

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: May 6, 2003  
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Enrofloxacin for Poultry: Withdrawal  
of Approval of Bayer Corporation's  
New Animal Drug Application  
(NADA) 140-828 (Baytril)  
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CVM's Opposition to Bayer's Motion to Supplement Document Submission under 21 C.F.R. §12.85 and Move Additional Documents into the Evidentiary Record

CVM respectfully submits this opposition to Bayer's motion moving additional documents into the evidentiary record. On April 28, 2003, Bayer Corporation filed a motion to add six additional documents to the evidentiary record. CVM has now had a chance to review these documents and opposes the entry of two of these documents into the evidentiary record. These two documents are B-1923 and B-1928. CVM does not oppose entry of the other four documents ( B-1924, B-1925, B-1926, and B-1927).

Bayer Corporation should not be allowed to supplement its witnesses testimony by adding witness statements after the period has passed for CVM to request permission to conduct cross examination of Bayer witnesses. Both B-1923 and B-1928 were authored by witnesses for

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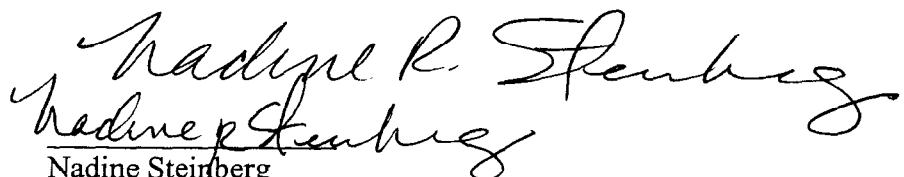
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Bayer in this hearing and both documents differ from the written direct testimony or attachments to the written direct testimony of these two witnesses.

Further, it is far from clear whether these articles meet the requirements for supplementing the record in 21 C.F.R. §12.85(c). In its Motion, Bayer states that B-1923 (the Silley article) "was published in April, 2003, in the peer reviewed journal, Environmental Microbiology." What is missing from Bayer's Motion however, is the date that Bayer became aware of this publication. For instance, Bayer does not provide what day of April this article was published, and when Bayer became aware that the article had been accepted for publication by this journal. Likewise, similar information is missing for B-1928. With respect to Exhibit B-1928, Bayer simply states that the article was recently accepted for publication and that "[T]he Russell article relates to other exhibits on the docket and placed into evidence. However, it is currently is (sic) unavailable to the docket and evidentiary record in this hearing in manuscript form, as accepted for publication in Poultry Science." Further, footnote 6, page 2 of Bayer's Motion, includes a citation to the article and a parenthetical that the publication is "forthcoming."

For these reasons, CVM respectfully opposes Bayer's motion and requests that this motion be denied with respect to Exhibits B-1923 and B-1928.

Respectfully submitted:

  
Nadine Steinberg  
Counsel for the Center for Veterinary Medicine

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**ORDER**

By Motion filed April 28, 2003, Bayer Corporation moves to supplement its document submission under 21 C.F.R. §12.85 and move additional documents (B-1923 through B-1928) into the evidentiary record. The Center for Veterinary Medicine ("CVM") indicates that it does not oppose entry of Exhibits B-1924 through B-1927. Therefore, Bayer's Motion is GRANTED with respect to Exhibits B-1924-1927. CVM has opposed Bayer's Motion with respect to Exhibit B-1923 and B-1928 on the grounds that it is improper to add articles authored by witnesses that differ from the witnesses' written direct testimony after the time has passed for CVM to request cross examination of Bayer witnesses. In that CVM's argument has merit, Bayer's Motion with respect to Exhibit B-1923 and B-1928 is HEREBY DENIED.

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

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

**CERTIFICATE OF SERVICE**

I hereby certify that an original and one copy of CVM's Opposition to Bayer's Motion to Supplement Document Submission under 21 C.F.R. §12.85 and Motion to Move Additional Documents into the Evidentiary Record will be hand delivered this 6th day of May, 2003, to:

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

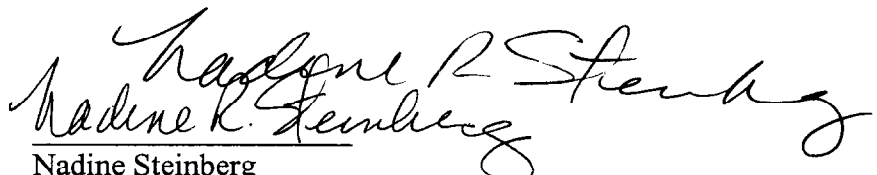
I hereby certify that one copy of the foregoing pleading will be hand delivered and e-mailed this 6th day of May, 2003, to:

The Office of the Administrative Law Judge  
Food and Drug Administration  
Room 9-57, HF-3  
5600 Fishers Lane  
Rockville, MD 20857

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Dated: 5/6/03  
5/6/03

  
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