

IRB PRODUCT PERFORMANCE REVIEW

PM: 10

12-18-92

65233-1
Treo
Primavera Products

MRID: 425072-01,02
DP: D183669

FORMULATION

Oil of Citronella.....0.05%

RTU Lotion

INTRODUCTION

Application for amended registration.

USES

See label copy. Addition of flea repellent claim to label. Applicant also wishes to delete label restriction stating up to 1 hour repellency, and wishes to add the claim long lasting protection.

SUBMITTED DATA

1. MRID 425072-01. Scott Carroll, Davis, CA. Test reference REF-161. GLP study. Clinical trial (domestic residence with flea infestation) using Ctenocephalides felis. One leg treated with Treo at 3 ml., the other either untreated or treated with 3 ml of lubri Derm lotion. Arena type study. 30 second exposure in infested area. Lite counts only. Results:

a. Subject 1. 33 total exposures over time. First confirmed failure at 220 minutes (trial 19). Average liting pressure over 19 trials to that point was 10.0 fleas per challenge. Product did not fail to give 90% reduction until 940 minutes.

b. Subject 2. No confirmed failures in 500 minutes of testing. UTC averaged 4.3 lites over 6 trials.

c. Subject 3. No flea bites over 120 minutes. UTC averaged 3.3 bites over 8 trials.

d. Subject 1, lubriderm control. 1st confirmed failure for tree at 90 minutes. Placebo control average 4 bites over 8 trials.

Average protection time= 4.5 hours (1.5-8.33).

2. MRID 425072-02. Same researcher and facility. Field tests in Sutter County, CA. Culex tarsalis and Anopheles Freeborni. Deep Woods Off positive control. Calves of subjects treated with either 5cc of TREE or 3 Second Spray of Off. Other leg untreated. Summary data (graphs) are reported. The number of subjects was not provided. The first confirmed bite for all controls is stated to be less than 3 min.

Report incomplete. The number of subjects, and treatments for each subject need to be submitted. The actual counts for each evaluation should be reported in tabular form.

CONCLUSIONS

1. The data are adequate to support the claim for flea repellency.

2. No additional complete data on the duration of repellency were submitted. The data thus far for this product (see our review of 5/4/92) are summarized as follows:

Pest	Duration of Repellency
Mosquitoes	1.2 hours
Fleas	4.5 hours
Deer Ticks	2 hours

While additional information from the mosquito data above could impact our analysis, we cannot utilize this report until the additional information are provided. Because the mosquito duration is short, we do not feel that the duration descriptor should be removed at this time.

3. We still object to general claims for insects and ticks that may be construed to contain other unnamed items.

Phil Hutton