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**MCDERMOTT, WILL & EMERY**

May 5, 2003

**VIA HAND DELIVERY**

Honorable Daniel J. Davidson  
Administrative Law Judge

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

0396 '03 MAY -5 P 4:40

Re: In the Matter of Notice of Hearing: Proposal to Withdraw  
Approval of New Animal Drug Application for Enrofloxacin  
for Poultry ("Enrofloxacin Hearing")  
FDA Docket: 00N-1571

Dear Judge Davidson:

Attached please find a courtesy copy of Bayer's Response To *Cvm's Motion To Supplement Document Submission Under 21 C.F.R. § 12.85 And Motion To Enter Exhibit G-1801 Into The Evidentiary Record* And Motion To Supplement Document Submission Under 21 C.F.R. § 12.85 And Motion To Enter Exhibits B-1937 - B-1941 Into The Evidentiary Record

Bayer has also sent you and the parties this Opposition via email and has served the docket this afternoon.

Please call with any questions.

Sincerely,



Robert B. Nicholas

Enclosures

cc: Kent D. McClure (without enclosure)  
Nadine Steinberg (without enclosure)

**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: May 5, 2003**

***BAYER'S RESPONSE TO CVM'S MOTION TO SUPPLEMENT DOCUMENT  
SUBMISSION UNDER 21 C.F.R. § 12.85 AND MOTION TO ENTER EXHIBIT G-  
1801 INTO THE EVIDENTIARY RECORD AND MOTION TO SUPPLEMENT  
DOCUMENT SUBMISSION UNDER 21 C.F.R. § 12.85 AND MOTION TO  
ENTER EXHIBITS B-1937 - B-1941 INTO THE EVIDENTIARY RECORD***

In response to the Center for Veterinary Medicine's ("CVM's") Motion To Supplement Document Submission Under 21 C.F.R. § 12.85 and Motion to Enter Exhibit G-1801 Into the Evidentiary Record, Respondent Bayer Corporation ("Bayer") respectfully states as follows:

Bayer does not object to CVM's proposal to supplement its document submission and motion to enter G-1801 into evidence, provided CVM does not oppose Bayer's submission and motion into evidence of document B-1937 through B-1941.

A. B-1937 is Bayer's reply to G-1801, a letter from Joseph A. Foster of CDC to Bayer's counsel Robert B. Nicholas.

B. B-1938 through B-1941 are, respectively, declarations of Bradley D. DeGroot, Gregory A. Burkhart, Michael Vaughn, and Nathan Beaver.<sup>1</sup> Each of said persons personally received and otherwise handled the CDC datasets in question and the first two

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<sup>1</sup> For the declarations of Drs. Burkhart and Vaughn, Bayer is submitting facsimile signature pages. Bayer will submit a Motion to Substitute Signature Pages as soon as they originals are received.

parties submitted written direct testimony in this proceeding based in part on the various CDC datasets.<sup>2</sup> These affidavits are responsive to CVM's mischaracterization of G-1801, with respect to effect of the potential data conversion errors on written direct testimony submitted on behalf of Bayer, and also with respect to Bayer's constructive knowledge about the possible effect of use of Microsoft Excel files.

Bayer herewith moves to supplement the document submission under 21 C.F.R. § 12.85 and to enter B-1937, B-1938, B-1939, B-1940, and B-1941 as exhibits into the evidentiary record. If G-1801 is admitted into evidence, its response, B-1937, and the related documents identified as B-1938 through 1941, should also be entered onto the docket and into the evidentiary record in order to prevent any prejudice to Bayer and for the reasons articulated below.

21 C.F.R. § 12.85(a) requires Respondent to submit to the Dockets Management Branch documents in Respondent's files containing factual information which relate to the issues (§ 12.85(a)(2)) as well as all other documentary data and information relied upon (§ 12.85(a)(3)). In accordance with 21 C.F.R § 12.85(c) and the July 17, 2002 Order entered in this matter, Bayer seeks to supplement its 12.85 document submission. 21 C.F.R. § 12.85(c) states:

Submissions required by ... this section may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material contained in the supplement was not reasonably known or available when the submission was made or that the relevance of the material contained in the supplement could not reasonably have been foreseen.

