

addition or subtraction, pending an Order of the Administrative Law Judge. Counsel for CVM has accepted that commitment to secure the documents, until the Judge makes any further Order concerning these documents.

CVM opposes Bayer's Motion, and its proposed Protective Order. Specifically, the Center opposes Bayer's Motion because that Motion is over-broad, seeking to protect an entire answer or document even if the majority of that answer or document is not confidential. Further, CVM opposes the Motion because it has not been given access to the documents to enable a reasonable determination as to the claimed confidentiality of the documents. Bayer has not even provided redacted versions of the documents to the Center. Therefore, CVM requests that the Administrative Law Judge require Bayer to immediately provide the documents to the Center pursuant to a limited Protective Order, to enable the Center to review the documents and determine whether to accept or challenge each of Bayer's claims of confidentiality. The Center could not responsibly concur with Bayer's withholding responsive documents under a claim of confidentiality without such an opportunity to review the documents. Further, Bayer should be required to immediately provide specific information of the particular nature of the claimed confidential status of each of the responsive documents thus far withheld from production and identify which portions of the document Bayer believes should be protected as confidential. Neither the Center nor the Administrative Law Judge (through some "*in camera*" review) should be put to the tedious review of 5,000 pages of responsive documents, without Bayer's specific identification of which parts of the answer and documents are alleged to be confidential commercial information, which are alleged to be trade secrets, and which are alleged to be otherwise confidential.

Bayer should also have the obligation of certifying to the Center and the Administrative Law Judge that the alleged confidential information contained in these documents has not already been released or otherwise been made available to the public.

Finally, Bayer's Motion for Protective Order attempts to create a blanket procedure for future use in this Hearing whenever a claim of confidentiality is raised. Although the Center agrees that a standard procedure would be useful, the Center believes its proposed Protective Order, attached, is less burdensome than that proposed by Bayer, and will provide the necessary level of protection to all parties.¹

For the above-stated reasons, the Center opposes Bayer's Motion and requests that the Administrative Law Judge instead enter the Center's attached Proposed Protective Order.

Respectfully submitted,



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¹ For example, CVM and other FDA employees are already bound by statutory provisions governing disclosure of commercial confidential and trade secret information, and routinely have access to such confidential documents in their everyday work related activities. It is unnecessary and overly burdensome to require these employees to execute a Written Assurance.

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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FDA DOCKET: 00N-1571
DATE: August XX, 2002

Enrofloxacin for Poultry: Withdrawal
of Approval of Bayer Corporation's
New Animal Drug Application
(NADA) 140-828 (Baytril)

PROPOSED ORDER

On July 26, 2002, Bayer Corporation ("Bayer") filed a Motion for a Protective Order. On August 5, 2002, the Center for Veterinary Medicine ("CVM" or "the Center") filed an Opposition to Bayer's Motion and a Motion for a Limited Protective Order. This Order governs the status of information certified as "CONFIDENTIAL" hereafter provided by a party to this hearing to the other party to this hearing.

Bayer's Motion is hereby DENIED.

The Center for Veterinary Medicine's Motion is hereby GRANTED:

It is ORDERED that:

1. Bayer shall provide the estimated 5000 pages of documents subject to its Motion for a Protective Order to the Center, and a sealed version to Dockets Management Branch, by August ____, 2002.
2. Bayer shall provide a particularized claim of confidentiality for each document and if the entire document is not claimed as "CONFIDENTIAL", shall provide a redacted version

of that document to CVM, and a sealed version of the unredacted documents to Dockets Management Branch, by August ___, 2002.

