

EFFICACY REVIEW

DATE: IN 5- 5-95 OUT 7-17-95

FILE OR REG. NO. 65331-R

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED November 4, 1994

DATE OF SUBMISSION November 4, 1994

DATE SUBMISSION ACCEPTED _____

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

DATA ACCESSION NO(S). 431211-14, -15, -16, -17, -18, -19, -20, -21 & -22;
D215030; S486457; Case# 014261; AC:115

PRODUCT MGR. NO. 10-Keigwin/Sibold

PRODUCT NAME(S) Frontline® Spray Treatment

COMPANY NAME Rhône Merieux, Incorporated

SUBMISSION PURPOSE Provide performance data in support of claims of
effectiveness and duration vs. fleas and 4 spp.
of ticks when applied topically to dogs & cats.

CHEMICAL & FORMULATION Fipronil: 5-amino-1-(2,6-dichloro-4-(tri-
fluoromethyl)phenyl)-4-((1,R,S)-(trifluoromethyl)sulfinyl)-1-H-py-
razole-3-carbonitrile 0.29%
(0.859 Sp. Gr. non-aqueous, ready-to-use pump spray)

CONCLUSIONS & RECOMMENDATIONS The data presented in EPA Accession
(MRID) Numbers 431211-14, 431211-15, 431211-16, 431211-17, 431211-
18, 431211-19, 431211-20, 431211-21 and 431211-22 have previously
been reviewed in connection with the application for an experiment-
al permit for a very similar formulation, containing 0.25% fipronil
instead of 0.29% as in the subject product. This review, completed
August 3, 1994, was for EPA File Symbol 65331-EUP-R. Summarizing
these data, MRID No. 431211-14, having been obtained from standard
kennel testing meeting the requirements of § 95-9(a)(1), (2) and (3)
on p. 263 and the standard of § 95-9(b)(2)(i) on p. 264 of the
Product Performance Guidelines, are adequate to establish satisfac-
tory control of fleas for up to 10 weeks and ticks for up to 6
weeks when the subject product is applied to dogs at the lowest
rate on the label. MRID No. 431211-15 is adequate to establish
satisfactory control of both fleas and ticks for 37 days when the
subject product is applied to dogs at the lowest label rate. MRID
No. 431211-16 is adequate to establish satisfactory control of the
cat flea, Ctenocephalides felis, for up to 107 days (continued)

when the subject product is applied to dogs at either of the rates on the label. MRID No. 431211-17 is adequate to establish satisfactory control of the American dog tick, Dermacentor variabilis, and the brown dog tick, Rhipicephalus sanguineus, for up to 44 days when the subject product is applied to dogs at the higher label rate of 6 ml per kg of body weight. MRID No. 431211-18 is adequate to establish satisfactory control of cat flea for up to 51 days when the subject product is applied to dogs at the 3 ml per kg of body weight rate, even when the dogs were subsequently subjected to bathing, shampooing or water immersion, and of brown dog tick for up to 23 days under the same treatment and exposure regime as for fleas. MRID No. 431211-19, the only data not derived from testing conducted according to GLP requirements, is adequate to establish satisfactory control of cat flea for up to 46 days on cats with one formulation of the subject product identified as Batch G01.00 and for up to 44 days with another formulation of the subject product identified as Batch G01.01 when applied at the 3 ml per kg of body weight rate. MRID No. 431211-20 is adequate to establish satisfactory control of cat flea for only 2 days whether applied at the 3 or 6 ml per kg body weight rate and flea counts on cats were obtained by means of combing. The 6 ml rate produced substantial reductions below the level of control for up to 30 days when counts were obtained either by hand or by combing. MRID No. 431211-21 is adequate to establish satisfactory control of cat flea for up to 43 days when the subject product is applied to cats at 3 ml per kg, for up to 50 days when applied at 6 ml per kg, and for up to 50 days when applied at a higher rate of 12 ml per kg. The only difference in results with the 12 ml rate compared to the 6 ml rate was a substantial reduction below the level of control for up to 57 days for 12 ml when the 3 ml and 6 ml rates produced little if any reduction. MRID No. 431211-22 is adequate to establish satisfactory control of nymphs of D. variabilis, R. sanguineus, Amblyomma americanum and Ixodes scapularis/dammini as well as adult C. felis within 2 days after exposure to hair clipped from dogs treated with either the 3 ml or 6 ml per kg body weight rate using the subject product. In fact, the 3 ml rate produced control of all but the Ixodes nymphs within 24 hours and the 6 ml rate control of all but the Amblyomma nymphs within the same period of time. Collectively, the data in these 9 volumes are adequate to support the label claims for the subject product as outlined in the listing of study titles submitted by the applicant accompanying proposed labeling for the subject product, namely: "Kills fleas and ticks for a minimum of 30 days.", "...may protect dogs for up to 90 days...", "...all stages of...ticks...", "...3 to 6 pumps per pound of the animal's body weight...", "...1 to 2 pumps per pound of the animal's body weight...", "Product performance is unaffected by exposure to moderate rainfall or by bathing with most brands of pet shampoos." and "To kill...brown dog ticks, American dog ticks, Lone Star ticks and deer ticks..."

NAC Vern L. McFarland, IRB