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. FDA-2010-N-0528 – Unapproved Animal Drugs

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 over 81,000 members representing over 83% of all veterinarians in the United States 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) is requesting comments on approaches for increasing the number of currently marketed animal drug products that have legal marketing status. The FDA wishes to explore additional mechanisms that utilize FDA's existing regulatory framework as well as novel strategies not currently employed by the agency to increase the number of approved or otherwise legally marketed animal drugs.

The AVMA commends the FDA on its pursuit of methods by which numbers of legal animal drugs could be increased. The AVMA is committed to the continuing availability of medicinal products that are pure, safe, potent and efficacious for animals. We offer the following current thinking on ways FDA can address the prevalence of unapproved animal drugs:

Utilization of AVMA expertise as the FDA considers ways forward

We understand that FDA is considering how it might adopt a viable monograph (or equivalent) evaluation system and that FDA is also discerning how it might prioritize enforcement action and discretion. As the FDA seeks to determine the relative risk of unapproved animal drug classes to animal health and public health, we ask that FDA reach out to AVMA, who, working with our allied veterinary organizations, can help the FDA to identify species- and discipline-specific experts to provide such assessments.

Preservation of medically necessary drugs for the prevention and relief of animal suffering

Some currently unapproved drugs, including but not limited to injectable vitamins, electrolytes, and fluids, have real medical legitimacy. Drugs that should be afforded continued availability illustrate at least one of the following criteria:

- Minimum to zero food residue risk
- Manufacturing that follows Good Manufacturing Practices principles and/or certain international production standards (such as drug manufacturing that follows Veterinary International Conference on Harmonization criteria)
- Other federal agency standards (such as Environmental Protection Agency assessments)

Active enforcement by FDA of egregious unapproved animal drugs

The AVMA asserts that large-scale manufacturing of new animal drugs produced as mimics of FDA-approved drugs clearly circumvent the FDA's New Animal Drug Application (NADA) process, and enforcement should be directed toward ceasing this type of illegal manufacturing. Such circumvention of the animal drug approval process yields substances with questionable safety and efficacy and it only serves to divert resources away from FDA-approved drugs that are manufactured legally. The AVMA also encourages the FDA to take greater enforcement action in regulating the marketing of products represented as medical devices to the veterinary profession but that appear to be unapproved new animal drugs.

We also assert that legitimate compounding must be preserved and that use of a compounded drug should be limited to:

a. Those drugs for which both safety and efficacy have been demonstrated in the compounded form in the target species; or
b. Disease conditions for which response to therapy or drug concentration can be monitored; or
c. Those individual patients for which no other method or route of drug delivery is practical.

Labeling of animal drug products that illustrate a drug's respective legal or illegal status

Currently, upon inspection of a drug container that has no NADA number, a veterinarian may not be able to readily discern whether it is an approved or unapproved drug. Unless drugs are labeled to indicate their respective category (approved, legally marketed, or unapproved), both veterinarians and laypersons may not be able to readily identify the legal or illegal status of the particular drug. In addition, drugs that have been indexed by FDA that state "Not Approved by FDA" without additional context might be misconstrued by end-users to mean these products are unsafe or untested.

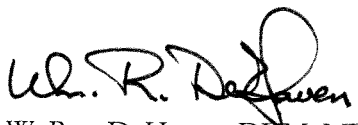
Increasing numbers of approved animal drugs and drug uses

In addition to increasing the number of legally marketed unapproved animal drugs and enforcing egregious, illegal animal drugs, FDA can also relieve some of veterinarians' *need* for unapproved drugs through:

- Expedited reviews and approvals for animal drug products and
- Allowance of extralabel use of medicated feeds in treatment of minor species

Thank you for your time and consideration. The AVMA appreciates the opportunity to comment and would like to continue the dialog on this and other important matters. 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,



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WRD/LAW