

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

In the Matter of:)
)
)
) FDA DOCKET: 00N-1571
) DATE: October 31, 2002
)
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 Motion to Withdraw Government Exhibit G-1557 and
Add Government Exhibit G-1572

On July 26, 2002, the Center for Veterinary Medicine ("CVM" or "the Center") submitted Exhibit G-1557 to Docket No. 00N-1571 as part of its response to Bayer's discovery requests. Exhibit G-1557 is a printout of raw data from an electronic document obtained from the Centers for Disease Control and Prevention ("CDC"). This printout includes information that could be used to help identify individual patients, and this identifying information was not properly removed before CVM submitted the exhibit to Docket No. 00N-1571. This information includes patient initials and, in approximately six cases, specific descriptive identifiers regarding patient occupations. The Center now moves to withdraw Exhibit G-1557 from Docket No. 00N-1571. The Center also moves

to add Exhibit G-1572 to Docket No. 00n-1571 to replace Exhibit G-1557. Exhibit G-1572 is a print-out of raw data from the CDC's electronic document in which CVM has removed the column containing the patients' initials and has modified, in approximately six cases, patient occupations to accommodate personal privacy concerns.

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).

Counsel for CVM has consulted counsel for Bayer; however, no agreement on this motion could be reached.

In the course of preparing this Motion, CVM became aware that the Exhibit G-1557, along with six other exhibits that are also printouts of computer (Excel) files, may not show all of the data found in each cell in the electronic versions of those documents. CVM has addressed this issue with respect to proposed Exhibit G-1572, which is subject

to this Motion. In the near future, CVM plans to move to submit supplemental exhibits to Dockets Management Branch for the remaining six exhibits.¹

Respectfully submitted:



Nadine Steinberg
Counsel for the Center for Veterinary Medicine
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Rockville, MD 20857
(303) 827-5050

¹ CVM previously submitted to Dockets Management Branch Compact Disks with the Excel files, along with paper versions, for at least five of the seven exhibits that are Excel file printouts. Although CVM's recollection is that it submitted all of the seven Excel files to Dockets Management Branch, Dockets Management Branch has currently only been able to confirm receipt of five of the seven Excel files.

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ORDER

By Motion filed October 31, 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 is HEREBY GRANTED and the Center for Veterinary Medicine's Motion to 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 31st day of October, 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 31st day of October, 2002, to:

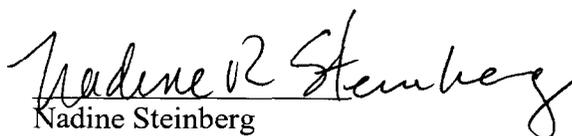
The Office of the Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

I also certify that a copy pleading was e-mailed and mailed by First Class U.S. mail, this 31st day of October, 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: 10/31/02



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