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EFFICACY REVIEW

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DATA ACCESSION NO(S). 441901-01;D232552;S516908;Case#034680;AC:571

PRODUCT MGR. NO. 13-LaRocca/DeLuise

PRODUCT NAME(S) Deltamethrin 4% Collar

COMPANY NAME Hoechst Roussel Agri-Vet Company

SUBMISSION PURPOSE Provide performance data summaries in support of claims for control of fleas and ticks on dogs to establish new use for active chemical ingredient.

CHEMICAL & FORMULATION (s)-α-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate 4.00% (impregnated material of unspecified bulk)

CONCLUSIONS & RECOMMENDATIONS The data summaries presented in EPA Accession (MRID) Number 441901-01, having been obtained from standard kennel tests presumably conducted according to a protocol that meets the requirements of § 95-30(b)(11)1. through 10. on pp. 280-4 and the standard of § 95-9(b)(2)(i) on p. 264 of the Product Performance Guidelines, are adequate to demonstrate the ability of the active ingredient deltamethrin to kill fleas and ticks on dogs in a preliminary manner when formulated as a collar. However, these data are incomplete for the purposes of supporting specific claims of duration of satisfactory control of fleas and ticks because of the lack of raw data for testing conducted in Arkansas, California and Oklahoma, along with lack of sufficient detail as to the manner in which testing was conducted, as required by § 95-30(b)1., 3. and 4., 6., 7., 8., 9. and 10., especially 4., 6.1, 6.4, 6.5, 6.7, 7.2, 7.3, 8.1, 8.2, 9.1, 9.2, 9.3, 9.4, 9.5, 9.7, 10.1, 10.2 and 10.4 as elaborated in paragraphs on p. 284. While Reference 1 comes closer to meeting these requirements, References 2 and 3 are only summary and abstract, respectively. References 4 through 6 are for kennel tests conducted in Europe, and while Reference 4 (to be continued)

actually gives more details as to these requirements than do the latter two reports from the U. S., it fails to identify all the formulations in the test as to active ingredient as required by § 95-30(b)2.5; References 5 and 6 are nothing more than conclusions and lack sufficient detail in many of the categories previously mentioned above. Furthermore, since the submission was not accompanied by either labeling or CSF, it is not possible to relate the conclusions and results of any of these references to the support of specific claims of duration of satisfactory control or range of flea and tick species against which the collar is found effective. Mention is made at the end of Reference 1 of original data found in the Appendix, pp. A41-A124, and of quality assurance unit inspections and the final report following the Appendix as pp. QUA1-QUA9. The submission of this information along with specific information meeting above requirements with respect to References 2 through 6 is necessary for proper review of the effectiveness of the collar, along with labeling as to the claims which these data are believed to satisfactorily support.

OBJ Vern L. McFarland, IRB