MEMORANDUM

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SUBJECT: Metam Sodium - Report of Adverse Effects Under Section 6(a)(2) of FIFRA

FROM: Yiannakis M. Ioannou, Ph.D., Section Head Review Section I, Toxicology Branch II Health Effects Division (H7509C)

TO: Christine Rice/Tom Myers, PM52 Accelerated Reregistration Branch SRRD (H7508W)

THRU: Marcia van Gemert, Ph.D., Branch Chief Toxicology Branch II Health Effects Division (H7509C)

Registrant: Metam Sodium Task Force

Action Requested: Review the Metam Sodium Task Force letter notifying the Agency of adverse effects seen in a range-finding study in dogs.

Recommendations: The Metam Sodium Task Force has recently submitted to the Agency a brief letter indicating that adverse effects were observed in a preliminary range-finding study conducted in dogs with metam sodium. The preliminary findings indicate that one male dog treated with 15 mg/kg/day of metam sodium for three weeks developed clinical jaundice and inappetence. Upon sacrifice it was determined that there were marked increases in bilirubin and the activities of several plasma enzymes indicative of liver damage. Histopathological evaluation of the liver revealed a fulminating hepatitis. Another male dog in the same dose group has also shown increases in bilirubin and the same plasma enzymes. Based on the aforementioned adverse effects, it is apparent that metam sodium at the dose of 15 mg/kg/day may cause high toxicity to male dogs (resulting in a fulminating hepatitis). The sponsor is requested to supply the Agency with the final report upon completion of this study so that an in-depth evaluation of these data can be made.