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, MD 20852

Re: Docket No. 2010-N-0358 - Agency Information Collection Activities; Proposed Collection; Comment Request; Sample Collection Plan for Dogs Treated with SLENTROL

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 more than 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 Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) is planning a pharmacogenomic study to examine whether adverse drug events (ADEs) experienced with SLENTROL, an anti-obesity drug approved for dogs, are associated with genetic variations in the dogs treated. In the study, blood and buccal swabs would be collected from dogs that were treated with SLENTROL and experienced ADEs, as well as from dogs treated with SLENTROL that did not experience ADEs. Samples would be analyzed by FDA using microarray analysis and single nucleotide polymorphism analysis, with the goal of determining possible genetic variations associated with the ADEs reported.

While the AVMA supports the advancement of medical knowledge and robust adverse event reporting (AER) systems, we are not convinced that FDA's performance of this highly technical research on SLENTROL would be resources well spent. Considering the FDA's limited resources and the critical nature of other AER needs – specifically a single AER reporting system on all FDA products that can be used by all audiences – we question whether the benefits of performing this technical study outweigh the risks of diverting resources from other AER needs. The AVMA also has concerns about the value of the information that will be obtained from the study. Since many of the dogs treated by veterinarians are mixed-breed it will be difficult to know which patients should not be treated. At this time genetic testing of dogs before treating them is not practical. If the FDA does perform the study, AVMA feels it is important that FDA explain clearly why this particular drug was selected for the testing. It would be easy for veterinarians and the public to get the impression that a drug is unsafe because this additional testing is being done. This could result in decreased use of a drug, with possible consequences for animal health and welfare.

The AVMA welcomes the opportunity for continued dialog on the strengthening of adverse events reporting. 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 and CEO

WRD/LAW