

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

9759 03 MAR 17 P3:08

\_\_\_\_\_)  
)  
)  
In the Matter of: ) FDA DOCKET: 00N-1571  
) DATE: March 17, 2003  
Enrofloxacin for Poultry: Withdrawal )  
of Approval of Bayer Corporation's )  
New Animal Drug Application )  
(NADA) 140-828 (Baytril) )  
)  
)  
\_\_\_\_\_)

**Center for Veterinary Medicine's Request to Submit Rebuttal Evidence**

Pursuant to Orders dated April 26, 2002,<sup>1</sup> and March 3, 2003, the Center for Veterinary Medicine (CVM) has been granted the right to request submission of rebuttal evidence. CVM hereby respectfully requests permission to submit rebuttal evidence for the reasons specified below.

In several written direct testimonies of respondent Bayer Corporation and Animal Health Institute (collectively, "Bayer"), Bayer argues that the human National Antimicrobial Resistance Monitoring System (NARMS) surveillance program and its data are flawed because of issues relating to protocol design and protocol compliance. Bayer concludes that, because of those purported flaws, NARMS data cannot provide meaningful estimates of the levels and trends of fluoroquinolone-resistant *Campylobacter* infections.

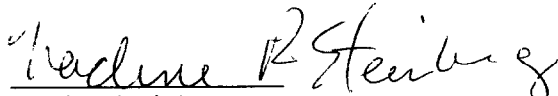
<sup>1</sup> The April 26, 2002, Order states: "Under sequential submissions of evidence, only the side that goes first [i.e., CVM] has a right to seek rebuttal based on the content of the opposing side's submission."

00N-1571

MO 39

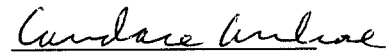
The flaws, however, are in Bayer's assessment. CVM seeks to provide rebuttal evidence to address why Bayer's criteria for assessing NARMS are inapplicable or immaterial and why Bayer's assertions regarding protocol compliance in NARMS are misinformed. The purpose of CVM's rebuttal evidence on the human NARMS surveillance program is to focus what CVM believes is the blurred lens through which Bayer has examined this program, which will consequently invalidate Bayer's attacks on the utility of NARMS in estimating fluoroquinolone-resistant campylobacteriosis.

Respectfully submitted, this 17th day of March by:

  
Nadine Steinberg

  
Robert Spiller, Jr.

  
Claudia Zuckerman

  
Candace Ambrose  
Counsel for Veterinary Medicine

**CERTIFICATE OF SERVICE**

I hereby certify that an original and one copy of the foregoing Center for Veterinary Medicine's Request for Rebuttal was hand delivered this 17th day of March, 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 Center for Veterinary Medicine's Request for Rebuttal has been hand delivered and e-mailed, this 17th day of March, 2003, to:

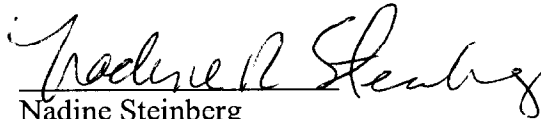
The Office of the Administrative Law Judge  
Food and Drug Administration  
Room 9-57, HF-3  
5600 Fishers Lane  
Rockville, MD 20857

I also certify that a copy of the Center for Veterinary Medicine's Request for Rebuttal was e-mailed and mailed by First Class U.S. mail, this 17th day of March, 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: 3/17/03

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