

IRB PERFORMANCE REVIEW

IN 9-10-80

OUT 10-15-80

FILE OR REG. NO. 2596-IU

PETITION EXP. PERMIT, S. 18, 24c, NO. _____

DATE OF SUBMISSION 9-4-80

DATE DIV. RECEIVED 9-5-80

TYPE PRODUCT(S): (I), D, H, F, N, R, S _____

DATA ACCESSION NO(S). 243175

PRODUCT MGR. NO. 15

PRODUCT NAME(S) Hartz 2-in-1 Plus 7- Month Collar for Dogs

COMPANY NAME Hartz Mountain Corp.

SUBMISSION PURPOSE Amendments

CHEMICAL & FORMULATION Rabon

200.0 Introduction - The submission is in response to the 4/10/80 review of the original submission of 3/21/80 and contains additional data to support the proposed amendments for a 7 month flea control claim and a 2 month aid in control of ticks claim beyond the existing 5 month tick control claim.

201.0 Data Summary - The data consist of a 210 day flea control test on cats and collar release rate data over a 252 day interval.

In the flea testing the cat flea was used. Six cats were collared with the subject collar, and six cats were collared with a placebo collar. Infestation rate was 100 fleas per cat. Initial infestation was at 7 days before collars were placed on the animals. Reinfestations were at 28, 56, 84, 112, 140, 168, and 196 days. Results are summarized in Graphs A and B.

For the release rate data an activated collar was stored under ambient conditions. The bloomed active ingredient was wiped from the collar surface periodically. Results are summarized as follows:

Sampling Period (Days)	Amount of Active Ingredient Recovered (mg/gm)
4	1.74
7	3.58
18	2.11
21	6.34
28	6.62
35	7.66
42	9.52
49	3.04
63	7.07
70	3.53
84	2.75
92	4.13
108	3.82
119	3.93
126	2.36
133	4.02
140	2.46
147	1.47
162	2.35
182	2.95
196	4.61
203	0.98
210	0.59
217	2.46
224	0.00
231	0.00
238	0.00
245	0.19
252	0.00

202.0

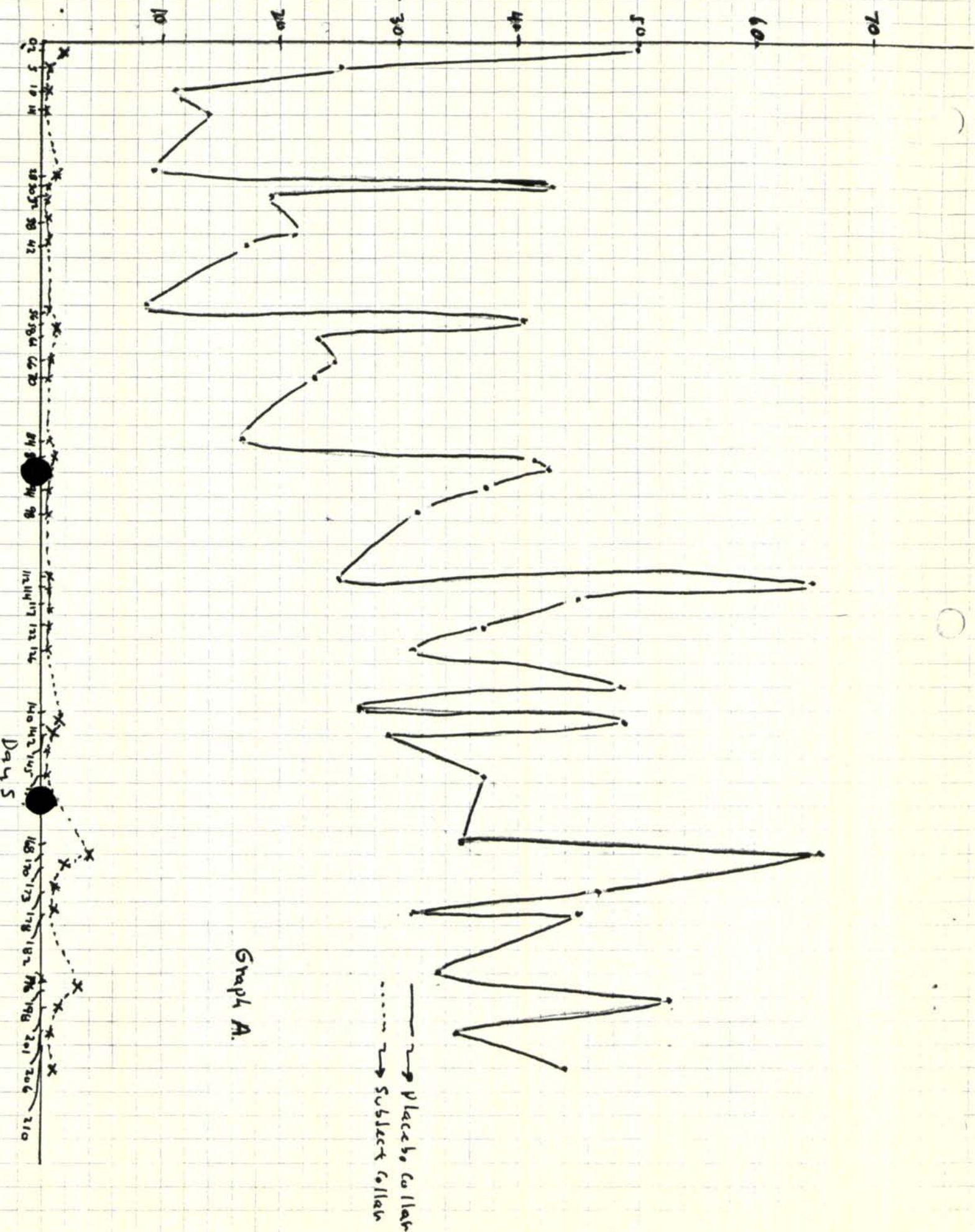
Conclusions - The submitted data are not adequate to support the proposed 7 month flea control claim for dogs. The flea control data indicate that the subject collar will control fleas on cats for 210 days (the duration of the test). The release rate data indicate that the amount of active material which was released dropped markedly after 196 days (between 196 and 203 days). This would indicate activity through at least 6.5 months. However, the collar was stored under ambient conditions. The data do not indicate the release rate under actual use conditions when the collar is on an animal. While the cat data are contributory with respect to flea control on dogs, the release rate data are critical in the absence of additional testing on dogs. These release rate data were not derived from a collar under actual use conditions.

