

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: August 16, 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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ORDER

By motion filed August 9, 2002, Respondent Bayer Corporation (Bayer) is seeking reconsideration and clarification of the Order of August 6, 2002. The Center for Veterinary Medicine (CVM) filed its reply in opposition thereto on August 14, 2002.

More specifically, Bayer:

- seeks clarification as to whether the August 6, 2002 Order protects Bayer's confidential discovery documents responsive to CVM's discovery requests;
- seeks clarification, pursuant to 21 CFR § 12.85(f), of the distinction between discovery documents and those required to be submitted to the docket;
- seeks clarification, pursuant to 21 CFR § 12.85(f), of the difference between documents submitted pursuant to 21 CFR § 12.85 and other docket filings;
- seeks reconsideration of the August 6, 2002 requirements that Bayer particularize its claims of confidentiality and undertake redaction of confidential documents;
- seeks reconsideration of paragraph 6 of the August 6, 2002 Order to include a limitation that disclosure of confidential documents and information can be made only if such confidential documents and information are reasonably related to the recipient's area of expertise or testimony; and

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seeks reconsideration of the Written Assurance included in the August 6, 2002 Order to include statements acknowledging that disclosure of confidential documents and information would result in irreparable harm to the Submitting Party and that the Written Assurance is a binding and enforceable contract between the Signatory and the Submitting Party.

The Motion for Reconsideration and Clarification of August 6, 2002 Order is GRANTED.

UPON RECONSIDERATION, it appears that Respondent is concerned that the protective order of August 6 does not clearly protect against public disclosure of all confidential information. The order should cover any and all documents or things designated as "CONFIDENTIAL" (as well as the material and/or data contained therein). The order will be so modified.

21 CFR § 12.85 is designed to replace the need for discovery by requiring the submission of all relevant information at the outset of the proceeding. The fact that the parties to this proceeding have elected to use discovery in addition to the Section 12.85 requirements, in no way eases their obligations under that section.

The fact that information is presented in response to discovery requests does not alter the basic character of the material as it relates to the issues in this proceeding. Pursuant to the order of April 10, 2002, Bayer was required to submit all such information under the provisions of 21 CFR § 12.85 (b) by April 22. If the confidential material (which is apparently now causing some confusion) was available and relevant, it should have submitted at that time. If the material was not known or available, or is not relevant to the issues, Respondent has/had appropriate remedies within the framework of this proceeding. As far as the Administrative Record is concerned, there is no difference between material submitted under Section 12.85 and other filings.

Within the framework of all Formal Public Hearings is the need for public access to information that is not protected from disclosure. To this end, the parties are not free to designate broad areas of information as confidential, without some kind of oversight. The order of August 6 attempts to insure public access to everything that is not properly subject to protection.

The modification of the Protective Order proposed by Respondent would limit access to confidential information to employees and outside persons only when related to their testimony. The proposed change is too limiting because would preclude access by persons providing technical and other assistance who are not witnesses.

The suggested additional language Respondent seeks to add to the Written Assurance form is unacceptable because it attempts to prejudge issues which may not be provable in a court of law.

Upon reconsideration, **It is ordered**, that Protective Order dated August 6, 2002 is modified so as to provide protection from public disclosure to all information and material labeled as "Confidential."

And **It is Further Ordered**, that Respondent's motion is DENIED in all other respects.

DATED the 16th day of August, 2002

s/s Daniel J. Davidson
Daniel J. Davidson
Administrative Law Judge

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