

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  
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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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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.

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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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**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

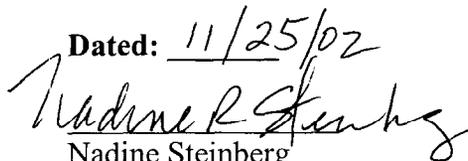
We also certify that a copy of the Memorandum was e-mailed and also mailed, postage prepaid, this 25th day of November, 2002, to:

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

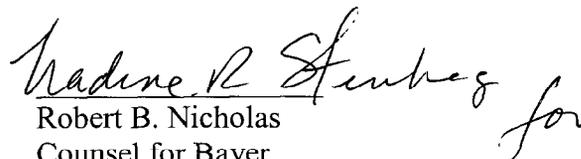
We also certify that a copy of this Memorandum was e-mailed, this 25th day of November, 2002, to:

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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