After reconsidering the results of the tick test in the original submission of 3/21/80, we will accept the percent reduction of ticks at the counting intervals between 5 and 7 months as being adequate to support the proposed claim for aid in control of ticks on dogs for 2 months after the existing 5 month tick control claim. The claim should be limited to small and medium size dogs and should exclude long-haired dogs since the test was conducted with beagles.

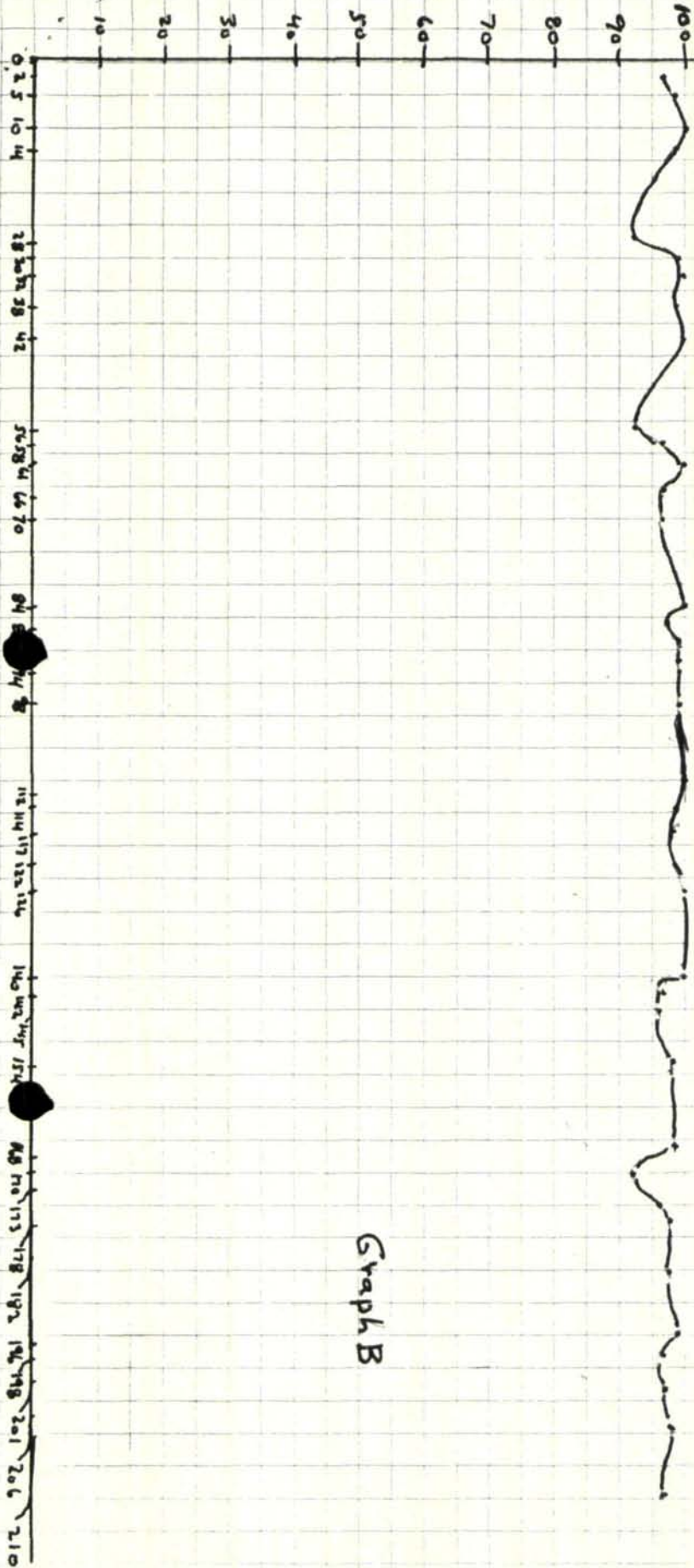
R. S. Van Denburg
10-15-80

IRB:RSVANDENBURGH:0015D:PMB:DCR#34463:RAVEN:479-2018:10/8/80

Mean No. Fleas / Cat



Percent Reduction in Fleas



Graph B

0.2.5

Record Number _____
Reference Number _____
Invent Date _____

COPIES FROM THE APPLICATIONS FOR REGISTRATION/AMENDMENTS

1. File Symbol/Req. No. 2596-14 2. PM 15 3. Action Code 166
4. Descriptor (Amend/Resubmissions only) Additional Data

5. Interstate Call-in ☐ (Y) Yes ☐ (N) No
6. Interstate Company and Accession Number _____

7. Child-resistant Packaging: ☐ (Y) Yes ☐ (N) No
8. Registration Type: ☐ (1) Conditional ☐ (2) Unconditional

9. Proposed Classification: ☐ (R) Restricted ☐ (G) General
10. Final Classification: ☐ (R) Restricted ☐ (N) Not Classified ☐ (G) General

11. Date on Application: 09/04/80 12. EPA Received Date: 09/05/80 13. Date Received by PM: 09/05/80

