DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

September 2, 2005

Kent D. McClure, DVM, JD
Animal Health Institute
1325 G St., N.W.
Suite 700
Washington, D.C. 20005

Dear Dr. McClure:

This decision responds to the August 26, 2005, "Petition for Stay of Action and Joinder in Petitions Filed by Veterinary Associations" requesting that I stay the September 12, 2005, effective date of the Final Decision and Order withdrawing approval of the new animal drug application (NADA) No. 140.828 for the use of enrofloxacin in chickens and turkeys. The petition was filed on behalf of the Animal Health Institute (AHI). For the reasons set forth in the attached response to the veterinary associations, I have determined that the veterinary associations do not meet the criteria for granting a stay in 21 CFR 10.35(e). Because AHI's petition for a stay does not provide adequate additional reasons why a stay should issue, I am likewise denying its request for a stay.

AHI's petition for a stay states that AHI will suffer irreparable injury because "the Final Decision expresses concern" that administering antimicrobial animal drugs via feed at water may result in dosing animals that are not ill and under-dosing ill animals and that the Final Decision will therefore prevent development and approval of new antimicrobials. Petition at 2. The Final Decision does not "express[ ] concern" with the practice of administering antimicrobial animal drugs in feed or water, as your petition states. It does not even mention the practice of administering antimicrobial products by feed. Contrary to your premise, the Final Decision acknowledges a stipulation by the participants that "FDA has long accepted drinking water delivery as a safe and effective means to administer therapeutic animal drugs, including antibiotics, to commercially grown broiler chickens and turkeys," Final Decision at 22, but notes, based on oral and written testimony in the administrative proceeding and product information from Bayer, that these methods of administering drugs dose animals that are not ill and may also lead to underdosing, *id.* at 22-23. Thus, not only is this alleged injury is speculative, it is unsubstantiated.

2000N-1571

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For the reasons set forth above and in the attached response to the veterinary associations, I hereby deny the petition for a stay or temporary stay of the effective date of the Order withdrawing approval of enrofloxacin for use in poultry.

Sincerely,

Lester M. Crawford, DVM, PhD
Commissioner of Food and Drugs

Enclosure
cc (w/attachment): Docket 2000N-1571