



December 22, 2008

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
5630 Fishers Lane, Rm. 1061
Rockville, MS 20852

**Docket No. FDA-2008-N-0546 - Electronic Data Collection Using
MedWatch\Plus\ Portal and Rational Questionnaire**

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 76,000 members comprise 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 FDA has launched the development and implementation of a new electronic system for collecting, submitting and processing adverse event reports and other safety information for all FDA-regulated products. This new system, MedWatch\Plus\ Portal, will serve as a central point-of-entry for persons with information to submit to the FDA. The new system will integrate the agency's existing safety reporting systems into the various FDA Adverse Event Report Systems (FAERS). FAERS will enable FDA staff to more efficiently analyze thousands of safety reports and to identify potential safety problems earlier than would be possible using paper forms.

The AVMA commends the Food and Drug Administration (FDA) on its leadership and its efforts to develop a user-friendly web portal through which health professionals and the general public may submit adverse events associated with FDA-regulated products. We believe a web portal would be a highly utilized resource by our membership and we encourage the FDA to solidify development and to implement this web resource.

Moreover, the AVMA welcomes the opportunity to serve as a resource to the FDA, specifically by providing the FDA with veterinary medical feedback regarding the anticipated functionality of the new adverse events reporting portal.

The AVMA provides the following feedback on the FDA's collection of information, for which it invites comments:

1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;

The AVMA asserts that the proposed collection of information will enhance the FDA's ability to execute its functions to regulate food, animal feeds, and human and animal health products.

The AVMA understands that the new reporting system will provide opportunities for reporting of adverse events associated with all FDA-regulated products, including drugs, biologics, and devices intended for use in humans, and animal foods/feeds and animal drugs. However, we also encourage the FDA to include a means by which veterinarians may report adverse events associated with devices used in animals, such as vaporizers used in general veterinary medical anesthesia. While veterinary devices are not approved by FDA prior to marketing (unlike medical devices intended for humans), the FDA is responsible for their safety and consequently is responsible for post-marketing monitoring of veterinary device safety. We contend that reporting of adverse effects associated with devices for animals should also be incorporated into the system.

2) Accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

The AVMA recommends that FDA gain and retain contact information from all individuals who submit adverse event reports. We contend that false reports could be submitted to FDA more readily if individual contact information is not required for report submission. We assert that such contact information is essential, so that the FDA is able to follow up with reporting individuals and to verify reported information if the FDA has any questions or concerns regarding an individual report.

3) Ways to enhance the quality, utility, and clarity of the information to be collected;

The AVMA maintains that, as stated previously, the new web portal should contain fields for reporting adverse events associated with devices used in animals. We also assert that contact anonymity should not be an option for individuals submitting adverse event reports, as we believe the numbers of false reports would increase if individual contact information is not a requirement for reporting.

We recommend that reporting of adverse reactions associated with compounded drugs for animals also should be specifically enabled through the reporting system. We believe that the reporting of adverse events from use of compounded drugs should be enabled specifically in the section of the reporting system that covers animal drugs.

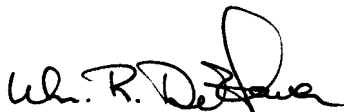
4) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The AVMA recognizes that while the FDA regulates safety and efficacy of biologics used in humans, it does not regulate the safety of biologics used in animals; rather, the United States Department of Agriculture regulates safety of animal biologics. For ease of reporting for general public, and for facilitating a more comprehensive adverse events reporting system, we recommend that the FDA coordinate with the USDA to incorporate adverse events reports associated with biologics for animals, into new web portal.

The FDA is to be commended on its continued efforts to ensure the safety of our Nation's people and their animals. The FDA's current activities to develop and to implement a new electronic adverse events reporting system are laudable. We look forward to the implementation of this new reporting system.

The AVMA appreciates the opportunity to comment. We also welcome the opportunity to provide our insights and feedback into the functionality of the new system. For further clarification on the AVMA's comments, please contact Dr. Lynne White-Shim at 800-248-2862 ext. 6784, or at lwhite@avma.org.

Respectfully,



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

cc: Mr. Glenn Peterson, Special Assistant to the Director of Surveillance and Compliance, FDA
Center for Veterinary Medicine