14. Data Reviewable Data Package Received:

☐ (Y) Yes ☐ (N) No

15. Product Type (circle one): A AR R/F O OE OF F K I IR PCR R S

16. Priority (circle one): 1 2 3 4 5 6 7

17. Applicant: _____

18. Chem. Code: _____ Chem. Name: _____
Chem. Code: _____ Chem. Name: _____
Chem. Code: _____ Chem. Name: _____
Chem. Code: _____ Chem. Name: _____

19. Proposed Use: _____

20. Method of Support: ☐ (1) Cite-All ☐ (4) Not Applicable ☐ (1) Yes ☐ (3) Not Applicable
☐ (2) Alternate ☐ (5) Not Submitted ☐ (2) Not Submitted
☐ (3) Combined

21. Submissions - only items in 20 are necessary to be completed.
Mandatory for New Chemicals/New Uses

22. Petitions Pending:

23. Sent to Federal Register Section for Publication:

Notice of Receipt ☐ (Y) Yes ☐ (N) No
Notice of Publication ☐ (Y) Yes ☐ (N) No

24. Reviews Requested:

	DATE SENT	DUE DATE	DATE RETURNED	RESPONSE DATE	RESPONSE DATE
REV					
EPA					
RC					
IR					
TS					

SP					
PM					
PL					
CH					
EP	9/9/80			11/21/80	10-15-80

25. Conditional registration Data Required (Enter due dates only):

☐ (Y) Yes ☐ (N) No

26. Status: 9 month extension granted 2/20/81

27. FINAL ACTION: Response Code 11 Response Date 11/21/80

28. 75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No

DEC 1 1980