

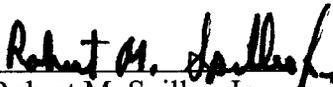


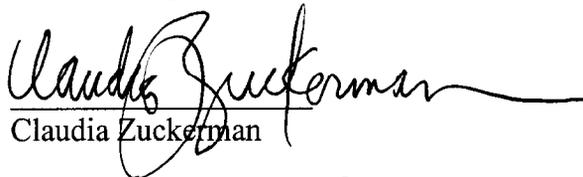
works cited; and that Dr. Cox's use of some data is either not correct or misleading without material qualification. Given these concerns, neither written questions, nor any series of written exchanges would be sufficient for a full and true disclosure of the facts, in response to questions which require Dr. Cox's direct responses, and the ability to pursue the responses with follow-up questions, in the manner that only live cross-examination can provide.

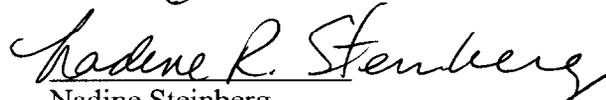
Denial of cross examination of Dr. Cox would prejudice the public and CVM because it would prevent the pursuit of concerns about the reliability, dependability, and accuracy of the testimony in the efficient conduct of cross examination, which will enable the Administrative Law Judge to determine from the witness' response and demeanor whether the witness is to be credited or not for the assertions made in his testimony. Attempting to resolve these concerns other than by cross examination would be less effective, because any other method would consume much more time, would prevent the ALJ's personal observation of the witness' responses, would prevent the witness and examining counsel from the prompt focus on areas of real concern, after any necessary clarifications can be pointed out. Oral cross examination is also the most efficient means to resolve questions about the reliability of the witness' testimony because examining counsel and the witness can efficiently recognize and dispose of some issues with clarifications and focus on issues of credibility and scientific rigor that will affect the whole of the witness' testimony. Any written exchange of cross-examination questions and answers would take much longer, and would frustrate the important process of follow-up questions that invariably assist the Administrative Law Judge and the record in understanding the witness' testimony and its value.

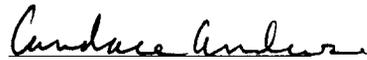
Pursuant to the provisions of the Administrative Law Judge's Order of December 19, 2002 the Center's realistic estimate of the time necessary for cross-examination of Dr. Cox is between 6 and 8 hours, not including interruptions or re-direct. This estimate is realistic because of the sweeping scope and length ( 95 pages) of this witness's testimony, and the number of issues, including apparent discrepancies and contradictions to be resolved.

Respectfully submitted for the Center for Veterinary Medicine by:

  
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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: April _____, 2003
Enrofloxacin for Poultry: Withdrawal	)	
of Approval of Bayer Corporation's	)	
New Animal Drug Application	)	
(NADA) 140-828 (Baytril)	)	

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**ORDER**

By its Motion filed April 14, 2003, the Center for Veterinary Medicine ("CVM") seeks permission to cross examine Bayer witness Dr. Cox, pursuant to 21 C.F.R. § 12.87 (b)(1)(ii), to supplement its document submission under 21 C.F.R. §12.85.

It appearing that the requested cross examination is the only appropriate means of developing the evidence for a full and true disclosure of the facts, that the public, the record, and the Center would be prejudiced by denial of the requested cross examination, and that oral cross examination is the most effective and efficient means to clarify the matters at issue, the Center for Veterinary Medicine's Motion to cross examine Dr. Cox is HEREBY GRANTED. The cross examination schedule will be set in a future Order after the parties have submitted a Joint Proposal. The parties are HEREBY ORDERED to confer and submit a joint proposal for the scheduling of witnesses to be cross examined, consecutively (with only a weekend break if the cross examination is expected to take longer than one business week), beginning no earlier than April 28, 2003, and ending no later than May 9, 2003.

DATED this \_\_\_\_ day of April, 2003.

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Daniel J. Davidson  
Administrative Law Judge

**CERTIFICATE OF SERVICE**

I hereby certify that an original and one copy of the foregoing Center for Veterinary Medicine's Motion for Permission to Cross Examine Bayer Witness Cox was hand delivered this 14th day of April, 2003 to:

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

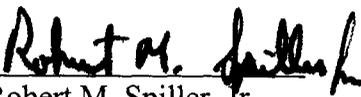
I also certify that a copy of this Motion has been hand delivered and e-mailed, this 14th day of April, 2003 to:

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 Motion was e-mailed and mailed by First Class U.S. mail, this 14th day of April, 2003, to:

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