

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

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In the Matter of:)

) FDA DOCKET: 00N-1571
) DATE: November 26, 2002
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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 Withdraw Government Exhibit
G-1557 and Add Government Exhibit G-1572

On October 31, 2002, the Center for Veterinary Medicine ("CVM" or "the Center") submitted a Motion to Withdraw Government Exhibit G-1557 and Add Government Exhibit G-1572. After consideration of CVM's Motion and Bayer's response to that Motion, on November 14, 2002, the Administrative Law Judge Ordered the parties to confer and submit a joint memorandum to resolve one outstanding issue on the Motion. The parties did confer and agreed, and submitted a Joint Memorandum on November 25, 2002. A copy of that Joint Memorandum is attached to this Motion. The November 14, 2002, Order denied CVM's original Motion to withdraw Exhibit G-1557 and add Exhibit G-1572 "without prejudice to resubmission, if it is appropriate to do so after November 25, 2002." Counsel for CVM has consulted with Counsel for Bayer, who

has authorized Counsel for CVM to represent that Bayer has no objections to this renewed Motion. CVM again moves to Withdraw Exhibit G-1557 and add G-1572 to Docket No. 00N-1571.

For the reasons set out in detail in its motion of October 31, CVM moves to withdraw Exhibit G-1557 because that exhibit contains personal identifiers such as the patients' initials, and, in a few cases, the patients' occupations. Taken together with other information available such as the sex, age and county of residence of the patients, it could be possible for someone to specifically identify the patients in the study. 21 C.F.R. §20.63(a) states, "The names or other information which would identify patients or research subjects in any medical or similar report, test, study, or other research project shall be deleted before the record is made available for public disclosure." Removal of this information is also consistent with the Administrative Procedure Act's protection against disclosure of "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." *See* 5 U.S.C. 552(b)(6).

Respectfully submitted:



Nadine Steinberg
Counsel for the Center for Veterinary Medicine
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
(303) 827-5050

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ORDER

By Motion filed October 31, and renewed without opposition November 26, 2002, the Center for Veterinary Medicine ("CVM") seeks to withdraw Exhibit G-1557 from Docket 00N-1571, and seeks to add Exhibit G-1572, which is a revised version of Exhibit G-1557. CVM seeks to withdraw Exhibit G-1557 in order to protect the personal privacy of patients enrolled in a Center for Disease Control and Prevention study.

The Center for Veterinary Medicine's Motion to Withdraw Exhibit G-1557 and Add Exhibit G-1572 is HEREBY GRANTED.

DATED this the ____ day of November, 2002.

Daniel J. Davidson
Administrative Law Judge

Food and Drug Administration
5600 Fishers Lane (HF-3)
Room 9-57
Rockville, MD 20857
Telephone: (301) 827-7120
FAX: (303) 594-6800

CERTIFICATE OF SERVICE

I hereby certify that an original and one copy of the foregoing Center for Veterinary Medicine's Motion to Withdraw Government Exhibit G-1557 and to Add Government Exhibit G-1572 was hand delivered this 26th day of November, 2002, 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 26th day of November, 2002, 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 pleading was e-mailed and mailed by First Class U.S. mail, this 26th day of November, 2002, 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: 11/26/02



Nadine Steinberg
Counsel for the Center for
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5600 Fishers Lane (GCF-1)
Rockville, MD 20857
(301) 827-5050

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

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In the Matter of:)

) FDA DOCKET: 00N-1571
) DATE: November 25, 2002

) Enrofloxacin for Poultry: Withdrawal
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Joint Memorandum Reporting Resolution of the Issue of Whether Exhibit G-1572 Accurately Represents the Material in Exhibit G-1557

On October 31, 2002, the Center for Veterinary Medicine ("the Center" or "CVM") filed a motion seeking to withdraw Government Exhibit G-1557 to protect personal privacy. In its place, CVM sought to add Government Exhibit G-1572, which was a copy of the same document with the following three changes: First, the personal identifiers, in the form of a column containing patient initials, were deleted. Second, the descriptions of six patients' occupations were modified to ensure that patient privacy was protected. Third, in the course of preparing the motion, the Center discovered that when it printed out certain Excel files, some of the data contained in the electronic file may not have printed. Therefore, the paper copy of Exhibit G-1572 submitted by CVM contains any additional information already contained in the electronic Excel file of the original document, G-1557, which had previously been submitted to Dockets Management Branch.

On November 12, 2002, Bayer Corporation ("Bayer") submitted its Response to CVM's Motion stating that it did not object to replacing G-1557 with G-1572 as long as CVM provides Bayer an electronic copy of G-1572 and provides certain information about the document, namely the data column variables and information on the genesis of the data set.

The November 14, 2002, Order stated that "[i]ssues relating to the admissibility of all exhibits will be dealt with, if and, when they are moved into evidence..." and further ordered that CVM and Bayer confer and resolve the issue of whether Exhibit G-1572 accurately reflects the material contained in Exhibit G-1557, with patient privacy information removed.

On November 19, 2002, CVM's counsel forwarded an electronic Excel file of G-1572, by e-mail attachment, to Robert Nicholas, Bayer's counsel. On November 21, 2002, CVM and Bayer counsel met to confer about the whether Exhibit G-1572 accurately reflects the material contained in Exhibit G-1557, with patient privacy information removed, and agreed that it did.

Respectfully Submitted:



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and



Robert B. Nicholas
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600 13th Street, NW
Washington, DC 20005
(301) 756-8000

CERTIFICATE OF SERVICE

The parties hereby certify that an original and a copy of the foregoing Joint Memorandum was hand delivered this 25th day of November, 2002, to:

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

and

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

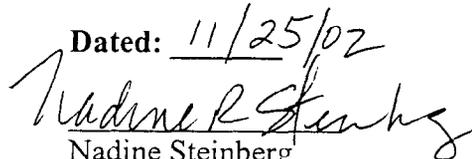
We also certify that a copy of the Memorandum was e-mailed and also mailed, postage prepaid, this 25th day of November, 2002, to:

Kent D. McClure
Animal Health Institute
1325 G Street, NW, Suite 700
Washington, DC 20005

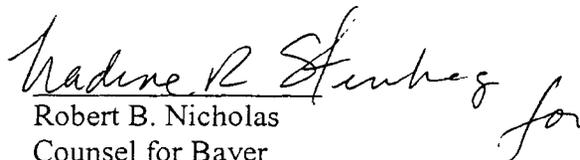
We also certify that a copy of this Memorandum was e-mailed, this 25th day of November, 2002, to:

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

Dated: 11/25/02



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