DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

September 2, 2005

Robert B. Nicholas
Gregory A. Krauss
McDermott Will & Emery
600 13th Street, N.W.
Washington, D.C. 20005

Dear Mr. Nicholas and Mr. Krauss:

This letter 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 Bayer Corporation (Bayer). Bayer's petition for a stay adopts the reasons set forth by the veterinary associations, but does not provide any additional reasons specific to Bayer why a stay should issue. Most notably, Bayer does not set forth any harm – irreparable or otherwise – that Bayer would suffer if a stay were denied. 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). For the same reasons, and because Bayer does not claim any harm, I hereby deny Bayer's petition for a stay or a 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

2000N-1571

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