

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

<p>In the Matter of:</p> <p>Enrofloxacin for Poultry: Withdrawal of Approval of Bayer Corporation's New Animal Drug Application (NADA) 140-828 (Baytril)</p>	<p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p>	<p>FDA DOCKET: 00N-15715</p> <p>DATE: May 6, 2003</p>	<p>2495</p> <p>03</p> <p>MAY</p> <p>-6</p> <p>P 3:23</p>
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Center for Veterinary Medicine's Opposition to Bayer's  
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 Bayer's Motion to Supplement Document Submission under 21 C.F.R. § 12.85 and Motion to Enter Exhibits B-1937 – B-1941, the Center for Veterinary Medicine ("the Center" or "CVM") respectfully objects to Bayer's last-ditch effort to flood the evidentiary record with unnecessary documents. For the reasons specified below, Bayer's motion to enter Exhibits B-1938 through B-1941 into the evidentiary record should be denied in its entirety.<sup>1</sup>

First, Bayer should not be permitted to submit revised written direct testimony (B-1938, declaration of Bradley DeGroot), particularly at a point in this proceeding when CVM has no opportunity to conduct cross-examination of this witness on the revisions to his testimony.<sup>2</sup>

Second, although CVM does not object to Bayer's withdrawal of portions of written direct

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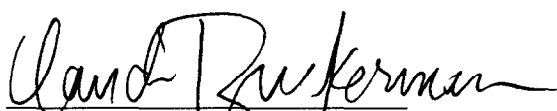
<sup>1</sup> In addition to objections to Bayer's adding these exhibits to the evidentiary record, CVM also objects to Bayer's attempt to add another 23 documents (not including the documents it seeks to add to the evidentiary record) to its 12.85 submission. Bayer does not even articulate the standard it must meet to add documents to the record pursuant 21 C.F.R. § 12.85, much less argue that it has met its burden.

<sup>2</sup> The information used by Bayer in revising Dr. DeGroot's direct testimony has been in Bayer's possession since March 18, 2003. There is no reasonable justification why Bayer waited until now to attempt to submit revised testimony based on information it has had for nearly seven weeks.

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testimony filed on December 13, 2002, it is not necessary for Bayer to file declarations (B-1938, B-1939) by its witnesses in order to withdraw direct testimony. Third, B-1940 (declaration of Michael Vaughn) is superfluous and irrelevant in that it merely recounts Dr. Vaughn's version of the documents he received from Bayer's counsel and subsequently forwarded to Bayer's witnesses. Fourth, B-1941 is Bayer counsel Nathan A. Beaver's second declaration filed in this proceeding (Mr. Beaver filed his first declaration in this proceeding on January 27, 2003). Either Mr. Beaver is counsel for Bayer or he is a witness; he cannot be both. Fifth, the "response" by Robert Nicholas (B-1937) to Mr. Joseph Foster's April 24, 2003, letter belies Mr. Nicholas's own claim that B-1937 is "essential" to evaluate Mr. Foster's letter and to make the evidentiary record complete. For example, the paragraph in Mr. Nicholas's letter beginning on page 2 and ending on page 3 ("As you know ... for the future") is gratuitously derisive, irrelevant to the substance of Mr. Foster's letter, and an obvious attempt to get purely self-serving information on the record. For all these reasons, Bayer's Motion should be denied.<sup>3</sup>

Respectfully submitted this 6th day of May 2003 by:



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<sup>3</sup> CVM does not believe that its Opposition to Bayer's Motion warrants further briefing. However, at the direction of the Administrative Law Judge, CVM will provide an additional, more detailed response to Bayer's Motion.

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In the Matter of: )  
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) FDA DOCKET: 00N-1571  
) DATE: May \_\_, 2003  
)  
Enrofloxacin for Poultry: Withdrawal )  
of Approval of Bayer Corporation's )  
New Animal Drug Application )  
(NADA) 140-828 (Baytril) )  
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ORDER

On May 6, 2003, the Center for Veterinary Medicine filed an Opposition to Bayer's 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 consideration of Bayer's 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 and the Center for Veterinary Medicine's Opposition to Bayer's 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, it is ordered that Bayer's Motion is HEREBY DENIED.

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Daniel J. Davidson  
Administrative Law Judge

**CERTIFICATE OF SERVICE**

I hereby certify that an original and one copy of the foregoing Center for Veterinary Medicine's Opposition to Bayer's 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 was hand-delivered this 6 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 pleading has been hand-delivered and e-mailed this 6 day of May 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 this pleading was e-mailed and mailed by First Class U.S. mail (as well as hand-delivered to Robert B. Nicholas) this 6 day of May 2003 to:

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

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

Dated: 6 May 03



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