Furthermore, the July 17, 2002 Order in this matter states that:

21 C.F.R. § 12.85(c) indicates that the required submissions "... may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material ... was not reasonably known or

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<sup>2</sup> Dr. Tony Cox also reviewed and analyzed CDC data sets in the drafting of his testimony, however, Dr. Cox was only provided SAS versions of data files, and thus there are no data conversion issues related to his testimony.

available ... or that the relevance of the material contained in the supplement could not reasonably [have] been foreseen.” It appears that the use of the word “may” allows the submissions to be voluntary and that the parties may therefore voluntarily limit their Section 12.85 supplements to relevant material.

Order at 1. Respondent also seeks to add these documents to its evidentiary record under 21 C.F.R. § 12.94, and pursuant to the Administrative Law Judge's authority under 12.70(h).<sup>3</sup>

B-1937 is a letter from Robert B. Nicholas, counsel for Bayer, to Joseph A. Foster, of the Centers for Disease Control and Prevention, dated May 5, 2003. The letter responds to Mr. Foster's letter dated April 24, 2003 (G-1801), and, where appropriate takes issue with certain alleged misstatements made by Mr. Foster, which statements are relevant to this hearing and include, specifically, that (1) Bayer requested CDC to convert and provide datasets in Microsoft Excel format rather than SAS format and (2) that Bayer was on notice that files converted by CDC from SAS to Excel and provided to Bayer may have been corrupted. Among other things, the letter documents that the only avenue available to Bayer to obtain data essential to evaluate and defend against CVM's effort to withdraw the approval of enrofloxacin in poultry (NADA 140-8282) was to obtain data and other materials relied on by CVM, which data are available only from CDC. Additionally the letter reaffirms that Bayer did not request CDC to convert SAS files to Excel format, and indeed would have had no reason to do so since it had been receiving and using SAS formatted files from CDC for many months prior to receiving Excel files.<sup>4</sup> Furthermore the letter challenges Mr. Foster's interpretation of an e-mail, concerning

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<sup>3</sup> 21 C.F.R. § 12.70(h) grants the ALJ authority to “[r]ule on, admit, exclude, or limit evidence.”

<sup>4</sup> Interestingly CDC apparently converted the Sentinel County Study dataset from SAS to Excel for CVM as well, perhaps at CVM's request, since CVM submitted to Bayer an Excel dataset for this study that was different

warning about the conversion of SAS files to Excel format since the e-mail does not mention Excel files at all, but was in the context of other formats and was sent nine months before CDC sent Bayer any data set in Excel format. Together with the declarations (B-1938-1941) B-1937 effectively refutes CVM's allegation that G-1801 "rebut arguments made by Bayer to the Administrative Law Judge in earlier communications...and demonstrates that certain written direct testimony submitted by Bayer and/or AHI may be based on inappropriate evaluations and analyses of data, even after counsel was specifically warned about the possibility of data conversion problems if SAS files were not used." CVM motion at 2.

B-1938 through B-1941. In light of the questions raised about the accuracy of data and other information provided by CDC to Bayer and/or its counsel, first raised in CDC's February 10, 2003 letter to Nathan Beaver (Attachment 2), and further addressed in the February 25, 2003 letter of Robert B. Nicholas to the Honorable Daniel Davidson (Attachment 3) Bayer has also attached hereto declarations of Drs. Bradley D. DeGroot (B-1938), Gregory A. Burkhardt (B-1939), Michael Vaughn (B-1940) and Mr. Nathan Beaver (B-1941). In addition to information that is already on the docket and in the evidentiary record, particularly the written direct testimony of Drs. DeGroot and Burkhardt (respectively, A-200 and B-1900), the declarations provide meaningful and relevant information that is currently unavailable to the docket and evidentiary record. Importantly, the declarations describe the handling of the datasets, review of the SAS files, and the impact (if any) of data conversion errors. The declarations address as well the efforts that have been undertaken by Bayer to ascertain whether there were, and the

