12627 San Jose Blvd., Suite 202
Jacksonville, Florida 32223-8638
904-425-5735 (Office)
281-664-4744 (Fax)
aaap@aaap.info
www.aaap.info

2/13/2012

Division of Docket Management
U.S. Food & Drug Administration – HFA-305
5630 Fishers Lane, Room 1061
Rockville MD 20852

Re: Docket No. 2008-N-0326: New Animal Drugs; Cephalosporin Drugs; Extralabel Animal Drug Use; Order for Prohibition and comments from the American Association of Avian Pathologists.

The American Association of Avian Pathologists (AAAP) is a non-profit 501c (6) organization that is allied with the American Veterinary Medical Association. We are the professional organization for poultry veterinarians. The primary mission of the AAAP is to provide continuing education opportunities for poultry veterinarians and microbiologists working with poultry. AAAP is actively engaged in field and research efforts to support food safety and public health as well as the health and well-being of the commercial poultry delivery chain. We appreciate the opportunity to make several comments regarding the recently published final rule on extra-label drug use of cephalosporins in food animals.

The goal of protecting critically important antimicrobials is an important function of the CVM of FDA. The actions of CVM should always be carefully based upon sound scientific evaluations with conclusions justified by that evidence. In the case of poultry specific evidence for prohibiting extra-label use, CVM has not made valid science based conclusions given the body of evidence available and even cited in the ruling. The following are cases in point which support our concerns.

1. FDA cites CIPRS data from Canada as a basis for establishing a relationship between *in ovo* cephalosporin use and resistance of Salmonella sps. in the U.S. Hatchery inspections are also cited in support of this hypothesis. While the *in ovo* uses may be similar, the very high levels of *S. heidelberg* cited by CIPRS are not comparable to those found in NARMS for chicken breast and likely related to the much lower use of cephalosporins in the U.S. due to their expense.

2. Extra-label use of cephalosporins has been prohibited in turkeys (other than day-of-age) yet no turkey facilities, farms or hatcheries were inspected to inquire about any use of cephalosporins in the turkey industry. Only investigations of broiler hatcheries are mentioned in the final rule. Additionally, no violative drug residues in chickens or turkeys (implicating overdosing or non-observation of appropriate withdrawal times) are reported by FDA.

3. *In ovo* methods are not used in the turkey or table egg industry; therefore, resistance selection that may have been associated with *in ovo* use of cephalosporins in "poultry" cannot be related to any findings of cephalosporin resistance in turkeys or egg layers. Findings in "poultry" cannot be validly extended to turkeys or egg layers because the production practices and product uses are inherently different.

4. An attempt is made to suggest that cephalosporin resistance was on an increasing trend in turkeys from the NARMS baseline studies in 1997 of 3.7% until 12.4% in 2009 (via ref. 21). This is simply not supported by the national sentinel system of food borne disease. Retail NARMS data summary of 2009 reveal something different. The overall cephalosporin resistance from ground turkey was 5.8%, only slightly above the 1996-97 baseline data! The NARMS 2009 Executive Report (Table 7b; P20) finds overall ceftiofur resistance to be at 4.7%, again very close to the 1996-97 baseline.

5. The NARMS Retail Meats findings from 2002 thru 2009 show that cephalosporin resistance among Salmonella spp. derived from ground turkey was low and stable at around 5.5% over the entire period. This was the lowest for all food animals over this period. If anything, there is a decreasing trend in β-lactamase inhibitor combinations from 2002 to 2009 in ground turkey documented in the NARMS 2009 data summary. It is at best, disingenuous to cite 33.3% (P.738: via refs. 22, 23) resistance to *S. heidelberg* in 2009 as indicative of the general picture in turkeys without stating that *S. heildelberg* was in fact at very low prevalence in ground turkey in 2009. Its prevalence was only 5.2% (10/190) according to NARMS. In addition, the 33.3% resistance reported appears to represent only one of three total *S. heidelberg* isolated from turkeys over the entire year of 2009!

6. Additionally, the individual animal injectable use of ceftiofur compounds could have measurable and substantial benefits to animal health and welfare as there are currently no approved and effective therapeutics for important gram positive infections and especially for acute or chronic forms of Fowl Cholera (caused by Pasteurella multocida) in broiler or turkey breeders. Fowl cholera can be an economically devastating disease. The potential use in these classes of poultry are below use levels associated with minor species (which are not impacted by the ruling) and would pose essentially no risk to public health. The current ruling prohibits use of ceftiofur compounds in any poultry other than the "day of age" production class.

For these reasons we believe CVM is needlessly imposing extra-label use prohibitions which will detrimentally impact broiler breeders and turkey breeders (and possibly egg layer breeders) without any evidence that an adverse event in humans is likely to occur. We also believe that the action in commercial turkeys is being proposed with no significant or actionable resistance trends, no documentable extra-label uses and no violative residue occurrences. Based upon our review of the published final ruling we believe this action by CVM is both unwarranted and unjustifiable at this time.

Respectfully Yours,

Patricia A. Dunn
President
American Association of Avian Pathologists, Inc.