

AVMA



American Veterinary Medical Association

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
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Docket No. 2007D-0449; Draft Guidance for Food and Drug Administration
Advisory Committee Members and Food and Drug Administration Staff: Voting
Procedures for Advisory Committee Meetings; Availability

Dear Sir or Madam:

I am writing on behalf of the American Veterinary Medical Association (AVMA), established in 1863, and the largest veterinary medical association in the world. As a not-for-profit association established to advance the science and art of veterinary medicine, AVMA is the recognized national voice for the veterinary profession. The association's more than 75,000 members represent approximately 86% of U.S. veterinarians, all of whom are involved in a myriad of areas of veterinary medical practice including private, corporate, academic, industrial, governmental, military, and public health services.

The American Veterinary Medical Association (AVMA) writes in strong support for the draft guidance addressing voting procedures for advisory committee meetings. The advisory committee most relevant to the AVMA is the Veterinary Medical Advisory Committee (VMAC), administered by the FDA Center for Veterinary Medicine (CVM).

In a 2005 letter to the FDA CVM Director, the AVMA expressed concern for the structure of the VMAC meetings which provided insufficient opportunity for VMAC members to deliberate prior to voting. Rather than allowing collaborative discussion that would enhance the quality of the decision-making process, we noted a process analogous to a jury, in which, at the end of testimony, the jury would be polled in the courtroom without opportunity for group deliberations. We believe collaborative advisory input broadens the base of information, enhances the deliberations, and improves the quality of decisions.

Also, we urge that questions posed to advisory committees be constructed quite carefully to ensure the agency receives the advice it seeks. And, it is necessary that advisory committee members be schooled in the application of the Food, Drug and Cosmetic Act and its regulations, at least to the degree required to answer the question in context. For example, we observed a meeting in which the committee was asked if a drug was "safe." As the individuals voted one after another and offered explanation, it became clear that there was little consensus on definition and little familiarity with the FDA's standard.

Consequently we strongly support the improvements cited in the draft guidance "Voting Procedures for Advisory Committee Meetings." The draft guidance includes points that particularly resonate with the AVMA, including:

- Arrange a robust discussion prior to voting
- Voting should be done simultaneously
- The question should be clarified ahead of voting, not during voting
- The Chair may believe a related or relevant question should be voted upon. The Chair should receive clearance from the proper FDA official prior to proceeding
- Briefing materials should be thorough, relevant and include the questions being posed

We appreciate this opportunity to comment. Please direct any questions to Dr. Elizabeth Curry-Galvin, Director, Scientific Activities Division.

Sincerely,



W. Ron De Haven, DVM, MBA
Executive Vice President

WRD/ECG