AVMA American Veterinary Medical Association

1931 N. Meacham Rd.
Suite 100
Schaumburg, IL
60173-4360

phone 847.925.8070
800.248.2862
fax 847.925.1329
www.avma.org

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Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2009-D-0461 -
Risk Evaluation and Mitigation Strategies;
Reopening of Comment Period

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, 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 recognizes the authority Congress gave the Food and Drug Administration (FDA) in 2007 through the FDA Amendments Act, which authorizes the FDA to require drug sponsors to submit and implement a Risk Evaluation and Mitigation Strategy (REMS) if the FDA asserts a REMS is needed to ensure the benefits of a drug outweigh the risks of the drug.

I am writing today to emphasize the critical need for veterinarians to continue having access to human-labeled drugs, in order to relieve animal pain,and suffering and to protect animal health. Human-labeled drugs are utilized by veterinarians on a routine basis for the treatment of their animal patients. There are relatively few animal-labeled drugs for the large variety of animal species and medical conditions veterinarians are expected to treat. It was for this reason the extralabel use of human-labeled drugs in veterinary medicine became a legal, FDA-regulated activity that was codified by the Animal Medicinal Drug Use Clarification Act of 1994.

The AVMA applauds the FDA for its outreach to the public and stakeholders as the FDA considers how best to design and implement REMS if/when such a strategy is deemed necessary to evaluate and mitigate risks associated with the use of specific drugs.

The risks associated with the human drug use can be very different from the veterinary use of that same drug. For meaningful risk evaluation and mitigation, REMS should be appropriately designed based on anticipated applications and use scenarios.

Regarding risks associated drug safety, human and veterinary pharmaceuticals are developed with extensive toxicological, safety and pharmacological data based on animal models. Such multi-species information serves to further minimize associated risks in veterinary clinical medicine—often providing a better understanding of patient response than data available for the same drug in humans.

Regarding risks associated with misuse potential, we are unaware of diversion being a significant concern in veterinary medicine. Among all the health professions under Drug Enforcement Administration (DEA) registration, veterinary medicine falls low in the list of diversion concerns.

The AVMA stresses the need to consider any possible unintended consequences from human-based REMS that could adversely impact the veterinarian's ability to protect the health and prevent suffering of animal patients.

We welcome the opportunity to continue providing feedback to the FDA as it considers how best to protect public health from unsafe uses of FDA-approved drugs. The AVMA looks forward to continuing the dialog on this important subject. Should you have any questions or comments regarding AVMA's perspectives, 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 and CEO