

March 21, 2002

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

IN THE MATTER OF NOTICE OF HEARING: §
PROPOSAL TO WITHDRAW APPROVAL § Docket No. 00N-1571
OF NEW ANIMAL DRUG APPLICATION §
FOR ENROFLOXACIN FOR POULTRY

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NOTICE OF PARTICIPATION

Under 21 CFR part 12, please enter the participation of:

Animal Health Institute
1325 G Street, NW Suite 700
Washington, D.C. 20005
202-637-2440

Service on the above will be accepted by:

Kent D. McClure
1325 G Street, NW Suite 700
Washington, D.C. 20005
202-637-2440

The following statements are made as part of this notice of participation:

A. *Specific Interest:*

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. Our member companies produce the vast majority of all such products in the United States, as well as the world market. AHI member companies are stewards for a number of antibacterial products utilized in food producing animals. Additionally, AHI member companies invest hundreds of millions of dollars into scientific research and development that leads to the approval of the animal health products that contribute significantly to the safety of the food supply and the health and well-being of animals. It is imperative that regulatory decision-making be based upon sound scientific principles. The ramifications of this proceeding will likely extend beyond the use of fluoroquinolones in turkeys and chickens. As such, AHI has a tremendous interest in this proceeding.

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AHI desires to be heard on the issue of whether new evidence shows that enrofloxacin is not now shown to be safe for use under the conditions of use upon the basis of which the application was approved, including the issues of whether there is a reasonable basis from which serious questions about the safety of enrofloxacin use in poultry may be inferred (and the identified questions in the Notice) and whether the use of enrofloxacin, under the approved conditions of use in poultry has been shown to be safe.

B. *Commitment to participate*

The Animal Health Institute commits to participate and will present documentary evidence or testimony at the hearing and will comply with the requirements of 21 CFR § 12.85 regarding disclosure of data and information by the participants.

Respectfully submitted,

Animal Health Institute

By:



Kent D. McClure
General Counsel

Certificate of Service

This certifies that a copy of this document was served on the following on the 21st day of March, 2002:

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