



July 20, 2010

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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, FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U. S. Food and Drug Administration

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 80,000 members comprise approximately 83% of U.S. veterinarians, who 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 introspective efforts made by the Food and Drug Administration (FDA) as well as its public outreach to enhance the Agency's transparency and functionality. In reference to the FDA's request for comments on the Transparency Task Force Report, "FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U. S. Food and Drug Administration," the AVMA offers the following comments for consideration.

While the AVMA recognizes potential benefits in all of the twenty-one proposals developed by the Task Force, our comments are confined to the top few proposals which could impart the greatest impact on veterinary medicine. Because FDA requested input on how to prioritize the proposals, we offer that those under the broader categories of "Adverse Events" and "Recalls" as well as some within the "Product Applications" are the most relevant to us at this time. A brief discussion of these in which relevant proposals and their respective numbers as assigned in the Task Force Report are reiterated and then addressed follows.

Adverse Events

- 1. FDA should expand the areas in which it provides the public with online access to public information from adverse event reports about FDA-regulated products submitted to FDA, in a format that is searchable and allows users to generate summary reports of this information, including, if known and as applicable, the trade name and/or established name of the product, dosage, route of administration, description of the adverse event, and the health outcome. Adverse event report information should continue to be disclosed with a clear disclaimer about the limits of the information.*

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 system described in the proposal could yield a versatile database of extremely useful and pertinent information beneficial to animal and public health and safety.

We are delighted to have had opportunities to work with FDA Center for Veterinary Medicine (CVM) as it has collaborated with other FDA Centers to develop a new MedWatch electronic adverse events reporting system. We appreciate that the MedWatch system is a big step forward in providing for a comprehensive means for veterinarians and the public to report adverse events related to pet food; however we urge the FDA to implement an FDA-wide system incorporating all FDA-regulated products for veterinarians and animal owners to use. In addition, we assert that the system should be harmonized with the Environmental Protection Agency (EPA) and the U.S. Department of Agriculture (USDA) adverse event reporting systems.

Furthermore, the AVMA has learned of a new FDA activity called the Sentinel program. We appreciate the FDA's initiative to utilize existing data sets in corporate veterinary practices to assist in post-marketing surveillance. We look forward to learning more about this initiative and strongly encourage the FDA to make implementation of the program a priority.

We do, also, recommend continuing to improve some aspects of the adverse event reporting system. Specifically, the AVMA asserts that the system needs ongoing efforts to improve the accuracy of the system with as much human bias removed as possible. Utilization of new, advanced technologies to fully utilize the data obtained through MedWatch or Sentinel could improve adverse event reporting efficiencies and accuracy.

Recalls

- 18. When a system is set up that provides FDA with authority to require companies to submit certain information to the Agency when they initiate an action to recover or correct a product that is in the chain of distribution, FDA should disclose this information as soon as practicable after receiving this information from the firm.*

19. *If FDA is aware of confusion in the marketplace about products that may be implicated in a food outbreak, and information gathered by industry or other sources may serve to alleviate that confusion, FDA should support efforts by industry and others to communicate information to the public about products that are not subject to the recall when sufficiently reliable information about products not connected with the recall exist, if FDA concludes that disclosure of this information is in the interest of public health.*
20. *If FDA determines that a recall is terminated, that information should be disclosed to the public. A recall is considered terminated when FDA determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy and when it is reasonable to assume that the recalled product has been recovered, corrected, reconditioned, or destroyed.*

An accurate and expeditious means for communicating recall information to the public and FDA stakeholders is imperative. This includes providing clarification for which products are and are not involved as well as when recalls have been terminated. The AVMA understands that the FDA has limited ability to comment about ongoing investigations; however, we respectfully request at least a brief discretionary warning about developing issues relevant to animal health and veterinary medicine to allow AVMA to make prioritize and address the issue for our members and stakeholders should the matter materializes.

Product Applications

9. *FDA should disclose: (1) whether an investigational new drug application (IND) has been placed on hold, terminated, or withdrawn, whether an investigational device exemption (IDE) has been terminated or withdrawn, or whether an investigational exemption for a new animal drug has been terminated and (2) if an IND has previously been placed on hold, whether and when the hold is lifted. A statement should be included that such actions may be taken for various reasons, only some of which relate to safety or effectiveness.*
11. *FDA should disclose that an unapproved NDA, ANDA, NADA, ANADA, BLA, or PMA, or uncleared 510(k) has been withdrawn or, if FDA determines that the application was abandoned, abandoned by the sponsor. If the drug, biological product, or device is associated with a significant safety concern, FDA should provide a brief description of the product, the use for which approval was sought or obtained, and the identified safety concern.*
12. *When an application for a designated orphan drug or a designated minor use/minor species animal drug has been withdrawn, terminated, or abandoned, FDA should disclose, if it determines, based on its review, that the application was not withdrawn, terminated, or abandoned for safety reasons and the product, if approved, could represent a significant therapeutic advance for a rare disease or for a minor animal species. A disclaimer that provides that FDA's expressed views about the product do not reflect whether a subsequent application involving the product will be accepted*

for filing or will be approved by FDA should accompany the disclosure of this information.

The AVMA is not seeking publication of proprietary information. We suggest that information sharing regarding why product applications are abandoned, withdrawn, or denied is important, especially in the instances related to safety issues or detrimental effects associated with the product. Such communication could potentially reduce pain and suffering of our animal patients.

- 16. FDA should disclose relevant summary safety and effectiveness information from an investigational application, or from a pending marketing application, if the Agency concludes that disclosure is in the interest of the public health, which includes when FDA believes it is necessary to correct misleading information about the product that is the subject of the application.*
- 17. FDA should convene a group of internal and external stakeholders to discuss the possible uses of non-summary safety and effectiveness data from product applications, the circumstances under which it would be appropriate for sponsors to disclose non-summary safety and effectiveness data from applications submitted to FDA, and if appropriate, the format and the method by which disclosure should occur.*

FDA's current conservative position precludes incorporation of relevant pharmacokinetic and pharmacodynamic data information into product labeling. This information would be useful in helping veterinarians decide how to most appropriately utilize a product. Labels that accompany animal drugs should provide relevant pharmacokinetic and pharmacodynamic data necessary for the rational design of dosing regimens specific for the individual patient. If these data cannot be incorporated into drug labels, having access to this clinically relevant information would be a valued resource by our profession. For example, perhaps the FDA would be willing to help support a supplemental scientific data website based on collaborative data provided by drug sponsors—no implied product claims, just available data summaries/reports.

Advisory Committee Meetings

The AVMA asks that the FDA explore ways to enhance the function of advisory committee processes. Specifically we ask that FDA strengthen the ability of its advisory committees to be able to engage in open, deliberative discussions among the experts who comprise the Committee. Full deliberations by Committee members on the subject matter at hand will promote Committee members' knowledge of the full scope of the issue including both the benefits and unintended consequences that could result from the Committee's vote or other action on the subject matter.

Conclusion

Acknowledging the difficulty in achieving the optimal balance between disclosure and confidentiality, the AVMA feels that the proposals within the Report are positive steps for the Agency achieving such and will be beneficial toward animal and public health and safety. To protect and enhance animal and public health, we believe it is imperative our nation's

veterinarians have the tools they need to treat their patients. We look forward to your feedback and cooperation. For additional information, please contact Dr. Lynne White-Shim (lwhite@avma.org; 847-285-6784) or Dr. Kristi Henderson (khenderson@avma.org; 847-285-6651).

Sincerely,



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