

EFFICACY REVIEW

DATE: IN 4-10-92 OUT 6-24-92

FILE OR REG. NO. 59-231

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED March 24, 1992

DATE OF SUBMISSION March 12, 1992

DATE SUBMISSION ACCEPTED _____

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

DATA ACCESSION NO(S). 422569-01; D176529; S415179; Case #053081; Action Code: 305

PRODUCT MGR. NO. 13-LaRocca/Arrington

PRODUCT NAME(S) EXspot[®] for Dogs

COMPANY NAME Coopers Animal Health, Incorporated

SUBMISSION PURPOSE Provide performance data in support of claims for killing & repelling mosquitoes and aiding in prevention of blood feeding for up to 4 weeks.

CHEMICAL & FORMULATION Permethrin (3-phenoxyphenyl) methyl (±) - cis, trans-3-(2,2-dichloroethenyl)-2,2-dimethyl cyclopropane carboxylate*

*Cis/trans isomer ratio: 65.0%

maximum 55% (±) cis,

minimum 45% (±) trans (9.16-9.82 lbs./gal. in 1 cubic centimeter individual dose)

CONCLUSIONS & RECOMMENDATIONS The data presented in EPA Accession (MRID) Number 422569-01, having been derived from field testing using protocols incorporating the essential features of § 95-9(a) on p. 263 and meeting the standard for § 95-9(b)(2) on p. 264 of the Product Performance Guidelines, are adequate to support the claims for repelling mosquitoes as indicated by reduction in numbers of landings on days 0, 1, 7, 14 and 28 after treatment; for killing mosquitoes as indicated by numbers of dead mosquitoes on days 0, 1, 7, 14, 21 and 28 after treatment (see tables 4 to 7 and 9 and 10 to 15, respectively; and for aids in prevention of blood feeding by mosquitoes as indicated by reduction in numbers of blood-fed mosquitoes captured on days 0, 1, 7, 14, 21 and 28 after treatment (see tables 16 to 21). Since this was a GLP study, we are willing to accept the validity of the concept of adjusting mosquito mortality in the controls to compensate for the increased mortality caused by urination by the control dogs on 16 of a total of 27 occasions when observations were made. However, we were unable to calculate a standard error as low as reported on p. 128 of 134 and would appreciate a copy of the calculations that gave this result, i.e. 1.13%. Nevertheless, using our figure of 1.725, the resulting $t = 9.565$ has a probability < 0.001 and would lead to the same conclusions. Therefore, the collective data do support the previously mentioned claims with respect to mosquito vectors of dog heartworm for up to 4 weeks. RL Vern L. McFarland, IRB