MEMORANDUM

SUBJECT: Fipronil Topical Spray (RM 1601C) - Request for Waiver of Dermal Sensitization and Acute Inhalation Studies with Technical Preparation

P.C. Code: 129121
DP Barcode: D206881
Case: 040837
Submission: S472422

FROM: Virginia A. Dobozy, V.M.D., M.P.H., Veterinary Medical Officer Review Section I, Toxicology Branch II Health Effects Division (7509C)

TO: Robert Brennis/Daphne Waldo/PM 10 Registration Division (7505C)

THRU: Yiannakis M. Ioannou, Ph.D., Section Head Review Section I, Toxicology Branch II Health Effects Division (7509C)

Registrant: Rhone Merieux, Inc.

Action Requested: Review and comment on request of waiver for dermal sensitization and acute inhalation studies with technical preparation

Recommendation: Toxicology Branch II recommends that the waiver be denied. Both of the acute studies in issue have been reviewed and although supplementary, could be upgraded with explanation and/or clarification from the registrant. See June 7, 1994 memo from Virginia Dobozy to Robert Brennis/Daphne Waldo/PM 10.