

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

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In the Matter of: ) FDA DOCKET: 00N-1571  
) DATE: December 18, 2002  
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Enrofloxacin for Poultry: Withdrawal )  
of Approval of Bayer Corporation's )  
New Animal Drug Application )  
(NADA) 140-828 (Baytril) )  
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Center for Veterinary Medicine's Request for Clarification of the April 26, 2002, Scheduling Order and Clarification of the December 3, 2002 Order

On April 26, 2002, the Administrative Law Judge issued an Order providing for sequential presentation of written direct testimony. That Order contained a footnote which provides, "Under sequential submissions of evidence, only the side that goes first has a right to seek rebuttal based on the content of the opposing side's submission." Further, on December 3, 2002, the Administrative Law Judge issued an Order providing that Dr. Harris would be provisionally added to Bayer's witness list pending a detailed explanation of how and when Bayer first became aware of Dr. Harris as a potential witness. That Order provided that, "[s]hould Dr. Harris remain a witness in this proceeding, CVM will be given the opportunity for limited additional direct testimony at the oral hearing prior their witnesses being made available for cross-examination."

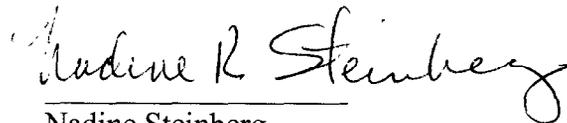
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The Center for Veterinary Medicine ("the Center" or "CVM") respectfully requests clarification on these two Orders. Specifically, CVM seeks guidance on the following questions:

1. With respect to rebuttal testimony, when is the deadline for CVM to request permission to present rebuttal testimony? CVM requests that any deadline for requesting rebuttal testimony be set for a date after the Administrative Law Judge rules on the parties' respective Motions to Strike, due January 27, 2003. This will preserve both the parties' and judicial resources in reviewing testimony and preparing/reviewing pleadings, if such review and preparation is unnecessary.
2. If rebuttal testimony is permitted, what will be the format of rebuttal testimony, written or oral?
3. If rebuttal testimony is permitted, what is the timeframe for presenting rebuttal testimony?
4. Does the Administrative Law Judge anticipate ruling on whether Dr. Harris will remain a witness before CVM's Motion to Strike Testimony (due January 27, 2003), or should his testimony be the subject of any such Motion by CVM based, *inter alia*, on the grounds that the detailed explanation does not justify addition to Bayer's witness list?

Respectfully submitted by,



Nadine Steinberg  
Counsel for the Center for  
Veterinary Medicine

Enrofloxacin Hearing  
Docket No: 00N-1571

**CERTIFICATE OF SERVICE**

I hereby certify that an original and one copy of the foregoing Center for Veterinary Medicine's Request for Clarification was hand delivered this 18th day of December, 2002, to:

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

I also certify that a copy of the pleading has been hand delivered and e-mailed, this 18th day of December, 2002, to:

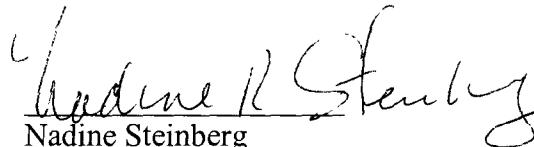
The Office of the Administrative Law Judge  
Food and Drug Administration  
Room 9-57, HF-3  
5600 Fishers Lane  
Rockville, MD 20857

I also certify that a copy of this pleading was e-mailed and mailed by First Class U.S. mail, this 18th day of December, 2002, to:

Robert B. Nicholas  
McDermott, Will & Emery  
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Washington, DC 20005

Kent D. McClure  
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**Dated:** 12/18/02



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