US EPA ARCHIVE DOCUMENT

EFFICACY REVIEW

DATE: IN12- 6-99 OUT12-29-99

FILE OR REG. NO. 65331-L

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED October 6, 1999

DATE OF SUBMISSION October 4, 1999

DATE SUBMISSION ACCEPTED

TYPE PRODUCT(S): (I,)D, H, F, N, R, S Insect Growth Regulator

DATA ACCESSION NO(S). 449421-05 & -06; D261554; S572130; Case # 066320; AC:175

PRODUCT MGR. NO. 03-Layne/Sibold

PRODUCT NAME(S) Frontline® Plus for Dogs

COMPANY NAME Merial Limited

SUBMISSION PURPOSE Provide performance data in support of claims for killing of adult fleas, flea eggs & larvae for new combination of active ingredients.

CHEMICAL & FORMULATION Fipronil 9.8%
(S)-methoprene 8.8%
(1.02 gm/cc Sp.Gr. ready-to-use liquid solution)

CONCLUSIONS & RECOMMENDATIONS The data presented in EPA Accession (MRID) Number 449421-05, having been obtained from a standard kennel test conducted according to the requirements of § 95-9(a)(1) to (3) on p. 263 and meeting the standard of § 95-9(b)(2)(i) on p. 264 of the Product Performance Guidelines, are adequate to support the ability of (S)-methoprene to prevent development of larval fleas to adult *Ctenocephalides felis* for 28 days following topical application of 2 mg/kg or higher to dogs of mixed sexes, ages and weights, including nearly complete prevention of maturation with doses of 6 mg/kg or higher for 35 days. Similarly, the same doses prevented larval flea hatch for 28 days or less at the 2 mg/kg rate but for 35 days at the 6 mg/kg rate or higher. Doses of 6 mg/kg or higher prevented most flea development for up to 6 weeks. Therefore, the utility of (S)-methoprene alone is established in the prevention of development of larval fleas to adult cat fleas for the lengths of time stated on the label when the subject formulation is applied to dogs according to label rates and directions. Also, the data presented in MRID (to be continued)

No. 449421-06, having been obtained from a standard kennel test conducted according to the same requirements and meeting the same standard, are adequate to demonstrate the superiority of the combination product to either fipronil or (S)-methoprene alone in prevention of maturation of flea larvae or prevention of larval hatch from deposited eggs collected from caged dogs. The combination product prevented nearly all larval flea hatching from eggs for 6 weeks, as well as the development of 91.4% of larvae to adult fleas for 85 days, when applied at 6.7 mg/kg to dogs, which is the optimum for label directions for the subject product. Thus, the subject product claims stated below are supported:

"Kills adult fleas, flea eggs & flea larvae"
"Prevents all flea stages (eggs, larvae, pupae) from developing"
"Kills fleas which cause flea allergy dermatitis"
"Prevents and controls reinfestations"
"Fast acting and long lasting".

which are found either on the front panel or the rear panel or both, along with the following claims found in the directions for use:

"...kills adult fleas, flea eggs and flea larvae for up to 3 months"
"...also prevents development of all flea stages for up to three months"
"When used monthly...completely breaks the flea life cycle..."

RL Vern L. McFarland, IB