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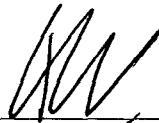
from the one CDC provided to Bayer (Bayer11.2.xls). See e-mail to Gregory Krauss from Nadine Steinberg dated August 28, 2002 (Attachment 1).

extent of, any such CDC data conversion errors and to address any inaccuracies that may have been caused solely by CDC's unsolicited conversion of the datasets from SAS to Excel files. For example, to the extent Dr. Burkhart used CDC data he relied entirely on SAS formatted files, except for a limited analysis Dr. Burkhart did related to the Sentinel County Study. Portions of Dr. DeGroot's testimony which relied on the corrupted data have been withdrawn, but the predominance of Dr. DeGroot's testimony is unaffected by the conversion errors. This clarifying information is provided in their respective declarations as well.

Having addressed the relevance and necessity of B-1937 through B-1941 to the issues of this hearing, allowing CVM to move into evidence G-1801 without also allowing Bayer to introduce B-1937 through B-1941 would therefore irreparably prejudice Bayer. B-1937 is essential to evaluate the validity of Mr. Foster's letter. Accordingly, unless B-1937 is included in the evidentiary record in the event G-1801 is as well, there will be an incomplete record of materials. B-1938 through B-1941 should also be allowed into evidence as they contain relevant, new information, not otherwise available on the Docket, and only recently documented in reply to CVM's motion to introduced document G-1801. Additionally it is necessary to correct certain matters contained in the Docket.

In conclusion, because B-1937 through B-1941 are related to the issues of the hearing, were created only recently, and come within § 12.85, Bayer respectfully moves to add Exhibits B-1937 through 1941 onto the docket and moves their entry into the evidentiary record of this hearing. With the entry of B-1937 through B-1941, Bayer does not oppose CVM's motion to add G-1801 to the docket and evidentiary record.

Respectfully submitted,



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Robert B. Nicholas  
Gregory A. Krauss  
Jeffrey C. Bates  
M. Miller Baker  
MCDERMOTT, WILL & EMERY  
600 13th Street, N.W.  
Washington, D.C. 20005-3096  
(202) 756-8000

**CERTIFICATE OF SERVICE**

I hereby certify that a copy of Bayer's Response to *CVM's Motion To Supplement Document Submission Under 21 C.F.R. § 12.85 and Motion to Enter Exhibit G-1801 Into the Evidentiary Record* And Motion To Supplement Document Submission Under 21 C.F.R. § 12.85 And Motion To Enter Exhibit B-1937 through B-1941 Into The Evidentiary Record was hand delivered, this 5th day of May 2003, to:

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

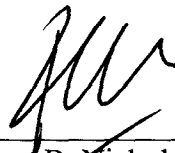
I also certify that a copy of the foregoing Opposition was hand delivered and emailed this 5th day of May 2003 to:

Administrative Law Judge Davidson  
Food And Drug Administration  
Room 9-57, HF-3  
5600 Fishers Lane  
Rockville, MD 20857

I also certify that a copy of the foregoing Response and Motion was emailed this 5<sup>th</sup> day of May 2003 and also hand delivered to:

Nadine Steinberg  
Counsel for the Center for  
Veterinary Medicine  
5600 Fishers Lane (GCF-1)  
Rockville, MD 20857

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



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Robert B. Nicholas  
*Counsel for Bayer*



**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**

**ORDER**

By Motion filed April 25, 2003, the Center for Veterinary Medicine (“CVM”) seeks to add Exhibit G-1801 to the docket and evidentiary record. By response and Motion filed May 5, 2003, Bayer does not oppose the admission of this document subject to the entry of Exhibit B-1937 through B-1941 to the docket and evidentiary record, and also moves to add Exhibit B-1937 through B-1941 to the docket and evidentiary record.

The Center for Veterinary Medicine’s Motion to add Exhibit G-1801 is **HEREBY GRANTED**; and it is further

**ORDERED** that Bayer’s Motion to add Exhibit B-1937 through B-1941 to the docket and evidentiary record is **HEREBY GRANTED**.

DATED this the \_\_\_ day of May, 2003.

\_\_\_\_\_  
Daniel J. Davidson  
Administrative Law Judge