

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

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In the Matter of:)
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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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_____)

FDA DOCKET: 00N-1571
DATE: November 14, 2002

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. Respondent, Bayer, does not object but questions whether the contents of Exhibit G-1572, equals Exhibit G-1557 minus only the patient privacy information. The Respondent also seeks additional information which would aid in the understanding and evaluation of the information contained in the Exhibit.

The Motion to Withdraw Exhibit G-1557 will be denied pending resolution of the nature of the changes embodied in Exhibit G-1572. For now, Exhibit G-1557 will be classified as confidential in order to protect the patient privacy. Issues relating to the admissibility of all exhibits will be dealt with, if and, when they are moved into evidence with the submissions now due on December 9 and December 13, 2002.

It is **Ordered** that Bayer and CVM are to confer and resolve the issue of whether Exhibit No. G-1572 accurately reflects the material contained in Exhibit No. G-1557, with patient privacy information removed. On or before November 25, 2002, the Bayer and CVM will jointly submit a detailed memo explaining the resolution of this issue. In the meantime, Exhibit No. G-1557 will be marked "Confidential" in order to protect the patient information

And, it is **Further Ordered**, That the motion, to withdraw Exhibit No. G-1557, and to add Exhibit No. G-1572, is denied without prejudice to resubmission, if it is appropriate to do so after November 25, 2002.

DATED this the 14th day of November, 2002.

S/S Daniel J. Davidson
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Administrative Law Judge
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