

**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

May 30, 2002

**RESPONDENT BAYER CORPORATION'S PARTIAL OPPOSITION
TO CVM'S MOTION FOR LEAVE TO CORRECT THE RECORD**

Respondent Bayer Corporation ("Bayer") hereby responds and partially opposes The Center for Veterinary Medicine's ("CVM") Motion for Leave to Correct the Record.

CVM's motion seeks to 1) correct copying errors and other minor non-substantive corrections to certain documents; 2) remove from the public docket certain documents that CVM asserts may contain confidential information, place them into the Confidential Docket, and replace the document in the public docket with a redacted copy; and 3) remove from the administrative record certain documents that CVM asserts are privileged and should not have been disclosed.

**Bayer Does Not Oppose Corrections of Copying
Errors or Other Non-Substantive Corrections**

Bayer does not oppose CVM's proposed corrections of the record that merely involve correcting copying errors and other non-substantive corrections. Specifically, Bayer does not oppose CVM's proposed corrections pertaining to documents G-62, G-208, G-415, G-444, G-691, G-832, G-876, and G-962.

**Bayer Does Not Oppose Corrections to Protect Bayer's
and Abbott's Commercial Confidential Information**

Bayer also does not object to the proposed redaction of those documents on the public docket that clearly contain commercial confidential information relating to Bayer's Enrofloxacin or Abbott's Sarafloxacin. Although CVM has not discussed with any specificity the "commercial confidential information" in the documents in this category, Bayer can attest to those documents that contain Bayer's confidential and/or commercial information. Therefore as to documents G-682, G-872, and G-937, Bayer does not object to the redaction of these documents and their placement into the Confidential Docket. Bayer cannot, however, agree with CVM's request that the Court "preclude the use of [] unredacted documents at hearing." CVM Motion For Leave to Correct the Record at 2-4. Bayer opposes this request and believes that with an appropriate protective order there is no reason that unredacted materials could not be used at the hearing. CVM provides no reason why unredacted versions should be precluded from use. Such request should be denied. Bayer believes that a protective order that allows Bayer and its attorneys full access to the unredacted copies is appropriate for documents in this category.¹ With this understanding, Bayer does not object to the documents G-682, G-872, and G-937 being redacted for the purposes of access on the public docket as long as an unredacted version is placed in the Confidential Docket and Bayer has access to them under a protective order and can use them in the hearing.

¹ In CVM's May 10, 2002, *Submission of Additional Documents Pursuant to the Administrative Law Judge's April 26, 2002, Order*, CVM states that it does not object to Bayer seeking disclosure of documents that contain confidential commercial or trade secret information under a protective order issued by the Administrative Law Judge. CVM *Submission of Additional Documents Pursuant to the Administrative Law Judge's April 26, 2002, Order* at 3. The proposed order herein includes such a protective order for these subject documents.

CVM alleges that document G-837 may contain commercial confidential information. Although Bayer cannot determine precisely what CVM wishes to redact from this document, Bayer believes that it does contain certain information that may be confidential to Abbot, as Abbott is the recipient of the letter. With the understanding that pursuant to a protective order Bayer would have access to the unredacted version, Bayer does not oppose the redaction of this document and its placement into the Confidential Docket.

Bayer Opposes CVM's Motion as it Relates to Documents Not Clearly Containing Commercial Confidential Information G-559 and G-812

Bayer opposes CVM's motion as relates to documents G-559 and G-812. CVM asserts that documents G-559 and G-812 should be redacted and removed from the public docket because each may contain commercial confidential information.² Upon review of these documents Bayer is unable to discern any potential confidential material and opposes CVM's motion unless and until CVM provides further specificity as to the information it wishes to redact.

G-559 is an August 16, 1995 letter from Dr. David Satcher, (head of CDC at the time) to Dr. David Kessler (Commissioner of FDA at the time). The letter describes CDC's pre-approval concerns related to the issue of antimicrobial resistance. The letter does not discuss any particular drug product or any particular company but provides some indication of what FDA knew about the potential for resistance developing in *Campylobacter jejuni* before it approved enrofloxacin. Upon review of this document, Bayer does not discern any information that might be classified as commercial confidential

² Although CVM proposes to only add G-812 to the Confidential Docket. It is unclear why CVM does not propose adding G-559 to the Confidential Record if it is correct that the document contains commercial confidential information.

information. Bayer and the public at large have had this document for three months now. Bayer intends to use this document in its case and will be prejudiced if not allowed to do so. As such, Bayer opposes any redaction or removal of this exhibit.

