

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: August 14, 2002
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 Opposition to Bayer's Motion for Reconsideration and Clarification of the Administrative Law Judge's August 6, 2002, Order

The Center for Veterinary Medicine ("CVM" or "the Center") respectfully submits this Opposition to Bayer's August 9, 2002, Motion for Reconsideration and Clarification of the Administrative Law Judge's August 6, 2002, Order. Counsel for the Center spoke with Counsel for Bayer on August 13, 2002, and Counsel agree that the Protective Order issued on August 6, 2002, should cover the approximately 5000 pages of allegedly confidential documents as of that date to provide the added protection sought by Bayer. Counsel were unable to reach any other specific agreements regarding matters subject to Bayer's Motion for Reconsideration and Clarification.

At the outset it should be noted that all documents on the Confidential Docket are already subject to the June 6, 2002, Protective Order issued by the Administrative Law Judge.¹ That Order provides, "that all parties and participants (including attorneys and clients personnel) and

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witnesses will have access to all documents contained in the confidential docket. However, these individuals shall not further disclose them to any other person, and the use of documents in the confidential docket shall be limited to those related to the hearing in this matter." (Order, June 6, 2002.) Thus, it would appear that the additional protection sought by Bayer would only apply to those allegedly confidential documents placed on the Confidential Docket by Bayer on or before August 12, 2002.

Bayer seeks reconsideration and clarification for four reasons; CVM will address each in turn. First, Bayer asserts that it was not given an opportunity to respond to CVM's Motion for a Limited Protective Order. However, CVM's Motion was, in essence, a Response to Bayer's original Motion for a Protective Order and Bayer, as the moving party, has no right of reply unless specifically allowed by the Administrative Law Judge (see 21 C.F.R. 12.99(c)). The Administrative Law Judge heard from both sides prior to making a ruling. Moreover, Bayer admits that, "CVM ...submitted its own proposed Protective Order ... that was substantially similar to Bayer's." (Bayer Motion, page 1, footnote omitted.) Therefore, Bayer was not prejudiced in any way by not having two opportunities to be heard on its Motion and the Proposed Order.

Second, Bayer asks for clarification on whether the August 6, 2002, Order protects discovery documents that Bayer designates as "confidential". While CVM does not object to Bayer seeking such clarification, and will abide by any clarification the Administrative Law Judge provides, CVM did intend its proposed Protective Order to cover the approximately 5000 pages of allegedly confidential documents. As mentioned above, Counsel for both CVM and Bayer agree that the Order should cover these documents now.

¹ This includes the documents Bayer placed on the Confidential Docket on or before August 12, 2002.

Third, Bayer states that the parties have different understandings of what is required to be submitted to the Docket and the general requirements of 21 CFR 12.85 submissions, and requests clarification of the distinction between discovery documents and those required to be submitted to the Docket. While the Center does not believe that the administrative regulations specifically require discovery responses to be placed on the Docket, CVM provided the Docket with its answers to Bayer's Interrogatories and the documents responsive to Bayer's Request for Production of Documents because CVM believes it preferable to fully disclose information and make this public hearing process as transparent as possible.² If Bayer chooses not to place all of the responsive documents on the Docket, CVM believes it (CVM) is still free to ask the Administrative Law Judge for permission to supplement its (CVM's) document submission under 21 CFR 12.85 to include those documents on the Docket under Government Exhibit Numbers.³ Because these documents would be ones that Bayer has provided in the first place, there would appear to be no prejudice to Bayer in having these documents added to the Docket at that point in time.

Bayer also requests clarification on whether any document in the Docket is available to be proffered as evidence during the hearing. CVM believes that any document submitted to the Docket should be eligible for proffer as evidence during the hearing. All documents relevant to the issues of the hearing should be treated similarly. Therefore, regardless of whether a document is placed on the Docket as part of a party's original submission under 21 C.F.R. 12.85, or whether a document is placed on the Docket in any other manner (i.e., responses to discovery, public comments, supplemental submissions etc.), CVM maintains that those documents are part

² If the Center should have asked permission to place these documents on the Docket prior to doing so, its failure to do so did not cause any prejudice to any party and it now requests such permission retroactively.

of the Docket and should be available for proffer into evidence at the hearing. The administrative regulations do not specifically address this issue. 21 C.F.R. 12.94(c)(1)(iii) gives the presiding officer the *discretion* to exclude written evidence under certain circumstances including that the evidence was not submitted as required under Section 12.85. However, this regulation should not be read as allowing only those documents submitted under 21 C.F.R. 12.85 as being available for proffer into evidence at the hearing. Further, it is likely that some of the documents that are responsive to the discovery requests should have been submitted under 21 C.F.R. 12.85 as documents containing factual information relating to the issues of the hearing.⁴ If these documents had been properly submitted with the documents submitted under Section 12.85, there would be no question as to their eligibility for proffer as evidence at the hearing. Therefore, regardless of whether these responsive documents are considered part of the Section 12.85 submission, and thus placed on the Docket, or whether they are responsive to Discovery requests and placed on the Docket, they should be available for proffer into evidence at hearing.

Fourth, Bayer claims that the Order's requirements for Bayer to particularize its claims of confidentiality and redact documents are unwarranted. CVM disagrees. CVM should not have to wade through approximately 5000 pages of documents to guess which claim of confidentiality may attach to each document. Further, not every part of each document is likely to be considered confidential. Neither the public, the Administrative Law Judge, the Docket Management Branch, nor CVM should have the burden of giving permanent "confidential" status to such parts of the documents until there has been a specific assertion, an opportunity for

³ While Bayer placed its approximately 5000 pages of allegedly confidential documents on the Confidential Docket, the remaining non-confidential discovery documents delivered to CVM on July 26, 2002, are not currently on the Docket.

