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)	FDA DOCKET: 00N-1571 DATE: March 17, 2003

Center for Veterinary Medicine's Request to Submit Rebuttal Evidence

Pursuant to Orders dated April 26, 2002,[1] 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.

[1] 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."

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

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 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