Document G-812 is equally perplexing. This document is titled as the “Fluoroquinolone Working Group Document List.” The document lists the title and citation for documents that appear to have been reviewed by the Fluoroquinolone Working Group while they were preparing their report. A review of the list indicates that most documents on the list are published articles in the public domain. Indeed 76 out of the 97 listed items appear to be published journal articles. While some of the remainder may indeed be unpublished articles or letters, there is no other information provided other than a descriptive citation of the document. CVM nevertheless asserts that G-812 contains commercial confidential information and should not have been placed on the docket. Bayer disagrees with this assertion and therefore opposes any redaction of this document.³

Bayer Opposes CVM’s Motion as it Relates to Documents G-140, G-341 and G-916 Because CVM Has Waived Any Privilege or Confidentiality

Bayer opposes CVM’s motion as relates to documents G-140, G-341 and G-916, all of which are purported to be exempt from production on grounds that they are somehow privileged or confidential. CVM proposes to redact or in some cases completely remove these documents from the record. The fact is that both Bayer and the public at large have had unfettered access to these documents for three months.⁴ Bayer has already

³ In Bayer’s Objections To CVM’s § 12.85 Submission And Motion To Compel Additional Submission (submitted April 15, 2002), Bayer asserted that the articles on the list should be submitted as part of CVM’s 12.85 submission.

⁴ Bayer contacted the Dockets Management Branch (“DMB”) at FDA and was informed that although the DMB would have FOIA records that would indicate persons who have requested copies of documents in

incorporated the subject documents into its case preparation. CVM's assertion that these documents should be redacted or in some cases completely removed from the record requires a more substantial showing than CVM has proffered in its motion. Moreover, under relevant case law, CVM has waived any privilege or confidential status these documents may have had by producing the documents to the public docket and allowing public access for three months.

CVM claims that document G-140 reflects the Center's internal deliberative process and should not have been placed on the docket. CVM requests that this document be withdrawn from the docket completely. Bayer has had this document for the past three months and has already incorporated this document into its defense. CVM's proposed correction should be denied because it is not clear that any privilege exists. To the extent any privilege might have existed at some point, that privilege was waived when the document was provided to Bayer and the general public. This is consistent with D.C. Circuit case law on privilege, which finds a waiver of a party's right to assert a privilege where a disclosure has been made, even if it is inadvertent. *See, In re Sealed Case*, 877 F.2d 976, 980 (D.C. Cir. 1989) ("the confidentiality of communications covered by the privilege must be jealously guarded by the holder of the privilege lest it be waived. The courts will grant no greater protection to those who assert the privilege than their own precautions warrant. We therefore agree with those courts which have held that the privilege is lost 'even if the disclosure is inadvertent.'"); *see also, In re UMW Employee Benefit Plans Litig.*, 156 F.R.D. 507, 510 (D. D.C. 1994) ("the release of privileged documents destroys their privileged nature irrespective of how the opposing party gains

the record, it has no records of persons who may have already viewed these materials. It would seem patently unfair to restrict Bayer's access to documents that may already be in the public domain.

access to the documents”). Although these cases address the attorney-client privilege, the reasoning is equally applicable to any purported privilege here. Therefore even though Bayer might disagree that the document was privileged in the first instance, through the disclosure of this document, CVM has waived any privilege that might have existed. Therefore Bayer opposes the removal of this document from the record.

