



Dr. McGlone has been asked to participate in all official matters on the microbial food safety of an antimicrobial drug application submitted by Intervet and currently under review for use in food-producing animals in accordance with the Center for Veterinary Medicine's Guidance for Industry 152. At its September 25, 2006, meeting, the VMAC will be asked to advise FDA as to whether the Agency's assessment of the information and strategies for managing any potential microbial food safety risks are appropriate.

The function of the Veterinary Medicine Advisory Committee (VMAC) is to review and evaluate available data concerning the safety and effectiveness of marketed and investigational animal drug products and make appropriate recommendations to the Commissioner of the Food and Drug Administration (FDA).

Dr. McGlone has advised the Food and Drug Administration (FDA) that he has financial interests that could potentially be affected by his participation in the matters described above. Dr. McGlone has a consulting relationship with [redacted] for [redacted] [redacted] The consulting topic is unrelated to the issues at hand, but [redacted] has competing products on the market for [redacted]

As a member of the Veterinary Medicine Advisory Committee, Dr. McGlone potentially could become involved in matters that affect him or any other person whose interests are imputed to him under Title 18 U.S.C. § 208. Under U.S.C. § 208, he is prohibited from participating in such matters. However, as noted above, you have the authority under 18 U.S.C. § 208(b)(3) to grant a waiver permitting Dr. McGlone to participate in such matters as you deem appropriate.

For the following reasons, I believe that it would be appropriate for you to grant Dr. John R. McGlone a waiver that would allow him to participate fully in the matters identified below.

First, arguably Dr. McGlone's potential consulting interests do not constitute financial interests in the particular matter within the meaning of 18 U.S.C. § 208(a), since they are unrelated to the product at issue. Nevertheless, in an abundance of caution, we recommend that this waiver be granted.

Further, the Federal Advisory Committee Act requires that committee memberships be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee. Also, the committee's intended purpose would be significantly impaired if the agency could not call upon experts who have become eminent in their fields, notwithstanding the financial interests and affiliations they may have acquired as a result of their demonstrated abilities. Dr. McGlone is an expert cell biologist and is knowledgeable in the field of biotechnology with 25 years of experience. He holds the position of Professor and Director, Pork Industry Institute, Department of Animal Science and Food Technology, Texas Tech University

