

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

2533 '03 MAY 12 P4:10

In the Matter of:

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

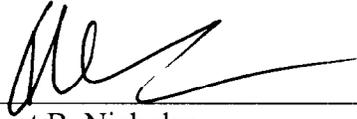
FDA DOCKET: 00N-1571

Date: May 12, 2003

**RESPONDENT BAYER'S UNOPPOSED MOTION TO SUBSTITUTE ORIGINAL
SIGNATURE PAGES FOR THE FACSIMILE VERSIONS FOR THE DECLARATIONS
OF MICHAEL VAUGHN AND GREG BURKHART**

Respondent Bayer Corporation ("Bayer") respectfully moves to substitute the attached original signature pages of Bayer declarants Drs. Michael Vaughn and Greg Burkhardt in place of the facsimile signature pages filed with their declarations on May 5, 2003. Despite best efforts, the original signature pages were not available to include 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. Bayer Counsel has consulted with Counsel for CVM, and CVM does not oppose this motion.

Respectfully submitted, this 12th day of May by:



Robert B. Nicholas
James H. Sneed
Gregory A. Krauss
M. Miller Baker
McDERMOTT, WILL & EMERY
600 Thirteenth Street, N.W.
Washington, D.C. 20005
(202) 756-8000

Attorneys for Bayer

CERTIFICATE OF SERVICE

I hereby certify that an original and one copy of the foregoing Respondent Bayer's Unopposed Motion To Substitute Original Signed Signature Pages for the Facsimile Versions for the Declarations of Drs. Michael Vaughn and Greg Burkhart was hand delivered this 12th day of May, 2003 to:

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

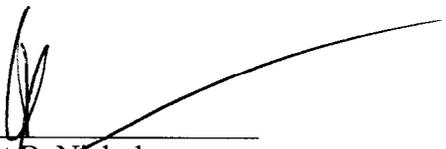
I also certify that a copy of Respondent Bayer's Unopposed Motion To Substitute Original Signed Signature Pages for the Facsimile Versions for the Declarations of Drs. Michael Vaughn and Greg Burkhart was e-mailed and also mailed, postage pre-paid, this 12th day of May, 2003 to:

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 Fishers Lane, Room 7-77
Rockville, MD 20857

I also certify that a courtesy copy of the foregoing Motion was hand delivered and e-mailed this 12th 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

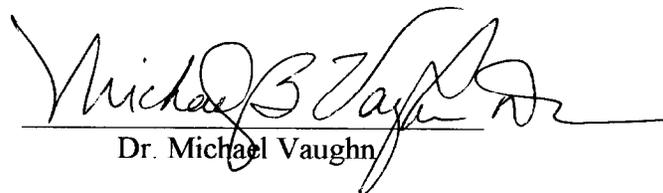
On May 12, 2003, Respondent Bayer Corporation filed an Unopposed Motion to Substitute Original Signature Pages for the Facsimile Versions for the Declarations of Drs. Michael Vaughn and Greg Burkhart. The motion seeks to replace original signature pages for the facsimile versions that were filed May 5, 2003 with the Declarations of Drs. Michael Vaughn and Greg Burkhart. Bayer's Motion is HEREBY GRANTED and the Dockets Management Branch is directed to substitute the original pages for the facsimile pages.

DATED this the ___ day of May, 2003.

Daniel J. Davidson
Administrative Law Judge

I declare under penalty of perjury that the foregoing is true and correct.

Date: May 5, 2003

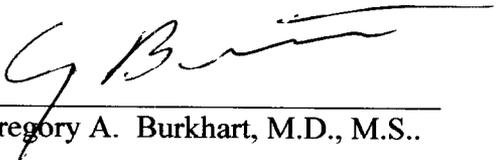


Dr. Michael Vaughn

more commonly referred to as the "Friedman dataset". Both of these files were in the SAS format, and I reviewed and analyzed them in the SAS format.

4. On approximately December 6, 2002, I received a copy of Bayer11.4(FOIA 02-0578).xls from Dr. Vaughn. This file is more commonly referred to as the "Sentinel County Study." I received this file in an Excel format, and reviewed and analyzed it in this same format.
5. Therefore, the only section of my testimony which is based on an analysis of an Excel format file is that related to the Sentinel County Study at P. 42 L. 19-30. I have reviewed this section of my testimony and based on the fact that CDC has represented that the Excel format is an inaccurate conversion from the original SAS file, I am withdrawing the section at L. 25 beginning with the sentence "Of the 471 samples...." to L. 28 "... this would give a percentage of 1.5%."
6. I represent that to the best of my knowledge and belief, the remainder of my testimony is truthful and accurate.
7. I declare under penalty of perjury that the foregoing is true and correct.

Date: May 5, 2003



Gregory A. Burkhart, M.D., M.S..