EFFICACY REVIEW

DATE: IN 11-21-90 OUT 2-26-91

FILE OR REG. NO. 59-231

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED October 26, 1990

DATE OF SUBMISSION October 24, 1990

DATE SUBMISSION ACCEPTED

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

DATA ACCESSION NO(S). 416839-03; D158513; 5386257; Case #053481; Action Code 305

PRODUCT MGR. NO. 15 - LaRocca/Richards

PRODUCT NAME(S) EXspot™ for Dogs

COMPANY NAME Cooper's Animal Health, Incorporated

SUBMISSION PURPOSE Provide performance data in support of claims for control and duration of effectiveness against deer tick, Ixodes dammini, on dogs w/subject product.

CHEMICAL & FORMULATION Permethrin 65.0%

(9.16-9.92 lbs/gal in 1 cubic centimeter individual dose)

CONCLUSIONS & RECOMMENDATIONS The data presented in EPA Accession (MRID) Number 416839-03, having been derived from testing using protocols incorporating the essential features of § 95-9(a) on p. 263 and meeting the standard for § 95-9(b)(2)(i) on p. 264 of the Product Performance Guidelines, are adequate to support claims that control deer tick, Ixodes dammini and American dog tick, Dermacentor variabilis, principal vector and contributory vector, respectively, of Lyme disease, when applied to dogs according to label directions and "controls American dog tick for more than 2 weeks and deer tick for up to 4 weeks on dogs weighing less than 35 lbs., and controls American dog tick for 21 days and deer tick for 28 days on dogs weighing more than 35 lbs., when applied to the animals according to label directions." In reference to proposed labeling, what is the purpose of the asterisk after 'repels' in the 3 claims on the front panel? There is no statement on either the back panel or inside panel at present which explains this. Nor was there any data in MRID Nos. 410388-02, 410388-03 and 416839-03 which specifically demonstrated repellency as opposed to kill of fleas and ticks. We recommend the registrant make a statement to the effect that permethrin is not a true repellent but kills so quickly, especially deer tick, that little opportunity for infesting host animals exists during the period of maximum toxicity to ticks. This is a more accurate description of the mode of action of this chemical with respect to ectoparasites.

RL Dow L. McFarland, IRB