AVMA American Veterinary Medical Association

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

Re: Docket No. 2006N-0106—New Animal Drugs; Adamantane and Neuraminidase Inhibitor Anti-influenza Drugs; Extralabel Animal Drug Use; Order of Prohibition

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, the AVMA was established to advance the science and art of veterinary medicine and to protect public health.

On March 22, 2006 the FDA published a final rule prohibiting the extralabel use of adamantane and neuraminidase inhibitor classes of antiviral drugs in chickens, turkeys, and ducks. The FDA approved the drugs for treating or preventing influenza A in humans. The FDA published the rule in spite of indicating that it is unaware of ongoing extralabel use of these human antiviral drugs by U.S. poultry producers. The National Chicken Council says the industry does not use the drugs. AVMA poultry veterinarians affirm the drugs are not used in commercial poultry production.

Though the AVMA is supportive of preserving drugs of public health importance, including the specified antiviral drugs, the AVMA believes that the FDA final rule is unnecessary because the drug use that is prohibited has no anticipated application in U.S. commercial poultry production. We regret the implication that U.S. veterinarians and the poultry industry are using antiviral drugs indiscriminately or have plans to do so.

If H5N1 or any other highly pathogenic avian influenza (HPAI) strain entered a poultry population in the United States, prompt depopulation, quarantine and enhanced surveillance would be implemented by veterinarians of the USDA Animal and Plant Health Inspection Service (APHIS). Drug therapy is not even a consideration in the USDA, APHIS, Veterinary Services HPAI Response Plan.

We considered whether FDA created this prohibition to deter hobbyist breeders and owners of backyard flocks from seeking antiviral drugs from veterinarians for their fowl. However, we see no hint of that in the FDA final rule which focuses on the large numbers of chickens, turkeys and ducks raised in commercial poultry operations.

Also, the list of references attached to the final rule suggests that the FDA approach is predicated upon information reported in news stories that the Chinese may be treating their poultry with an amantadine compound that is not legal in this country. Whether or not legitimate investigation of the Chinese confirms use, we believe it is poor policy for FDA to substantiate its regulatory actions upon information found in news stories. If more substantial evidence exists, we encourage the FDA to include it among the cited references.

In short, the prohibition is unnecessary because there is insufficient veterinary science to justify the use of FDA approved human anti-influenza drugs in commercial poultry production. The costly human drugs have not been studied for poultry use because of the inherent impracticality of their use. Furthermore, veterinarians recognize that our nation is stockpiling these critically important drugs for human use.

We are very disappointed that the FDA did not consult with us early in the decision making process; especially when proposed final rulemaking clearly involves the therapeutic conduct of the veterinary profession. Potentially, we may have been able to resolve your concerns and avoid an unwarranted order of prohibition.

Sincerely,

Bruce W. Little

Bruce W. Little, DVM
Executive Vice President

BWL/ECG