

4-24-95

EFFICACY REVIEWDATE: IN 12-21-94 OUT 4-24-95FILE OR REG. NO. 6148-RR

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED October 11, 1994DATE OF SUBMISSION October 11, 1994

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCT(S): (I,) D, H, F, N, R, S RepellentDATA ACCESSION NO(S) . 433815-05;D210372;S478781;Case#031292;AC:166PRODUCT MGR. NO. 10-Johnson/TavanoPRODUCT NAME(S) Coppertone™ Sun & Bug BlockCOMPANY NAME Schering-Plough Health Care Products, IncorporatedSUBMISSION PURPOSE Provide performance data in support of claims
for repellency against mosquitoes and duration
of protection against biting for new formulation.CHEMICAL & FORMULATION N,N-diethyl-meta-toluamide 9.5%
Other isomers 0.5%
(Semi-aqueous, ready-to-use lotion, 1.048 Sp.Gr.)

CONCLUSIONS & RECOMMENDATIONS The data presented in EPA Accession (MRID) Number 433815-05, having been obtained from a standard laboratory repellency test conducted according to a protocol which meets requirements of § 95-9(a)(2) and (3) on p. 263 and the standard of § 95-9(b)(1)(iv) on p. 264 of Product Performance Guidelines, as well as the GLP requirements of 40 CFR 160, are adequate to support the claim for repellency against mosquitoes for the subject product when used according to label directions on human skin. We note the inclusion of "deer ticks" among pests claimed for this product, but without the usual accompanying phrase "which may carry Lyme disease". The registrant should be informed that a claim for deer tick entails submission of product specific efficacy data demonstrating activity against nymphal Ixodes dammini, or presentation of a rationale for claiming deer ticks on the basis of existing registrations of similar or lower concentration of active ingredients. Presentation of such rationale would allow the claim for carriers of Lyme disease to be added to the subject product label.

RL Vern L. McFarland, IRB

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