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

1394 '03 MAR 24 P3:35

In the Matter of:	FDA DOCKET: 00N-1571
	DATE: March 24, 2003
Enrofloxacin for Poultry: Withdrawal of Approval of Bayer Corporation's New Animal Drug Application (NADA) 140-828 (Baytril)	

Center for Veterinary Medicine's Supplement to its Request to Submit Rebuttal Evidence

Pursuant to the Order dated March 19, 2003, the Center for Veterinary Medicine (CVM) hereby supplements its request, made on March 17, 2003, to submit rebuttal evidence. CVM respectfully requests the opportunity to submit the written rebuttal testimony of Dr. Robert V. Tauxe,[1] in response to certain testimony by AHI witness Dr. Bradley DeGroot.

CVM intends to show, through the testimony of Dr. Tauxe, that specific criticisms of the human NARMS surveillance program in Dr. Bradley DeGroot's testimony (Exhibit A-200) are inapplicable, immaterial, or misinformed and that those criticisms provide no basis for undermining the utility of the human NARMS surveillance program, data from human NARMS, or analyses conducted on those data. CVM seeks to submit rebuttal testimony on the following two issues raised in Dr. DeGroot's testimony: (a) the effect of including ill people seeking medical care in the human NARMS surveillance program (DeGroot (A-200): P.25, L.7 to P.27,

[1] Dr. Tauxe has provided written direct testimony for CVM, which can be found on the Docket as Exhibit G-1475.

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L.4 and P.29, L.17-L.24); and (b) the effect of not collecting data on prior antimicrobial use and foreign travel in the human NARMS surveillance program (DeGroot (A-200): P.19, L.16 to P.20, L.9 and P.29, L.17-L.24).

CVM could not have reasonably anticipated the testimony that CVM seeks to rebut. Routine public health surveillance (such as the human NARMS surveillance program) is not conducted by the methods that form the basis for Dr. DeGroot's critique of human NARMS. Dr. DeGroot's testimony reveals a general confusion between methods of laboratory-based public health surveillance and methods of more detailed epidemiological studies that are conducted as a result of findings from surveillance programs. That non-interchangeable methods exist for different types of epidemiological endeavors is so fundamental that CVM could not be expected to anticipate that Dr. DeGroot, who according to his curriculum vitae earned a Ph.D. in epidemiology, would analyze the methodology of a surveillance program with criteria inapplicable to surveillance programs.

More specifically, CVM intends to show through rebuttal testimony that: (1) including ill people seeking medical care in the human NARMS surveillance program is not a bias; (2) data from human NARMS or analyses conducted on those data are not rendered uninterpretable or meaningless because the human NARMS surveillance program is based on ill people seeking medical care; (3) estimates of the levels and trends of fluoroquinolone-resistant *Campylobacter* cases can be generalized beyond the samples tested in human NARMS even though human NARMS is based on ill people seeking medical care; (4) not collecting data on prior antimicrobial use and foreign travel in the human NARMS surveillance program is not a bias; (5) data from human NARMS or analyses conducted on those data are not rendered uninterpretable or meaningless because the human NARMS surveillance program does not collect data on prior

antimicrobial use and foreign travel; and (6) estimates of the levels and trends of fluoroquinolone-resistant *Campylobacter* cases can be generalized beyond the samples tested in human NARMS even though human NARMS does not collect data on prior antimicrobial use and foreign travel.

CVM anticipates that the specific issues described above can be addressed in fewer than ten pages of written testimony, not including any references.

Respectfully submitted, this 24th day of March by:

Claudia J. Zuckerman
Nadine Steinberg
Counsel for Veterinary Medicine

CERTIFICATE OF SERVICE

I hereby certify that an original and one copy of the foregoing Center for Veterinary Medicine's Supplement to its Request to Submit Rebuttal Evidence was hand-delivered this 24th 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 pleading has been hand-delivered and electronically transmitted this 24th 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 pleading was electronically transmitted and deposited in First Class U.S. mail this 24th day of March 2003 to:

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Dated: 03/24/03

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