

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: April 7, 2003
Enrofloxacin for Poultry: Withdrawal)	
of Approval of Bayer Corporation's)	
New Animal Drug Application)	
(NADA) 140-828 (Baytril))	
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_____)	

CVM's Unopposed Motion to Supplement Document Submission under 21 C.F.R. §12.85
and Motion to Enter Additional Document into the Evidentiary Record

The Center for Veterinary Medicine ("CVM" or "the Center") respectfully requests permission to supplement its document submission under 21 C.F.R. §12.85 with the accompanying document. The document has been numbered Government Exhibit G-1800 and has been submitted to Dockets Management Branch along with this Motion. The Center also moves to enter Exhibit G-1800 into the evidentiary record. Counsel for Bayer has indicated that Bayer has no objections to the addition of this document into the docket of this hearing and entry of this document into the evidentiary record of this hearing.

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21 C.F.R. §12.85(c) allows documents to be supplemented with the approval of the Administrative Law Judge under certain circumstances; namely, upon a showing that the material was not reasonably known or available at the time of the original submission, or the relevance of the information could not have reasonably been foreseen at the time of the original submission.¹

The document subject to this Motion is an article by Luo, Sahin, Lin, Michel and Zhang, published in a peer reviewed journal in January 2003, and relates to other exhibits already on the docket and placed into evidence by the Animal Health Institute (A-190) and CVM (G-1465, p. 38). This new article, published in the journal Antimicrobial Agents and Chemotherapy, is the report of the study represented by the two page summary submitted by AHI at A-190, and contained in the slides attached to Dr. McDermott's written direct testimony (G-1465).

CVM believes that this article contains updated information from that submitted in A-190 and G-1465, and for this reason important information will be unavailable to the record if this document is not admitted onto the docket and into the evidentiary record. G-1800 is the complete report of the study conducted by Luo et.al. Currently, only partial information on this important study is on the docket and in the evidentiary record.

Because this document is related to the issues of the hearing, and has been published, acquired, or come to the attention of CVM, since its last document submission, and after its Motion to enter written direct testimony and other evidence into the evidentiary record was filed on December 9, 2002, the document falls under 21

¹ 21 C.F.R. §12.85(c) provides, "Submissions required by...of 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."

C.F.R. §12.85(c), and the Center respectfully moves to add this exhibit to the docket and moves its entry into the evidentiary record of this hearing.

Respectfully submitted,



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