⁴ Such documents may have come to light after the original Section 12.85 submissions, or the party may not have then understood the relevance of such documents to the issues of the hearing at the time of the original submission under 12.85.

response after examination of the documents, and, if necessary, a ruling by the Administrative Law Judge. This burden would extend to the hearing process in that such information would be heard *in camera*. Thus, every time a party wanted to refer to such a document or information contained in such a document, the Administrative Law Judge would have to clear the room and the transcript would have to indicate *in camera* proceedings. The parties and the Administrative Law Judge should strive to reduce the burden and stigma associated with such "secret" proceedings to the maximum extent possible.

Bayer states that "CVM suggests that prior to being subject to a protective order, it be able to review Bayer's confidential documents to determine whether to accept or challenge each of Bayer's claims of confidentiality." (Bayer's Motion, page 6). Bayer's assertion is not correct. CVM understands the August 6, 2002, Protective Order to protect those discovery documents claimed as confidential pending review and until the time that an opposing party successfully challenges that claim. However, CVM believes it is entitled to review what is being claimed as confidential in conjunction with Bayer's specific assertion of which parts of which documents qualify for which claim of confidentiality in order to evaluate whether or not to challenge such a claim.⁵ And, if any parts of the documents are not specifically identified as confidential, they should have already been made available, by redacting the document, to the public Docket and to the Center.

Finally, with respect to the Protective Order itself, CVM opposes Bayer's requests for modifications to the Protective Order. Bayer requests that the Protective Order be modified to

⁵ CVM provided redacted copies of documents containing commercial confidential and trade secret information to the Docket as part of its submission under 21 C.F.R. 12.85. Bayer received complete unredacted copies of all information considered confidential commercial information or trade secret information that related to Bayer. The only documents placed on the confidential docket by CVM that Bayer did not receive from CVM were documents that were considered commercial confidential or trade secret information from another company, or documents excluded as privileged pursuant to Section 12.85.

provide that confidential information be disclosed only to CVM employees and outside persons who will be testifying and only if the confidential information is relevant to the testimony to be given by such employees or outside persons. CVM and non-CVM FDA employees working on the hearing have access to this kind of confidential information on a daily basis and are already subject to regulations controlling disclosure of commercial confidential and trade secret information. Further, these FDA employees that are necessary in preparing for the hearing may not all be witnesses and Bayer's proposed language would limit their access to these documents. Likewise, CVM's outside experts (not all of whom will necessarily testify) may need to review these documents to assist in CVM's preparation for cross-examination, if such cross-examination is allowed by the Administrative Law Judge, of Bayer's expert witnesses and Bayer's proposed language would limit the disclosure of the confidential documents to these persons. Therefore, CVM opposes Bayer's request for this revised language in the Protective Order.

Additionally, CVM opposes Bayer's proposed addition of language to the Order making the Protective Order/Written Assurance a "contract" and an explicit allegation that disclosure of protected information would result in irreparable harm. Persons gaining access to documents under the Protective Order are subject to any sanctions available under the administrative rules (or other regulations, if applicable) and the Protective Order/Written Assurance should not be made into a contract.

Further, the signatory could not, by definition, know whether or not the disclosure of information would or would not be irreparable harm when he or she signs the Written Assurance. Such a determination must be made on a case-by-case basis and should not be made part of the Protective Order/Written Assurance.

CVM understands Bayer's desire to convey to the signatories that Bayer believes the information to be highly confidential. Therefore, CVM would not oppose adding the following sentence on the condition that Bayer submits a signed representation of confidentiality of the documents prior to any such Written Assurance: "Bayer represents that all of the information it has designated as CONFIDENTIAL is highly confidential, has not been previously disclosed or otherwise been made available to the public, and represents that the disclosure of any of the information would result in material irreparable harm to the company. In the event of an unauthorized disclosure, the signatory acknowledges that Bayer has asserted that it intends to pursue all available remedies under law."

Respectfully submitted,



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2. As CVM's Opposition to Bayer's Motion for a Protective Order and Motion for a Limited Protective Order was, in essence, a Response to Bayer's original Motion, Bayer was not prejudiced in any way by not having an additional opportunity to be heard on its Motion.
3. Documents responsive to discovery but not otherwise required to have been submitted to the docket pursuant to 21 C.F.R. 12.85 are not required to be submitted to the Docket. However, if any party wishes to submit such documents to the Docket, the party is permitted to file a Motion to Supplement their document submission under 21 CFR 12.85.
4. All documents contained in the Docket are eligible for proffer into evidence in the hearing.

DATED this ____ day of August, 2002.

Daniel J. Davidson
Administrative Law Judge
Food and Drug Administration
Rm. 9-57, HF-3
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Rockville, MD 20857
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CERTIFICATE OF SERVICE

I hereby certify that an original and two copies of the foregoing Center for Veterinary Medicine's Opposition to Bayer's Motion for Reconsideration and Clarification of the Administrative Law Judge's August 6, 2002, Order was hand delivered this 14th day of August, 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 14th day of August, 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 pleading was e-mailed and mailed by First Class U.S. mail, this 14th day of August, 2002, to:

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Dated: 8/14/02



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