

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION 0391
DEPARTMENT OF HEALTH AND HUMAN SERVICES

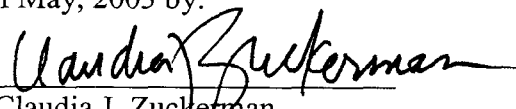
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In the Matter of:) FDA DOCKET: 00N-1571
) DATE: May 5, 2003
)
Enrofloxacin for Poultry: Withdrawal)
of Approval of Bayer Corporation's)
New Animal Drug Application)
(NADA) 140-828 (Baytril))
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Center for Veterinary Medicine's Unopposed Motion to Substitute Original Signed Written Declaration of Lynn Armstrong for the Signed Facsimile Version of Declaration of Lynn Armstrong filed May 2, 2003

The Center for Veterinary Medicine ("the Center" or "CVM") respectfully moves to substitute the original signed declaration of Lynn Armstrong for the facsimile version (signed) of Lynn Armstrong's declaration. Although Ms. Armstrong signed and sent, via federal express, her signed declaration to CVM on Thursday, May 1, 2003, that original declaration did not arrive at the Center in time to include it in CVM's May 2, 2003, Supplemental Motion to Reinstate Documents and Written Direct Testimony into the Evidentiary Record and Add Government Exhibits G-1802 and G-1803 and G-1804 into the Evidentiary Record. Robert Nicholas, counsel for Bayer, has indicated that this Motion is unopposed.

Respectfully submitted, this 5th day of May, 2003 by:



Claudia J. Zuckerman
Counsel for the Center for Veterinary Medicine
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
(301) 827-5050

00N-1571

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ORDER

On May 5, 2003, the Center for Veterinary Medicine filed an Unopposed Motion to Substitute Original Signed Written Declaration of Lynn Armstrong for the Signed Facsimile Version of Declaration of Lynn Armstrong filed May 2, 2003. The Center's Motion is HEREBY GRANTED.

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 Unopposed Motion to Substitute Original Signed Written Declaration of Lynn Armstrong for the Signed Facsimile Version of Declaration of Lynn Armstrong was hand-delivered this 5th day of May 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 e-mailed this 5th day of May 2003 to:

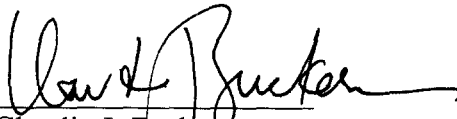
The Office of the Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

I also certify that a copy of this pleading was e-mailed and mailed by First Class U.S. mail this 5th day of May 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: 5 May 03



Claudia J. Zuckerman
Counsel for the Center for
Veterinary Medicine
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
(301) 827-7144

3. By letter dated May 7, 2002, from Nathan A. Beaver from McDermott, Will & Emery, the CDC FOIA Office received a request (FOIA request # 02-0578) for the following:
 1. A copy of the protocol and raw data pertaining to the sentinel county survey conducted in selected counties in 1989-1990, where "331 *Campylobacter* isolates were isolated from patients with diarrhea and submitted to CDC for antimicrobial susceptibility testing." As reported in "Update: National Antimicrobial Resistance Monitoring System (NARMS) activities pertaining to fluoroquinolone resistance." Please include case reports, laboratory records/results and all pertinent information gathered to document the findings as presented in the reporting of the results.
 2. A copy of the protocol and raw data pertaining to the sentinel county survey as reported in the abstract entitled, "The Burden of *Campylobacter jejuni* Infections: A Target for Early Treatment?" by Sobel J., Tauxe R., et al. Please include case reports, laboratory records/results and all pertinent information gathered to document the findings as presented in the abstract.
 3. Copies of the final reports on file at CDC for both of the above studies.

Please also provide information on the time frame of the testing; when the isolates were originally taken, how they were stored, when they were tested for antimicrobial susceptibility, results of all antimicrobials tested and methods for confirming the campylobacter spp. being tested.

4. In response to Mr. Beaver, my office sent a letter dated November 6, 2002, stating:

The electronic data file containing raw data you requested was transmitted electronically to nbeaver@mwe.com. Program staff inform me that they do not have a copy of the protocol but the methods are described in a manuscript by Charlotte Patton, et al. titled "Common Somatic O and Heat-Labile Serotypes among *Campylobacter* Strains from Sporadic Infections in the United States" (enclosed). The request items 2 and 3 are identical in that this data was used for both reports. Finally, there is no final report on file at CDC for this study.

The following additional information you requested was provided by our lab:

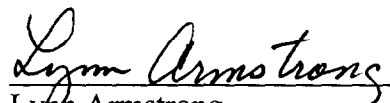
The methods used to identify species were detailed on page 1526 of the manuscript (last paragraph of "Bacterial strains"). The isolates were stored in the usual manner. A single colony picked from a non-selective blood agar plate was transferred to a fresh blood agar and the plate was incubated at 42 degrees C for 24 hours. A sterile cotton swab was used to harvest growth which was suspended in trypticase soy broth with 20% glycerol, frozen rapidly in a dry ice/alcohol bath, and stored at minus 70 degrees C.

Under authority of the Freedom of Information Act at 5 U.S.C. 552(b)(6) and the Department's implementing regulations at 45 C.F.R. 5.67, names and other information, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, were deleted.

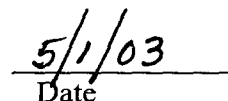
5. The reference to "request items 2 and 3" in Paragraph 4, above, should have stated "request items 1 and 2."
6. Since the time of the November 6, 2002, response to Mr. Beaver's FOIA request, CDC has searched its archives at the Federal Records Center and located a copy of the protocol used in the study described by Patton, et al. and this protocol was sent to Mr. Beaver on January 17, 2003 (see number 7 below).
7. On December 13, 2002, Mr. Beaver sent a FOIA appeal of the November 6, 2002, response to his initial May 7, 2002, request for information under the Freedom of Information Act to the Deputy Assistant Secretary for Public Affairs at the Department of Health and Human Services. My office received this appeal on January 7, 2003.
8. On January 17, 2003, at the request of the PHS FOIA Officer, I sent additional responsive records to Mr. Beaver in response to his December 13, 2002, appeal of 02-0578. These documents were the protocol and key that had been located at the Federal Records Center.
9. On February 14, 2003, Mr. Beaver supplemented his appeal of the November 6, 2002, CDC response, requesting:
 1. Identification of when antimicrobial susceptibility testing was performed.
 2. Identification of whether the isolates have been tested for antimicrobial susceptibility more than once.
 3. Identification of the species of the isolates.
 4. Identification of the columns of data in the dataset that are not identified on the questionnaire.
 5. Any raw laboratory data sheets outlining microbial and susceptibility testing included in the dataset.
 6. Confirmation that the dataset provided to me is responsive to my request for the dataset on the Sentinel County Survey, since it does not comport with another dataset provided to FDA in response to a similar request for data.

10. A response to Mr. Beaver's December 13, 2002, FOIA appeal, and February 14, 2003, supplement is pending with the PHS appeals office.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.



Lynn Armstrong
CDC/ATSDR FOIA Officer
Office of Communication



Date