

August 26, 2005

Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

9549 05 AUG 26 P4:00

In the Matter of:

**Enrofloxacin for Poultry:  
Withdrawal of Approval of  
New Animal Drug Application  
NADA 140-828**

**FDA DOCKET: 00N-1571**

**ANIMAL HEALTH INSTITUTE'S PETITION FOR STAY OF ACTION  
AND JOINDER IN PETITION FOR STAY OF ACTION FILED BY  
VETERINARY ASSOCIATIONS**

The undersigned, Animal Health Institute,<sup>1</sup> submits this petition pursuant to 21 CFR §§ 10.35 and 12.139 requesting that the Commissioner of Food and Drugs stay the effective date of the following matter. AHI hereby joins in the Petition for Stay of Action filed by several veterinary associations and adopts by reference their Statement of Decision Involved, the Statement of Action Requested, the Statement of the Standard for Granting a Stay, and parts b, c, and d of the Statement of Reasons for Granting a Stay.

**A. Decision Involved**

AHI seeks a stay of the effective date of the Order published in the Federal Register effectuating the Commissioner's Final Decision in Docket No. 2000N-1571, *Withdrawal of*

<sup>1</sup> AHI is the national trade association representing research based manufacturers of animal health products—the pharmaceuticals, vaccines, and feed additives used in modern food production, and the medicines that keep livestock and pets healthy. AHI member companies produce the vast majority of all such products in the United States, as well as in as the world market. AHI member companies are stewards for a number of antimicrobial products utilized in food producing animals. As such, AHI has a tremendous interest in the Final Decision of the Commissioner relative to the withdrawal of approval of the New Animal Drug Application for enrofloxacin in poultry.

2000N-1571

PSA 2

*Approval of the New Animal Drug Application for Enrofloxacin in Poultry*, signed on July 27, 2005. The Order in question is *Animal Drugs, Feeds, and Related Products; Enrofloxacin for Poultry; Withdrawal of Approval of New Animal Drug Application*, 70 FR 44048 (Aug. 1, 2005). AHI's request for a stay relates to those portions of the Order and Final Decision that withdraw approval of NADA 140-828 for the use of enrofloxacin in turkeys.

**B. Action Requested**

AHI requests the same relief described in the Petition for Stay filed by the veterinary associations and adopts that request by reference.

**C. Statement of Grounds**

**1. Standard for Granting Stay**

AHI adopts the statement of the standard for granting a stay described in the Petition for Stay filed by the veterinary associations and adopts that description by reference.

**2. Reasons for Granting Stay**

**a. *AHI Will Suffer Irreparable Harm If a Stay Is Not Granted.***

AHI will suffer irreparable harm if a stay is not entered because the implementation of the Final Decision will effectuate an FDA policy preventing the development and approval of any new antimicrobial products that must be administered by water or feed. It is well-known, and recognized by the FDA, that the administration of new animal drugs via water or feed may be the only practical or feasible delivery method, particularly in the case of chickens and turkeys. The Final Decision expresses concern that these methods of treatment may result in the dosing of some animals that are not infected and may also result in under-dosing of animals that are infected. Enrofloxacin's use in chickens and turkeys, however, was the most restrictive approval of any veterinary antimicrobial, as it was a short-term, therapeutic product that could be used only on the order of a veterinarian. If even these restrictive conditions are deemed by FDA to be

unsatisfactory to allow the use of such a product, then the practical effect is that no new antimicrobial product that can be administered via feed or water can be approved.

**b. *Judicial Review of the Final Decision Would Not Be Frivolous and Would Be Pursued in Good Faith.***

AHI hereby joins in the Petition for Stay filed by the veterinary associations and adopts by reference their description of why judicial review of the Final Decision would not be frivolous and would be in good faith. In addition, AHI notes that the decision may have a ripple effect far beyond the immediate impact on the development and production of new animal drugs for use in poultry. The principles underpinning the Final Decision are broad principles that the FDA may easily elect to expand to all areas of animal health. For example, as noted above, the Final Decision expresses concern over the medication of chickens and turkeys by use of medications distributed via drinking water. Such a conclusion could easily be extended, for example, to the beef industry. In addition, the Final Decision approves the withdrawal of a drug based mainly on suppositions about a theoretical negative effect of a drug when the evidence shows that the actual incidence of such theoretical effect is minimal. It is reasonable to conclude that manufacturers of new animal drugs will be wary of expending the time and effort to develop, test, and seek approval of new animal drugs in light of the Final Decision.

**c. *Sound Public Policy Supports This Request for a Stay.***

AHI hereby joins in the Petition for Stay filed by the veterinary associations and adopts by reference their description of why sound public policy supports this request for a stay. AHI also believes that the Final Decision takes the FDA's ongoing refusal to abide by the D.C. Circuit's instructions on how "safety" is to be assessed to a new level: Where in the past the FDA has simply ignored D.C. Circuit precedent in favor of its own formulation (even though there was never any question about the viability of such precedent), in this proceeding the FDA

has flat-out rejected D.C. Circuit precedent by claiming that the Supreme Court has overruled it. Public policy dictates that the courts determine whether such agency action is permissible. If the courts agree with AHI and Bayer, then the Final Decision will have applied the wrong standard and will need to be reconsidered. Accordingly, public policy favors a stay until the courts have reviewed the question.

**d. *The Delay Resulting from the Stay Will Not Be Outweighed by Public Health or Other Public Interests.***

AHI hereby joins in the Petition for Stay filed by the veterinary associations and adopts by reference their description of why the delay resulting from the stay will not be outweighed by public health or other public interests.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'K. McClure', written over a horizontal line.

Kent D. McClure, DVM, JD

Animal Health Institute

1325 G Street, NW Suite 700

Washington, DC 20005

(202) 637-2440

*Counsel for Animal Health Institute*

**CERTIFICATE OF SERVICE**

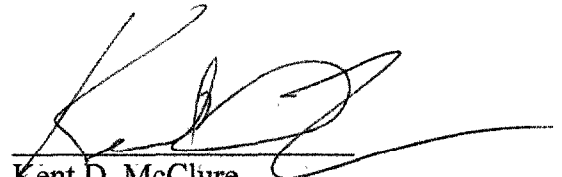
I hereby certify that an original and one copy of Animal Health Institute's Petition for Stay of Action and Joinder in Petition for Stay of Action Filed by Veterinary Associations was hand-delivered this 26th day of August, 2005, to:

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

Nadine Steinberg  
Counsel for the Center for  
Veterinary Medicine  
5600 Fishers Lane (GCF-1)  
Rockville, MD 20857

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

Robert B. Nicholas  
Gregory A. Krauss  
M. Miller Baker  
Richard B. Rogers  
McDermott Will & Emery LLP  
600 Thirteenth Street, N.W.  
Washington, D.C. 20005

  
Kent D. McClure  
*Counsel for Animal Health Institute*