

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

In the Matter of:

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

FDA DOCKET: 00N-1571

Date: July 3, 2003

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RESPONDENT BAYER CORPORATION'S REQUEST FOR CLARIFICATION

Respondent Bayer Corporation seeks clarification of the May 9, 2003 Notice and Order scheduling the briefs in this matter, particularly the provision ordering the parties to submit "initial concurrent briefs not to exceed 100 pages". Specifically, Bayer seeks clarification of whether the regulation requirement that briefs must "contain proposed findings of fact and conclusions of law" requires them to be included within the brief or whether they may be included in a separate document submitted concurrently, and merely cited to in the briefs.

21 CFR § 12.96 states that "briefs must contain proposed findings of fact and conclusions of law." *See* 21 CFR 12.96(a). After consultation with CVM, it remains unclear to the parties whether the required proposed findings of fact and conclusions of law must be included within the briefs' 100 page limit and be included in the briefs, or whether they may be included in a separate document outside of the page limitations for the briefs. Bayer believes that the briefs would be more readable if the proposed findings of fact and conclusions of law were provided in a separate document, allowing the briefs to include only numbered citations to the proposed findings of fact and conclusions of law. Bayer

believes having a separate set of proposed facts and conclusions of law will be valuable to the tribunal and could make the briefing process more efficient, in that the briefs may then refer and cite to the proposed findings of fact and conclusions of law. Since this document will be numerically organized, it will allow the Administrative Law Judge to easily locate citations to this document. Additionally, given the complexity of this matter, this would seem to make sense. To the extent the Administrative Law Judge is concerned about the size of the proposed findings of fact and conclusions of law, he could impose limits on the number of proposed findings of fact and conclusions of law or impose separate page limits.

This procedure would not be unprecedented, since what Bayer is suggesting is the procedure used in the nitrofurans case, presided over by the Administrative Law Judge in the 1980s. In that hearing, CVM submitted a brief and proposed findings of fact and conclusions of law separately, as Bayer proposes to do here. Again, this provides the advantage of making the briefs more readable, both in terms of citation format, and in terms of the flow of the document.

Therefore, Bayer requests that Administrative Law Judge Davidson clarify whether the parties may include the proposed findings of fact and conclusions of law in a separate document and whether the page limitations apply to the proposed findings of fact and conclusions of law mandated by May 9, 2003 Order. Although Bayer believes this procedure would make the briefing process more efficient, Bayer's primary concern is that the parties have a common understanding of the limitations provided in the May 9, 2003

Notice and Order. Bayer consulted with CVM on this issue, and CVM counsel stated they have no position on the matter.

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 3th day of July, 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 3th day of July, 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, 3th day of July, 2003 to:

Nadine Steinberg
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McDERMOTT, WILL & EMERY

July 3, 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 one copy of Respondent Bayer Corporation's Request for Clarification.

Please call with any questions.

Sincerely,



Robert B. Nicholas

Enclosures

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