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October 29, 2008

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

RE: American Association of Avian Pathologists (AAAP) response to Docket No. FDA-2008-N-0326 pertaining to banning the extra label uses of third generation cephalosporins in all classes of food animals.

Before banning extra label drug use and taking regulatory action, the Center for Veterinary Medicine, Food and Drug Administration (FDA-CVM) must demonstrate a cause and effect relationship between the increase in antimicrobial resistance in animals and either a demonstrative negative impact on human health or an imminent danger to human health. Neither has been proven for third generation cephalosporins by data reported by FDA-CVM. Establishing US policy based on international data where third generation cephalosporins are in wide spread use and prescribed in virtually all animal species is an example of precautionary steps in which FDA-CVM continues to play the "what if" scenario while poultry health is at risk because of the lack of efficacious preventative and therapeutic agents.

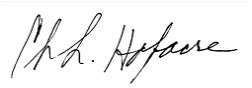
A cause and effect relationship between the use of ceftiofur in poultry and resistance to 3rd generation cephalosporins in humans has not been established. No imminent danger has been demonstrated to human health based on extra-label use in poultry. Criteria for banning extra label use in any or all food animal species have not been met.

This regulatory action is clearly pointed at poultry producers and the ban on extra label use of ceftiofur will result in the withdrawal of the product from the poultry market. *In ovo* application of vaccines and therapeutics has been a significant advance in poultry health in recent years because the practice minimizes handling and injection stress in newly hatched chicks. This action would ban the use of *in ovo* application of cephalosporins (Cefiofur) without scientific justification.

Likewise, the ban on extra label use of ceftiofur in primary and commercial broiler and turkey breeder hens for *Staphylococcus* spp. and *Pasteurella* spp. will negatively impact health of the hens. This action will result in no effective injectable antibiotic for individual treatment to control bacterial arthritis and fowl cholera in valuable breeders. The consequence will be an unnecessary increase in mortality due to diseases that have been effectively controlled through the extra label use of ceftiofur under veterinary supervision.

It is important to the AAAP that due process be fair and equitable for everyone concerned. Placing the blame for cephalosporin failures in human medicine on veterinary medicine and food animal production is not supported by a cause and effect relationship based on NARMS and Food Net Data. A science-based regulatory decision making process should be the framework for FDA-CVM evaluation of veterinary products in food animals. Broad-based regulatory action of banning extra label use of cephalosporin without convincing supporting data unnecessarily and negatively impacts poultry health and undermines confidence in the regulatory process.

The American Association of Avian Pathologists
Board of Directors



Dr. Charles Hofacre, Secretary-Treasurer