

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 20, 2002  
)  
Enrofloxacin for Poultry: Withdrawal )  
of Approval of Bayer Corporation's )  
New Animal Drug Application )  
(NADA) 140-828 (Baytril) )  
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Center for Veterinary Medicine's Unopposed Motion to Supplement Document  
Submission under 21 CFR §12.85 and Motion to Enter Exhibits G-1486 through G-1495  
into the Evidentiary Record of the Enrofloxacin Hearing

By Order dated December 13, 2002, the Administrative Law Judge granted leave to file a Motion to Supplement the parties' respective §12.85 filings by December 20, 2002. The Center for Veterinary Medicine ("CVM" or "the Center") respectfully submits this Motion to supplement its submission with ten additional documents; Exhibits G-1486 through G-1494 are documents were attached to various government witnesses' testimony and submitted as part of those testimonies on December 9, 2002; Exhibit G-1495, which CVM received for the first time on December 18, 2002, is the document that was subject to Bayer's November 29, 2002, Motion to Compel.

The first nine documents (or these versions of the documents) came to CVM's attention as the witnesses were preparing their written direct testimony, and CVM

believes that they are relevant to the issues in the hearing, therefore, this Motion meets the requirements of 21 C.F.R. §12.85 (c). The tenth document became available to CVM on December 18, 2002, and is relevant to the issues of the hearing. Therefore this document meets the requirements of 21 C.F.R. §12.85 (c).

Additionally, CVM respectfully moves Exhibits G-1486 through G-1494 into the evidentiary record. These nine documents were attached to various CVM witness' testimonies and are, therefore, already part of the evidentiary record. However, with the goal of making reference to these documents easier for all of the participants and the Administrative Law Judge, CVM requests that these exhibits be placed on the evidentiary record under separate exhibit numbers.

Moreover, because Exhibit G-1495 was unavailable at the time CVM submitted its written direct testimony, CVM's December 9, 2002, Motion to Enter Written Direct Testimony and Exhibits and Documents into the Evidentiary Record could not have included a request to enter this document. Therefore, CVM is also respectfully requesting that Exhibit G-1495 be placed on the evidentiary docket. CVM is today providing Bayer and AHI a copy of all of the Exhibits subject to this Motion.

Counsel for Bayer has authorized Counsel for CVM to represent that Bayer has no objections to this Motion.

Respectfully submitted by:

  
Nadine Steinberg  
Counsel for the Center for Veterinary Medicine  
5600 Fishers Lane (GCF-1)  
Rockville, MD 20857  
(303) 827-5050

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**ORDER**

By unopposed Motion filed December 20, 2002, the Center for Veterinary Medicine ("CVM") seeks to Supplement its document submission under 21 C.F.R. §12.85 and enter Exhibits G-1486 through G-1495 into the evidentiary record of this hearing.

The Center for Veterinary Medicine has represented that Bayer's counsel has stated that Bayer has no objections to this Motion. Accordingly, the Center for Veterinary Medicine's Motion to Supplement its document submission under 21 C.F.R. §12.85 and to move Exhibits G-1486 through G-1495 into the evidentiary record of this hearing is HEREBY GRANTED.

DATED this the \_\_\_\_ day of December, 2002.

\_\_\_\_\_  
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 Motion to Supplement its Document Submission under 21 C.F.R. §12.85 and to enter Exhibits G-1486 through G-1495 into the evidentiary record of this hearing was hand delivered this 20th 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 the pleading has been hand delivered and e-mailed, this 20th day of December, 2002, to:

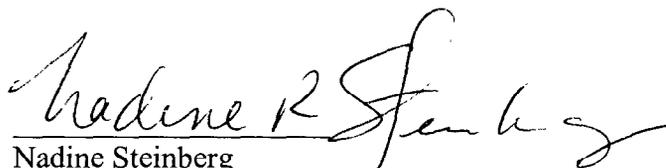
The Office of the Administrative Law Judge  
Food and Drug Administration  
Room 9-57, HF-3  
5600 Fishers Lane  
Rockville, MD 20857

I also certify that a copy pleading was e-mailed and mailed by First Class U.S. mail, this 20th day of December, 2002, 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:** 12/20/02



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