

June 1, 2010

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Ms. Tracey Forfa
Executive Director
Center for Veterinary Medicine
Food & Drug Administration
7519 Standish Place (HVF-1)
Rockville, MD 20857

Dear Ms. Forfa:

The American Veterinary Medical Association (AVMA) appreciates the opportunity to provide the Food and Drug Administration Center for Veterinary Medicine (FDA CVM) with stakeholder input for its 2010 Environmental Scan. Founded in 1863 and currently representing more than 80,000 member veterinarians, the AVMA is one of the oldest and largest veterinary medical organizations in the world. The AVMA is dedicated to advancing the science and art of veterinary medicine, including its relationship to public health and agriculture.

Comments for the Environmental Scan were provided by AVMA volunteer councils and committees, whose members use their expertise to assist the association in developing official AVMA policy. As requested, the AVMA focused on three areas:

- 1) Forces outside the CVM boundaries that are helping to shape the organization;
- 2) Perceived strengths, weaknesses, opportunities and threats influencing CVM;
- 3) Organizational sustainability to support external trends, opportunities and challenges.

Forces outside Center boundaries that are helping to shape the organization;

- Activist groups that are opposed to modern agriculture and technology.
- Demands of population growth both in the U.S. and globally.
- Public risk aversion on the topic of food safety where 100% is not achievable.

Perceived strengths, weaknesses, opportunities and threats influencing CVM

Strengths

- Agency driven by science, but limited by a risk-averse public disconnected from science.
- FDA is the logical single drug approval and post-approval monitoring agency.
- Continued willingness by CVM to work collaboratively and in close communication with the AVMA on issues of importance to veterinary medicine. For example, CVM personnel serve as invited representatives to AVMA Councils and Committees and CVM outreach to AVMA to gain technical expertise on veterinary issues.

- Implementation of a web-based adverse events reporting system (Safety Reporting Portal). This new system is a big step forward in providing opportunities 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.
- Outreach by CVM to practicing veterinarians regarding FDA-approved animal drugs (e.g, trilostane and phenylbutazone) that are available for use in veterinary clinical medicine in lieu of compounded preparations.

Weaknesses

- Slowed by regulations and inordinate attempts to function with zero risk.
- Hesitance to define and document acceptable risk above zero and defend this position.
- CVM's current conservative interpretation of regulations is precluding the inclusion of available information in product labeling that 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.
- Educational outreach to veterinarians and the public. CVM must focus its Animal Health Literacy Campaign efforts on regulatory issues that require more clarity for both practicing veterinarians and the public. Examples of helpful educational materials pertaining to CVM's jurisdiction could cover how drugs are approved, how CVM conducts post-marketing surveillance, and what products/processes CVM is charged with overseeing.

Opportunities

- Only credible agency for drug approval and monitoring.
- CVM has enforcement discretion for unapproved animal drugs that are sometimes medically necessary in practice. AVMA encourages CVM to prioritize enforcement of illegal activities that are clearly egregious and are not meant to fill a critical need in animal health.
- FDA should work more closely with EPA on issues related to regulation of parasiticides (regulated as drugs by FDA and pesticides by EPA). There continues to be confusion regarding what federal agencies regulate parasiticides and how these products are regulated.
- Exploration of ways to enhance function of advisory committee process. Strengthen the Veterinary Medicine Advisory Committee's abilities to engage in open, deliberative discussions among the experts that comprise the Committee.
- As critical needs for FDA-approved animal drugs across animal species and of disease conditions in animals continue, ensure science-based yet expeditious review and approval processes, in order to help ensure the adequate availability of veterinary drugs. New technologies (e.g. biopharmaceuticals) could provide novel therapeutic possibilities.
- Provide enforcement and act on the published violators identified by the USDA Food Safety Inspection Service (FSIS) tissue residue transparency program. The FDA has the responsibility to investigate violation of residue in the food chain. If FDA's findings were

published similar to the USDA FSIS method, it would address the safety concerns of U.S. and international consumers of U.S. animal protein. The FDA should provide enforcement and act on the violations identified by the FSIS tissue residue transparency program.

Threats

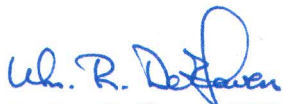
- Legislation that would further reduce the efficiency, functionality and credibility of the agency.
- Widespread sales of nutraceuticals with unsubstantiated drug claims and poor quality control. FDA should require all pet food products with implied or explicit health or drug claims include a prominent statement on the label indicating that these claims have not been evaluated by the FDA. Additionally, FDA could provide some type of compliance guidelines on efficacy, risks and claims associated with nutraceuticals.
- Inadequate funding of the Food Animal Residue Avoidance Databank (FARAD).
- Risk aversion could lead to a slower registration process for certain new therapeutic agents, which could limit applications and approvals of new animal drugs as FDA-approved tools for veterinarians to use.

Organizational sustainability to support external trends, opportunities and challenges

- The organization must insist that all legislative mandates receive full funding for FDA to implement.

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. The AVMA is committed to working with CVM to address the issues and concerns outlined above. We look forward to your feedback and cooperation. For additional information, please contact Dr. Lynne White-Shim (lwhite@avma.org; 847-285-6784).

Respectfully,



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

WRD/ml 6/1/2010