AVMA American Veterinary Medical Association

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

Docket No. FDA- 2009–N–0143 – Risk Evaluation and Mitigation Strategies for Certain Opioid Drugs; Notice of Public Meeting

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 Food and Drug Administration Amendments Act (FDAAA) of 2007 (Public Law 110-85) created section 505-1 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 355-1). Under section 505-1 of the Act, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) when FDA determines that a REMS is necessary to ensure the benefits of a drug outweigh the risks associated with the drug.

On February 9, 2009, FDA announced its plans to exercise its authority under FDAAA to require REMS for many of the opioid drug products. The FDA's goal is a single REMS for all opioid drug products. As part of this process, FDA met with participants in a stakeholder meeting forum, and the design and implementation of REMS for opioid drug products was also discussed in an FDA-sponsored public meeting May 27-28.

The AVMA understands that the FDA is concerned that human patients have experienced overdoses of opioids and that diversion continues to be a problem in human patients. While we are not aware of similar problems with overdoses in our animal patients, we certainly recognize the need to be vigilant to minimize diversion.

The AVMA acknowledges the efforts by the Food and Drug Administration (FDA) to examine the benefits and risks of certain opioid medications for use in human medicine. Certainly we understand the FDA's concern and its need to assure safety of

opioids use in people. However, we want to be certain that as the FDA Center for Drug Evaluation and Research (CDER) considers its next steps in the REMS process, it takes into consideration the needs of the veterinary profession. Specifically, we strongly recommend that all Drug Enforcement Administration (DEA)-registered, licensed veterinarians continue to be able to prescribe opioids, even if we must do so under new requirements for additional certification. Ideally, however, we assert that DEA registration and tight federal and state oversight over use of controlled substances has been effective in controlling diversion. We believe diversion concerns are minimal in veterinary medicine.

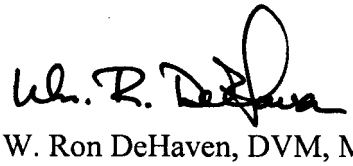
Most of the opioid drugs used by veterinarians are drugs labeled for use in human medicine. Veterinary administration of human drugs is tightly regulated by FDA, codified by the Animal Medicinal Drug Use Clarification Act. We continue to need such human-labeled drugs for our animal patients. Opioids are used in animals for severely painful conditions, including orthopedic-associated pain and pain associated with cancer. Opioids are also used in animals for sedative purposes. Opioid products that are required to go through a REMS process and that are used in animals include, but are not necessarily limited to, fentanyl transdermal patches, oral methadone, and oral morphine.

We believe the risks posed by veterinary use of opioids are small. Consequently, we urge continued access to needed opioids and an exemption from the REMS process that is being crafted for human health care providers. If not feasible, we would like to discuss alternatives with the FDA.

The FDA's current activities to examine the benefits and risks of opioid products in human medicine are laudable, yet the AVMA cautions against the unintended consequences that we believe would result if veterinarians do not continue to have access to opioid drugs to reduce pain and suffering in our animal patients.

The AVMA appreciates the opportunity to comment. We also would welcome the opportunity to further provide our insights and feedback. 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: Dr. Bernadette Dunham, Director, FDA Center for Veterinary Medicine
Ms. Tracey Forfa, Chief of Staff, FDA Center for Veterinary Medicine