

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

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In the Matter of:

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

FDA DOCKET: 00N-1571

Date: June 20, 2003

RESPONDENT BAYER CORPORATION'S REQUEST FOR CLARIFICATION

Respondent Bayer Corporation seeks clarification of the April 10, 2002 Scheduling Order in this matter, particularly the provisions by which the participants were ordered to submit "numbered findings of fact, with record references, based on that which each participant believes the evidence has established" and then to submit "correspondingly numbered critiques of other participants' numbered findings of fact". Specifically, Bayer seeks clarification of the effect any proposed finding of fact for which no critique was provided by the other participant. Are such facts deemed unopposed and therefore admitted?

By way of background, CVM submitted 1675 proposed findings of fact. Bayer/AHI responded to each proposed finding of fact, specifically setting forth whether they disputed or agreed to each of the proposed findings. In all, Bayer/AHI agreed to approximately 700 of CVM's proposed findings. Bayer/AHI submitted 1507 proposed findings of fact. CVM responded with a critique of approximately 707 of the proposed findings. CVM provided no response whatsoever to approximately 800 of Bayer/AHI's

proposed findings. Naturally, Bayer presumed that if CVM did not provide a critique, CVM agreed to the proposed finding of fact.

The end result of this lengthy and expensive process was what Bayer thought were over 1,500 *agreed* findings of fact.

In the process of preparing briefs, undersigned Bayer counsel contacted CVM counsel Nadine Steinberg, Esquire on June 17, 2003 to inquire about the manner in which CVM was citing to the agreed findings of fact. Ms. Steinberg replied in words or substance that: there were no *agreed* findings of fact; that the only agreement the parties had were the Joint Stipulations; that under the April 10, 2002 Order the parties were only required to submit "critiques" of proposed findings of fact; and in instances where CVM did not respond to a given Bayer/AHI proposed finding of fact, it did not mean that CVM agreed with the fact.

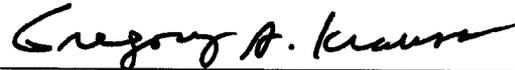
Bayer contends that proposed findings of fact for which no critique was provided should be deemed admitted. To find otherwise would render the entire proposal/critique process seemingly without purpose. What was the purpose of the process if not to winnow down any disputed facts and narrow the issues? Why should any participant respond to any proposed finding of fact if there was no consequence to silence? The process only makes sense if the purpose was to afford the parties an opportunity to evaluate their respective positions at a crucial juncture in the case-- after the Stipulation process, after the evidence was submitted, and before cross-examination. Bayer relied on CVM's lack of critique on certain facts in making its final decision on whom to cross-examine.

Clarification of this issue is important for the briefs, due July 18, 2003. There are over 1500 facts that were proposed but not disputed. This set of facts will be valuable to

the tribunal and could make the briefing process more efficient. If a fact is agreed to, the parties can simply cite to the agreed fact number, rather than the underlying supportive evidence.

Therefore, Bayer requests that Administrative Law Judge Davidson clarify the intent of the exchange of proposed findings of fact and “critiques” mandated by the April 10, 2002 Order as well as the effect of a proposed finding of fact for which no critique has been presented.

Respectfully submitted,



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Counsel for Bayer

CERTIFICATE OF SERVICE

I hereby certify that an original and one copy of Respondent Bayer Corporation's Request for Clarification was hand-delivered this 20th day of June, 2003 to:

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

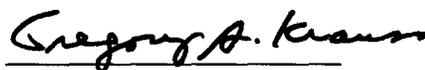
I also certify that a copy of the foregoing Request for Clarification was e-mailed this 20th day of June, 2003 to:

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 the foregoing Request for Clarification was e-mailed and mailed via first-class mail, postage pre-paid, 20th day of June, 2003 to:

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June 20, 2003

VIA HAND DELIVERY

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

Re: Enrofloxacin for Poultry: Withdrawal of Approval of
New Animal Drug Application
NADA 140-828; FDA Docket: 00N-1571

Dear Sir/Madam:

Enclosed for filing please find an original and two copies of Respondent Bayer Corporation's Request for Clarification.

Please call with any questions.

Sincerely,



Gregory A. Krauss

GAK:jeh
Enclosures

cc: Nadine Steinberg, Esquire (w/enclosure)
Kent McClure, Esquire (w/enclosure)

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