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Dr. Cindy L. Burnsteel, Director  
Division of Therapeutic Drugs for Food Animals  
Document Control Unit, HFV-199  
Center for Veterinary Medicine  
7500 Standish Place, MPN-2  
Rockville, MD 20855

RE: Potassium permanganate use in aquaculture

Dear Dr. Burnsteel:

The purpose of this submission is to request that CVM review the enclosed "white paper" titled "Potassium Permanganate: What is it and how can we ensure it is safely used in US Aquaculture." Potassium permanganate is a chemical that has been used for many years and for a variety of uses in domestic aquaculture and fishery management programs. Its varied uses likely arise from its broad oxidizing properties. To date, FDA/CVM has deferred regulatory judgment on potassium permanganate. Perhaps, this is the result of the fact that it has not been clear if it is best to regulate potassium permanganate as a drug, a pesticide, or something else? For nearly 20 years various aquaculture groups have engaged in activities intended to support FDA-approval for the use of potassium permanganate in aquatic species, but have made very limited progress. We would like to explore with FDA/CVM options for approval of potassium permanganate, assuming of course, that it should in fact be regulated as a drug.

The enclosed white paper has been prepared in an effort to help in such exploration. The white paper is intended to provide an over-view summarizing various aspects of aquaculture uses, some of the research conducted to date, and some of the challenges associated with NADA approval efforts.

Once you and staff have had the opportunity to review the white paper, we propose further discussions to enable us to chart our best course. I would like to thank you in advance for CVM review of the enclosed white paper, and please let me know when would be a good time for further discussion.

Sincerely,

John R. MacMillan, Ph.D.

Enclosure: Potassium permanganate White Paper

cc: John Boll, CARUS Chemical Co.  
Don Prater, FDA/CVM  
Jennifer Matysczak, FDA/CVM

Dave Erdahl, USFWS/AADAP  
Steve Sharon, AFWA/DAWG