

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

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In the Matter of:

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

**FDA DOCKET: 00N-1571**

**BAYER CORPORATION'S PETITION FOR STAY OF ACTION AND  
JOINDER IN PETITION FOR STAY OF ACTION FILED BY  
VETERINARY ASSOCIATIONS**

The undersigned, Bayer Corporation, submits this petition pursuant to 21 CFR §§ 10.35 and 12.139 requesting that the Commissioner of the Food and Drugs stay the effective date of the following matter. Bayer hereby joins in the Petition for Stay of Action filed by The American College of Poultry Veterinarians, American Association of Avian Pathologists, Association of Veterinarians in Turkey Production, Association of Veterinarians in Broiler Production, and Association of Poultry Primary Breeder Veterinarians ("the Veterinary Associations") 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**

Bayer 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 Approval of the New Animal Drug Application for Enrofloxacin in Poultry*, signed on July 27,

2000N-1571

PSA 1

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).

**B. Action Requested**

Bayer 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**

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

Bayer files this Petition for Stay to support the request for a stay filed by the Veterinary Associations, and Bayer hereby commits to keep enrofloxacin on the market for the approved use if the stay is granted.

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

Bayer 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.

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

Bayer 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.

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

Bayer 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,



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**CERTIFICATE OF SERVICE**

I hereby certify that an original and four copies of Respondent Bayer Corporation'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:

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