



November 4, 2009

1931 N. Meacham Rd.
Suite 100
Schaumburg, IL
60173-4360
phone 847.925.8070
800.248.2862
fax 847.925.1329
www.avma.org

Division of Dockets Management (HFA-305)
Food And Drug Administration
Rm 1061
5630 Fishers Lane
Rockville, MD 20852

**Re: Docket Number FDA-2009-N-0247, Food and Drug Administration
Transparency Task Force**

Dear Sir/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, the AVMA is the recognized national voice for the veterinary profession. The association's more than 78,000 members comprise approximately 85% 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 AVMA applauds the Food And Drug Administration (FDA) for its goal of establishing improved transparency, which will undoubtedly facilitate greater communication and collaboration between it and its stakeholders. Although most of our concerns may seem more communication-related than transparency-related, the two really go hand-in-hand in that communications are directly related to a PERCEPTION of transparency. In reference to the request by the FDA for comments pertaining to the "issues for discussion" by the FDA Transparency Task Force (*Federal Register* Docket Number FDA-2009-N-0247), the AVMA offers the following comments about the considerations and principles the FDA should assess regarding its communications to the public. Our comments are assembled under the relative "issues for discussion," as established by the FDA in its notice.

1. **Emerging safety issues concerning FDA-regulated products**
 - a. Being committed to the continuing availability of medicinal products that are pure, safe, potent, and efficacious for animals, the AVMA encourages continued development and strengthening of adverse event reporting systems.

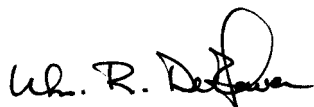
This includes continued collaboration with constituent professional organizations, industry organizations, government entities and other stakeholders. The AVMA is pleased to have worked with FDA on the new Med Watch portal, and we further recommend other ways to enhance adverse events reporting such as syndromic surveillance.

- b. We emphasize our desires for enhanced communications with FDA regarding matters relevant to animal health and the veterinary profession. On several occasions, the AVMA has brought developing issues to the FDA's attention, and has collaborated with the FDA in resolving these. Nonetheless, enhancing cooperation with the FDA in regard to sharing information of mutually relevant issues, such as current status of recalls, is crucial. Specifically, with regard to the 2007 pet food recall, the communications by FDA to the AVMA were delayed, patchy, and inadequate. We understand that the FDA has limited ability to comment about ongoing investigations; however, the AVMA respectfully requests at least a brief discretionary warning about developing issues relevant to animal health and veterinary medicine because AVMA staff may need to make priority and logistical changes to handle the issue for our members and stakeholders if the matter materializes.
- c. The AVMA has concerns about the FDA's lack of transparency when it comes to follow-up on investigations. For example, during a recent issue regarding *Salmonella* sp. found in chicken jerky treats, the AVMA was informed by the FDA that it had not identified any toxins or abnormalities in the chicken jerky treat products. When we asked if the FDA planned to release that information, we were told it would not. Subsequently, we could not provide the important information to our members or the public regarding the FDA's findings. Such a lack of follow-up and transparency created a public impression that the FDA had not done anything about the matter.
- d. The AVMA asserts that if the FDA finds a particular trend identified in the National Antimicrobial Resistance Monitoring System (NARMS) disconcerting, then FDA should inform stakeholders of the noticed trend and of any thresholds for regulatory action associated with it if applicable so that any needed corrections on the part of the stakeholders can be made. For example:
 - i. In its Order of Prohibition regarding extralabel drug use (ELDU) of cephalosporins last year, the FDA's findings included the ELDU of cephalosporins in egg production as being a primary public health hazard and reason to prohibit ELDU of cephalosporins. We contend that FDA's transparency could have been greatly enhanced by immediately notifying stakeholders as the trend first became apparent to FDA so that the ELDU in question could be evaluated by the relevant stakeholders. Clouding the issue further is that FDA has since relayed that the egg use was not the primary concern.
 - ii. Similarly, we have been informed that FDA perceives cephalosporin tissue residues as a concern for cephalosporin resistance; however, FDA has not shared its data on this. Such data would be helpful so that needed process changes can be examined.

- iii. In reference to above mentioned cephalosporin tissue residues for which data has not been shared, the primary causes for the tissue residues remain unclear. It is extremely concerning that the FDA seems to be inferring during its discussions with the AVMA that veterinarians are responsible regardless of the cause. The inability to identify the primary cause decreases or eliminates the effectiveness of potential control measures and may lead to deleterious unintended consequences.
2. **Product applications that are abandoned or withdrawn by the applicant before approval.**
 - a. The AVMA is not seeking publication of proprietary information. We suggest that knowing why product applications are abandoned or withdrawn by the applicant before approval may be helpful in cases where the reasons for such are because the applicant discovered detrimental effects associated with the product. Such information sharing could potentially reduce pain and suffering by animal subjects.
 3. **Agency Decisions about pending product applications.**
 - a. The AVMA compliments the FDA for its continuing efforts on its literacy campaign, such as FDA's willingness to share health information with the public online through web pages such as <http://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/default.htm>. We encourage the FDA to focus its efforts on regulatory issues, such as how drugs are approved, how the Center for Veterinary Medicine (CVM) functions as a federal entity, and how FDA implements safety oversight over the many products over which it has specific jurisdiction.
 - b. Similar to 2(a) above, we suggest that knowing why product applications are approved or denied would be helpful to potentially reduce pain and suffering by animal subjects. Providing such information, not necessarily in detail but in general context, may also facilitate increased efficiency with the application process of subsequent applicants.
 - c. The AVMA believes the FDA/CVM should prohibit placebo control studies for assessment/approval of new pain control medications where there are already FDA/CVM approved pain management products available and require that only positive controls be used in these prospective randomized parallel or cross-over dose studies.

The AVMA appreciates the opportunity to comment. We also welcome the opportunity to further provide our insights and feedback. For further clarification on the AVMA's comments, please contact Dr. Kristi Henderson at 800-248-2862 ext. 6651, or at khenderson@avma.org.

Sincerely,



W. Ron DeHaven, DVM, MBA
Executive Vice President
American Veterinary Medical Association