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Stacy
6/16/83

JUN 28 1983

The Hartz Mountain Corporation
700 South Fourth Street
Harrison, NJ 07029

Dear Mr. Perlberg:

Subject: Conditional Registration Application
Hartz 2 in 1 Plus Collar for Dogs
EPA File Symbol 2596-IU
Your Application Dated April 25, 1983

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is not acceptable, for the reasons given below:

1. The claim for 7 months control of fleas is not acceptable. We would be prepared to reevaluate the data for a 7-month flea claim for small dogs or small to medium dogs if the experimental details concerning exercise and the exposure of the animals to water for the recently submitted data are submitted.
2. You did not resubmit proposed labels and therefore it was not possible to make a review for content and format. For example, please refer to PR Notice 83-3 for revised storage and disposal statements. With your next submission enclose five revised labels (include pouch labels).

We have summarized the data you submitted on April 25, 1983, and have made the following observations.

The original proposed label claims 5 months control of ticks, 2 months "aids in the control of ticks," and 7 months control for fleas.

Acc. No. 250034. Test number 81-7. Young Veterinary Research. This test is on the 14.5% (13.7) reflective strip collar. Six test dogs and six placebo collared animals were used. No positive controls. The mean weight of the rabon collared animals was 16.38 kg. and for the placebo collared animals 18.10 kg. (approx. 36 lbs. for the rabon animals). Thus the test is a medium-large dog test. Animal housing was in individual cages. Details on exercise, exposure to sunlight, and wetting were not submitted. 100 Ctenocephalides felis and 50 Rhipicephalus sanguineus per dog were inoculated

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via drop-on technique. One infestation also used Dermacentor variabilis (day 84). All parasites were from Stanford Research Institute. Dogs were anesthetized for inoculation and for counting. Counts were made at numerous intervals postinoculation but the closed appropriate interval for the purposes of evaluation was 4 days. Results as follows:

Fleas

Mean infestation pressure at 4 days: 56.2/dog
1st confirmed failure at 90%: 200 days
Linear regression analysis: 138
Last day \geq 90%: 144
Graph Prediction: 171
Mean 163.3
Range 138-200

Ticks

Mean infestation pressure at 4 days: 14.2/dog
1st confirmed failure at 85%: 172 days
Linear regression analysis: 164
Last day \geq 85%: 116
Graph Prediction: 152
Mean 151
Range 116-172

The sum of all submitted data indicate that the product will control ticks for up to 5 months and aid in the control of ticks for 2 additional months.

The recent data for fleas indicate adequate control for 5 months, for these medium to large dogs. Previous data indicated good control on cats for 7 months.

The claims for 5 months control of ticks and 2 months "aids in control" are acceptable.

Please submit the above requested information within 75 days from the date of this letter. If additional time is needed an extension must be requested.

Sincerely yours,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767)