

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

2583 '03 MAY 14 P1:28

In the Matter of:

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

FDA DOCKET: 00N-1571

Date: May 13, 2003

**NONPARTY PARTICIPANT ANIMAL HEALTH INSTITUTE'S MOTION FOR
CLARIFICATION OF NOTICE AND ORDER DATED MAY 9, 2003**

Non-party participant Animal Health Institute (AHI) requests clarification of the Notice and Order dated May 9, 2003. The order establishes the briefing schedule with initial briefs due on or before July 18, 2003 and reply briefs due on or before August 15, 2003. The initial briefs are limited to 100 pages and the reply briefs are limited to 50 pages. However, the Notice and Order only mentions the Center for Veterinary Medicine and respondent Bayer Corporation.

AHI desires to submit briefs, and 21 CFR § 12.89 (a)(3) recognizes that nonparty participants may submit briefs. AHI has been an active participant in this proceeding, submitting testimony of six witnesses and approximately 200 written exhibits. Indeed, AHI has participated in all phases of this proceeding except for the submission of interrogatories and cross-examination of witness, and that is because 21 CFR § 12.89(b) precludes non-party participants from participating in these aspects of the hearing. AHI became a non-party participant to (1) ensure that the information it had relative to Campylobacter and enrofloxacin use in chickens and turkeys was considered during the procedure, and (2) to ensure that the larger issues that will impact the entire animal health industry are addressed and briefed. AHI's interest in the proceeding is different than that of Bayer Corporation. AHI is a trade association representing the animal health industry – the research based manufacturers of animal health products. Although Bayer is a member, all other leading animal health companies are also members.

00N-1571

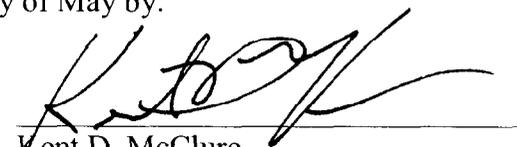
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AHI's perspective in this proceeding is much broader than Bayer's, as the results of this hearing will impact the future development of animal health products by all manufacturers.

Throughout this proceeding, AHI has been cognizant of the large volume of material in the record and has attempted not to burden it with unnecessary paper. AHI does not anticipate its briefs to be as lengthy as the parties to the case. Limits of 50 pages for the initial brief and 25 pages for the reply brief are requested. Additionally, in fairness to the Center for Veterinary Medicine, CVM should have the opportunity to reply to the AHI brief, and a limit of 25 pages is requested.

A proposed order is attached.

Respectfully submitted, this 14th day of May by:



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

CERTIFICATE OF SERVICE

I hereby certify that an original and one copy of the foregoing was filed with the docket this 14th day of May, 2003 and copies were sent as follows:

Nadine R. Steinberg – mail and email
Food and Drug Administration
Office of General Counsel (CGF-1)
5600 Fischers Lane, Room 7-77
Rockville, MD 20857

Robert Nicholas – mail and email
McDERMOTT, WILL & EMERY
600 Thirteenth Street, N.W.
Washington, D.C. 20005



Kent D. McClure

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Proposed ORDER

On May 14, 2003, Non-party participant Animal Health Institute filed a Motion seeking clarification of the Notice and Order dated May 9, 2003, which established the briefing schedule. The Motion is HEREBY GRANTED. The Animal Health Institute may file an initial brief, not to exceed 50 pages, on or before July 18, 2003, and a reply brief, not to exceed 25 pages, on or before August 15, 2003. Additionally, the Center for Veterinary Medicine may file a reply brief, not to exceed 25 pages, to the brief of the Animal Health Institute on or before August 15, 2003.

DATED this the ___ day of May, 2003.

Daniel J. Davidson
Administrative Law Judge