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

In the Matter of:	FDA DOCKET: 00N-1571
	DATE: December 6, 2002
Enrofloxacin for Poultry: Withdrawal of Approval of Bayer Corporation's New Animal Drug Application (NADA) 140-828 (Baytril)	

Center for Veterinary Medicine's Response to Bayer's Motion to Compel Additional Document Submission Under 21 CFR §12.85

On November 29, 2002, Bayer Corporation (Bayer) filed a Motion to Compel the Center for Veterinary Medicine ("CVM" or "the Center") to submit "additional relevant documents to this proceeding" (Bayer's Motion, page 1). Bayer believes that CVM is in possession of a study conducted by a CVM witness concerning mortality associated with fluoroquinolone-resistant Campylobacter, and claims "it strains credulity to believe that CVM has not yet reviewed the only study to date purporting to show a fluoroquinolone resistant Campylobacter-related death..." (Bayer's Motion, page 3). Bayer's Motion recites previous correspondence between the parties on this issue (Bayer's Motion at footnote 2) and characterizes CVM's November 27, 2002, correspondence as an attempt to distinguish between published and unpublished studies (Bayer's Motion, page 4). As a basis for this Motion, Bayer cites 21 CFR §12.85(a), putting particular emphasis on §12.85(a)(3). CVM responds as follows:

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1. CVM does not have a copy of the subject study, and understands from the witness that this information has not yet been published.

2. CVM itself has not reviewed this "study". The Center has invited the testimony of world-renowned scientists who have expertise in the relevant subject matter and plans to rely on their expertise at hearing. While Bayer may find it incredulous that CVM would rely on a study that CVM did not itself review, it is not only proper but should also be anticipated that CVM will rely on its expert witnesses' explanations of studies that these experts have themselves conducted, or ongoing studies that these witnesses are conducting, and that are obviously within their scope of their expert knowledge. On December 9, 2002, CVM will submit the testimony of these expert witnesses.

3. 21 CFR §12.85(a)(3) cannot be read to mean that a party must disclose any fact within the knowledge its witnesses or disclose the complete subject matter of each witness' testimony prior to its submission. Such information may be stored within the knowledge of a witness as a published paper, an unpublished manuscript, personal notes of the witness, or in the mind of the witness.

4. The governing regulations do not require, and did not contemplate that each witness would have to submit all his or her files as part of the document submission under 12.85, and certainly did not intend for each witness to disclose all information within his expertise. The plain language of 12.85(a)(3) indicates that only "other documentary data and information relied on" must be submitted under that subsection. The word documentary means "being or consisting of documents: contained or certified in writing" (see Merriam-Webster Collegiate Dictionary, 2002 on-line addition). Therefore, CVM was never under any obligation to submit a description of this anticipated oral evidence.

5. Bayer erroneously suggests that CVM is making a distinction between published and unpublished studies. CVM has neither a published nor unpublished copy of the subject study. The abstract of a related study is on the Docket at G-770.

In addition, the Center notes that Bayer incorrectly and negatively characterizes CVM's actions in its Motion. While it is true CVM did not respond to Bayer's November 11, 2002, letter until November 27, 2002, CVM did not ignore Bayer's letter (Bayer's motion, page 3). In fact, CVM had been looking into Bayer's request for additional information to see what, if any, additional information it could provide to Bayer.

Further, Bayer states that the study in question is the "only study to date purporting to show a fluoroquinolone resistant Campylobacter-related death...", however, neither Bayer nor CVM can know what study or studies are being conducted by each and every scientist

researching the issue of fluoroquinolone–resistant Campylobacter and/or human deaths attributable to fluoroquinolone-resistant Campylobacter. If CVM had this study in hand, it would certainly be in this Docket already.

For the above reasons, CVM respectfully urges the Administrative Law Judge to deny Bayer's November 29, 2002, Motion to Compel CVM to submit a document that CVM does not have.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that an original and a copy of the foregoing Center for Veterinary Medicine's Response to Bayer's November 29, 2002, Motion to Compel was hand delivered, this 6th day of December, 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 CVM's Response has been hand delivered, this 6th day of December, 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 of CVM's Response was e-mailed and also mailed, postage prepaid, this 6th day of December, 2002, to:

Robert B. Nicholas
McDermott, Will & Emery
600 13th Street, NW
Washington, DC 20005

and

Kent D. McClure
Animal Health Institute
1325 G Street, NW, Suite 700
Washington, DC 20005

I also certify that a copy of CVM's Response was e-mailed, this 6th day of December, 2002, to:

Judge Daniel Davidson
The Office of the Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
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Dated: 12/6/02

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