

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

2550 '03 MAY 13 P3:24

In the Matter of:

**Enrofloxacin for Poultry:  
Withdrawal of Approval of  
New Animal Drug Application  
NADA 140-828**

**FDA DOCKET: 00N-1571**

**May 13, 2003**

**RESPONDENT BAYER CORPORATION'S AND  
PARTICIPANT ANIMAL HEALTH INSTITUTE'S JOINT MOTION TO WITHDRAW  
WRITTEN DIRECT TESTIMONY SUBMITTED BY DRS. GREGORY A. BURKHART  
AND BRADLEY D. DEGROOT**

On December 13, 2002, Bayer Corporation ("Bayer") and the Animal Health Institute ("AHI") filed the written direct testimony of Dr. Gregory A. Burkhart (B-1900) and Dr. Bradley D. DeGroot (A-200), respectively. This testimony was based in part on the witnesses' review of raw data obtained by Bayer from the Centers for Disease Control and Prevention ("CDC") through the Freedom of Information Act ("FOIA") process. These data files include specifically data and information related to the CDC National Antimicrobial Resistance Monitoring System ("NARMS") program and CDC's Sentinel Counties Survey.

On February 14, 2003, Bayer learned that the data files provided by CDC to Bayer that these Bayer and AHI witnesses relied on may have been converted incorrectly from the original SAS format to Excel format and that the conversion may have caused inaccuracies in the data.

On March 18, 2003, CDC provided the original SAS format data files to Bayer. In light of the newly produced files, Drs. Burkhart and DeGroot were asked to review their testimony to determine whether their testimony was still accurate.

On May 5, 2003, Bayer moved to withdraw and correct certain portions of the testimony of Drs. Burkhart and DeGroot and explained these portions in declarations submitted by both. Administrative Law Judge Davidson denied the admission into evidence of these declarations but requested that Bayer submit a motion to withdraw the relevant affected portions of testimony.

These matters are more fully set forth in Bayer's *Response To CVM's Motion To Supplement Document Submission Under 21 C.F.R. § 12.85 And Motion To Enter Exhibit G-1801 Into The Evidentiary Record And Motion To Supplement Document Submission Under 21 C.F.R. § 12.85 And Motion To Enter Exhibits B-1937 - B-1941 Into The Evidentiary Record* filed on May 5, 2003.

**Written Direct Testimony of Dr. Greg Burkhart**

As noted in Dr. Burkhart's Declaration, Dr. Burkhart received and analyzed an Excel format version of the Sentinel Counties Survey, which he relied on in drafting his testimony. This data file, as originally provided to Bayer by CDC, contained inaccuracies. Bayer and AHI therefore move to withdraw the only portion of Dr. Burkhart's testimony that addresses his review of this data set:

- P. 42 L. 25-28. - "Of the 471 samples ... a percentage of 1.5%."

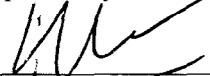
All other data files reviewed by Dr. Burkhart and addressed in his testimony were based on a review of the original SAS format files. None of Dr. Burkhart's overall conclusions are affected by the inaccuracies.

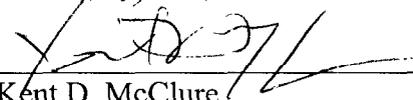
**Written Direct Testimony of Dr. Bradley DeGroot**

As noted in Dr. DeGroot's Declaration, Dr. DeGroot analyzed and compared the NARMS data files in the Excel format with the new SAS data files provided by CDC. Dr. DeGroot discovered differences between the two types of files. However, as noted by Dr. DeGroot, "[t]hese differences between the data sets in Excel and SAS format affect only a few points of my testimony, but do not effect overall my conclusions in my testimony." DeGroot Declaration at 4. Based on Dr. DeGroot's review, Bayer and AHI are now seeking to withdraw the following portions of Dr. DeGroot's testimony:

- A-200 P. 37 L 1 - P. 38 L. 3. - "While the patterns ... in the month column."
- A-200 P. 41 L 22 - P. 42 L 5. - "Twenty-nine percent ... specimen collection date."<sup>1</sup>
- A-200 P. 67 L 5 - 9. - "Values and observations ... not distorting data."

Respectfully submitted,

  
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<sup>1</sup> As described in Dr. DeGroot's declaration, although the numbers stated in the testimony are no longer accurate, the conclusions drawn in his testimony have not changed.

**CERTIFICATE OF SERVICE**

I hereby certify that an original and one copy of Respondent Bayer Corporation's And Participant Animal Health Institute's Joint Motion To Withdraw Written Direct Testimony Submitted By Drs. Gregory A. Burkhardt and Bradley D. DeGroot was hand delivered this 13th day of May, 2003 to:

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane (Room 1061)  
Rockville, MD 20852

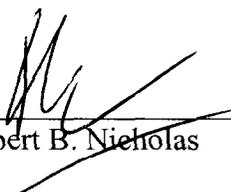
I also certify that a copy of Respondent Bayer Corporation's And Participant Animal Health Institute's Joint Motion To Withdraw Written Direct Testimony Submitted By Drs. Gregory A. Burkhardt and Bradley D. DeGroot was e-mailed and also mailed, postage pre-paid, this 13th day of May, 2003 to:

Kent D. McClure  
Animal Health Institute  
1325 G Street, N.W., Suite 700  
Washington, D.C. 20005

Nadine R. Steinberg, Esquire  
Food and Drug Administration  
Office of General Counsel (CGF-1)  
5600 Fischers Lane, Room 7-77  
Rockville, MD 20857

I also certify that a courtesy copy of the foregoing Joint Motion was hand delivered and e-mailed this 13th day of May, 2003 to:

Administrative Law Judge Davidson  
C/o Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane (Room 1061)  
Rockville, Maryland 20852

  
\_\_\_\_\_  
Robert B. Nicholas

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**ORDER**

**UPON CONSIDERATION** of Respondent Bayer Corporation's And Participant Animal Health Institute's Joint Motion To Withdraw Written Direct Testimony Submitted By Drs. Gregory A. Burkhart and Bradley D. DeGroot, is hereby

**ORDERED** that the following portions of the testimony of Dr. Greg A. Burkhart and Dr. Bradley D. DeGroot are withdrawn:

- B-1900 P. 42 L. 25-28. - "Of the 471 samples ... a percentage of 1.5%."
- A-200 P. 37 L 1 - P. 38 L. 3. - "While the patterns ... in the month column.";
- A-200 P. 41 L 22 - P. 42 L 5. - "Twenty-nine percent ... specimen collection date.";
- A-200 P. 67 L 5 - 9. - "Values and observations ... not distorting data."; and

DATED this the \_\_\_\_ day of May, 2003.

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Daniel J. Davidson  
Administrative Law Judge