed label claims, what criteria to use a performance standard is extremely difficult. For the subject study, the collar was still performing at 100% when the report was generated. However, it remains to be seen what level of control below 100% (if any) would be considered to be acceptable. Therefore the applicant should submit information leading to the development of such a standard if less than 100% prevention of emergence is to be used to determine label duration in future submissions. Items such as the average number of eggs laid should be correlated with percentage survival to adults to support such a performance criterion.

LABELING

1. The labeling will be acceptable with the inclusion of a washing statement.

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