

Dr. Riddell 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. Riddell 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. Riddell owns stock in [redacted] has competing products on the market for [redacted] [redacted]

As a member of the Veterinary Medicine Advisory Committee, Dr. Riddell 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. Riddell 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. M. Gatz Riddell a waiver that would allow him to participate fully in the matters identified below.

First, Dr. Riddell's stock interest represents a minimal percentage of his total net worth and is not so substantial as to preclude his participation in this matter.

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. Riddell is the Executive Director of the American Association of Bovine Practitioners (AABP) and has over 25 years of expertise in veterinary medicine.

Dr. Riddell's experience includes Auburn University's College of Veterinary Medicine; Animal Clinics and Hospitals; and he specialized in large animal surgery and medicine at Auburn University. He has numerous scientific abstracts and publications, has conducted many research projects, and served on numerous committees as a member, as well as chairperson. He is a Diplomate of the American College of Theriogenologists; and a member of various veterinary societies including AVMA, AABP, NASV, Society of Theriogenology, and the National Mastitis Council. I believe that Dr. Riddell will contribute to the diversity of views, opinions and expertise represented on the committee and will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Dr. Riddell, a waiver that will permit him to participate in all official matters concerning 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. The Agency seeks recommendations from VMAC as to whether the Agency's assessment of the information and strategies for managing any potential microbial food safety risks are appropriate. I believe that such a waiver is appropriate, because in this case the need for the services of Dr. Riddell outweighs the potential for a conflict of interest created by the financial interests attributable to the individual.

CONCURRENCE: _____ /S/ _____ 8/29/06
Jenny Slaughter Date
Director, Ethics and Integrity Staff
Office of Management Programs, OM

DECISION:

 X Waiver granted based on my determination, made in accordance with § 208 (b)(3), that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest attributable to the individual.

 Waiver denied.

_____ /S/ _____ 9/1/06
Randall W. Lutter, Ph.D. Date
Associate Commissioner for Policy and Planning
Food and Drug Administration