CVM claims that document G-916 contains information obtained from another U.S. government agency under a signed confidentiality agreement. The document contains data on 1999 Young Chicken Ready to Cook pounds produced by state. CVM used this data in its Notice of Opportunity for Hearing (“NOOH”) to weight the 1999 NARMS poultry resistance data that was approximately 9%, but increased to 12% after CVM weighted the data. *See*, 65 Fed. Reg. 64,954, 64,958 (October 31, 2000). In its NOOH reply filed over a year ago, Bayer objected to the comparison of weighted versus non-weighted data that CVM had done in the NOOH. *See*, Bayer’s Submission of Facts, Information and Analyses In Response to the Notice of Opportunity for Hearing at 6. Bayer also requested this information through the Freedom of Information Act from both FDA and USDA and had its request denied. In the three months Bayer has had this information it has already incorporated it into its case and would be prejudiced at this point in the proceeding to have it withdrawn. CVM has not claimed this document is privileged, but to the extent it were to make such an argument it is Bayer’s position that the privilege has been waived. *See, In re Sealed Case*, 877 F.2d 976, 980 (D.C. Cir. 1989); *In re UMW Employee Benefit Plans Litig.*, 156 F.R.D. 507, 510 (D. D.C. 1994).

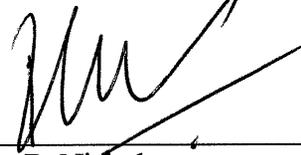
Finally, G-341 is a document that CVM is “investigating whether [the] information was obtained under a signed confidentiality agreement.” CVM Motion For Leave to

Correct the Record at 2. Since CVM admits that it does not yet know whether this document was indeed obtained pursuant to a confidentiality agreement it is premature to redact any information until CVM makes such a showing. Once documents have been placed in the public domain a presumption should be made that those documents are public until a showing has been made to the contrary. CVM has made no such showing here. Therefore CVM's request should be denied with respect to this document. Even should CVM show the document was obtained under a signed confidentiality agreement, the disclosure of the document has made the document no longer confidential.

CONCLUSION

For the reasons stated herein, Bayer requests that the Court deny CVM's Motion as relates to documents. Bayer has attached a proposed Order which outlines the scope of Bayer's proposal.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that a copy of Respondent Bayer Corporation's Partial Opposition to CVM's Motion for Leave to Correct the Record was hand-delivered this 30th day of May 2002, via first-class mail, postage pre-paid to:

Kent D. McClure
Animal Health Institute
1325 G Street, N.W., Suite 700
Washington, D.C. 20005

I hereby certify that a copy of Respondent Bayer Corporation's Partial Opposition to CVM's Motion for Leave to Correct the Record was e-mailed and also mailed, postage pre-paid, this 30th day of May 2002, to:

Nadine R. Steinberg, Esquire
Food and Drug Administration
Office of General Counsel (CGF-1)
5600 Fischers Lane, Room 7-77
Rockville, Maryland 20857

I hereby certify that a copy of Respondent Bayer Corporation's Partial Opposition to CVM's Motion for Leave to Correct the Record was e-mailed, faxed and also mailed, postage pre-paid, this 30th day of May 2002, to:

Honorable Daniel J. Davidson
Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, Maryland 20857



Robert B. Nicholas

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

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**Enrofloxacin for Poultry:
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NADA 140-828**

FDA DOCKET: 00N-1571

ORDER

UPON CONSIDERATION of the Center for Veterinary Medicine's Motion for Leave to Correct the Record, it is hereby **DENIED IN PART** and **GRANTED IN PART**.

It is **ORDERED** that the following documents listed in the Center's Motion be corrected and replaced as described in CVM's Motion: G-62, G-208, G-415, G-444, G-682, G-691, G-832, G-837, G-872, G-876, G-937, and G-962.

It is **FURTHER ORDERED** that all Persons having copies of the original Exhibits G-682, G-837, G-872, and G-937 return the original and any copies of these documents to CVM's counsel within 3 days from this Order. It is **ORDERED** that the unredacted version of these documents are subject to a protective order of the following terms:

1. Unredacted versions of G-682, G-837, G-872, and G-937 shall be placed in the confidential docket.

2. Parties and participants shall treat unredacted documents G-682, G-837, G-872, and G-937 as confidential and shall not further disclose them to any other person.

3. Unredacted versions of G-682, G-837, G-872, and G-937 may be used by the parties at the hearing herein subject to the provisions of paragraph 1 above.

The Center for Veterinary Medicine's Motion for Leave to Correct the Record is hereby **DENIED** with respect to documents: G-140, G-341, G-559, G-812, and G-916.

SO ORDERED:

DATED this the ___ day of _____ 2002.

Daniel J. Davidson
Administrative Law Judge