

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

\_\_\_\_\_)  
\_\_\_\_\_)  
\_\_\_\_\_)  
In the Matter of: \_\_\_\_\_)  
\_\_\_\_\_)  
Enrofloxacin for Poultry: Withdrawal \_\_\_\_\_)  
of Approval of Bayer Corporation's \_\_\_\_\_)  
New Animal Drug Application \_\_\_\_\_)  
(NADA) 140-828 (Baytril) \_\_\_\_\_)  
\_\_\_\_\_)  
\_\_\_\_\_)  
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\_\_\_\_\_)  
\_\_\_\_\_)

FDA DOCKET: 00N-1571  
DATE: July 5, 2002

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CVM's Motion to Supplement Document Submission under 21 C.F.R. §12.85

The Center for Veterinary Medicine ("CVM" or "the Center") respectfully requests permission to supplement its document submission under 21 C.F.R. §12.85. These documents are attached to this Motion, in a sealed envelope, for the Administrative Law Judge's review. If the Administrative Law Judge grants CVM's Motion, these documents will be submitted to the Dockets Management Branch, and served on Bayer and the Animal Health Institute. These documents are related to the issues of the hearing and have been published, acquired, or come to the attention of CVM, since it's last submission.

Because there is a great deal of ongoing research into issues related to those in the hearing, CVM anticipates that the parties may need to supplement their document submissions in the future. CVM invites an Order from the Administrative Law Judge as to whether 21 C.F.R. §12.85 imposes an ongoing obligation on the parties to periodically

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update their document submissions, or whether these updated document submissions are discretionary with the parties. If the updated document submissions are discretionary, CVM invites guidance on whether the parties can limit their updated submissions to documents that they wish to use at hearing, or must submit all newly generated, acquired or discovered documents.

Respectfully submitted by:



Nadine Steinberg  
Counsel for the Center for  
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5600 Fishers Lane (GCF-1)  
Rockville, MD 20857  
(301) 827-5050



Enrofloxacin Hearing  
Docket No: 00N-1571

**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 was hand delivered this 5th day of July, 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 Motion, without attachments, has been hand delivered and e-mailed, this 5th day of July, 2002, to:

The Office of the Administrative Law Judge (ddavidso@oc.fda.gov)  
Food and Drug Administration  
Room 9-57, HF-3  
5600 Fishers Lane  
Rockville, MD 20857

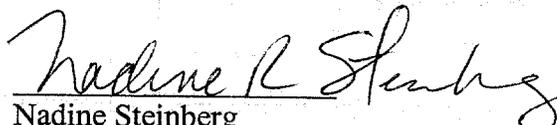
I also certify that a copy of the Motion, without attachments, was e-mailed and sent by U.S. mail, postage prepaid, this 5th day of July, 2002, to:

Robert B. Nicholas (rnicholas@mwe.com)  
McDermott, Will & Emery  
600 13th Street, NW  
Washington, DC 20005

and

Kent D. McClure (KmcClure@ahi.org)  
Animal Health Institute  
1325 G Street, NW, Suite 700  
Washington, DC 20005

Dated: 7/5/02

  
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