3. In the future, any party may designate any document or thing produced by that party as "CONFIDENTIAL" by stamping or otherwise applying the above designation on each page or portion of the document or thing that is claimed to be confidential. In the event it is not practical to affix a sticker or to stamp "CONFIDENTIAL" on an object or document produced, the party seeking protection will take reasonable steps to notify the other party that the object or document is deemed confidential.
4. For each document or thing, or portion of document or thing, claimed confidential, the party so claiming shall provide a basis for that claim and certify that, to the best of their knowledge, the information contained therein has not been publicly released or otherwise been made available to the public.
5. Any document or thing designated "CONFIDENTIAL" (as well as the material and/or data contained therein) shall remain confidential, and shall be used solely for the purposes of this administrative hearing (including any subsequent appeals) until the Administrative Law Judge, the Commissioner of FDA, or a reviewing court directs otherwise.
6. With respect to any documents or things designated "CONFIDENTIAL," access to such documents or things and the material contained therein shall be limited to the Administrative Law Judge, the Commissioner of FDA or a reviewing court and its officers, and to the attorneys for the parties (including their office associates, legal assistants and stenographic and clerical employees), and to any author or previous recipients of such documents, things or materials. Access may also be given to non-attorney employees of the parties (including non-CVM FDA employees) for purposes of work connected with this hearing. Outside independent persons, e.g., persons not employees of or consultants who are otherwise retained by the either party to furnish technical or expert services and/or give testimony with respect to the subject matter of the hearing may be given access to such documents upon the execution of a "WRITTEN ASSURANCE" as described below. "CONFIDENTIAL" information will be disclosed to such employees and outside persons only to the extent necessary for such persons to perform work in connection with this hearing. Each such outside independent person designated to receive "CONFIDENTIAL" information shall execute a "WRITTEN ASSURANCE" in the form attached, and the party which has provided such person with the "CONFIDENTIAL" information shall provide the executed "WRITTEN ASSURANCE" to the opposing party within ten days of the execution thereof.
7. All persons with access to confidential materials in this hearing shall avoid disclosing confidential material received from another party.
8. All testimony in this action concerning confidential information or trade secrets or documents or things designated "CONFIDENTIAL" shall be held *in camera*, and subject to this Protective Order.

9. "Confidential" documents and things, and any copies or extracts thereof, shall be retained solely in the custody of the attorneys during the pendency of this hearing, except as reasonably necessary to provide access to persons authorized under the provisions of this Protective Order.
10. No party or its attorneys shall in any manner transfer the other party's documents or things designed "CONFIDENTIAL" or copies thereof, or communicate orally or in writing any of the information contained in the documents or things, to any person except as permitted by this Order for purposes directly related to this hearing.
11. The parties will not make use of any confidential business information or trade secrets acquired as a result of the documents or things produced or the testimony given by the parties in this hearing except as necessary in the conduct of this hearing and shall treat such confidential business information and trade secrets in accordance with the terms and provisions of this Protective Order.
12. The designation of any testimony, document, thing or response to an interrogatory as "CONFIDENTIAL" by a party shall not be construed as an agreement by the other party that any such testimony, document, thing or response to an interrogatory is in fact confidential, and such other party shall not have waived its right to challenge any such designation as provided herein.
13. In the event either party disagrees at any stage of these proceedings with a designation by the other party pursuant to this Order, the parties shall first attempt to resolve such dispute in good faith on an informal basis. If the dispute cannot be resolved, the objecting party may seek appropriate relief from the Administrative Law Judge, the Commissioner of FDA or a reviewing court, and the person asserting confidentiality shall have the burden of proving the same. The parties recognize that in the absence of agreement between counsel, the propriety of a designation of "CONFIDENTIAL" shall be determined by the Administrative Law Judge, the Commissioner of FDA or a reviewing court.
14. Any party herein may request a change in the designation of any information designated as "CONFIDENTIAL." Such request shall be served on the attorneys for the other party, and the Dockets Management Branch. Any such document or thing shall be treated as "CONFIDENTIAL" unless or until the parties resolve the matter by agreement, or by Order of the Administrative Law Judge, the Commissioner of FDA or a reviewing court.
15. This Order shall not be construed so as to prevent any party or its representatives from disclosing or making use of information which:
 - a. appears in a printed publication;
 - b. is a matter of public knowledge;
 - c. was obtained from a source or sources not under an obligation of secrecy to the other party; or
 - d. a party or any third party is compelled to disclose by Court Order.

16. Any party for good cause shown may apply to the Administrative Law Judge, the Commissioner of FDA or a reviewing court for a modification of this Protective Order.
17. Nothing in the foregoing provisions of this Protective Order shall be deemed to preclude any party from seeking and obtaining, on an appropriate showing, such additional protection with respect to the confidentiality of documents or other discovery material as that party may consider appropriate; nor shall any party be precluded from claiming that any matter designated hereunder is not entitled to protection, or is entitled to a more limited form of protection than designated.

DATED the ____ day of August, 2002

Daniel J. Davidson
Administrative Law Judge

WRITTEN ASSURANCE

declares that:

I reside at _____, in the City of

_____, State of _____, in the Country of

I have read the Protective Order dated _____ and of record in the Administrative Hearing:

Enrofloxacin for Poultry: Withdrawal of Approval of New Animal Drug Application

NADA 140-828, FDA DOCKET: 00N-1571, pending before Administrative Law Judge

Davidson of the Food and Drug Administration;

I agree to comply with and be bound by the provisions of said Order;

I will not divulge to persons other than those specifically authorized by said Order, and will not copy or use except solely for the purposed of the Administrative Hearing, any designated CONFIDENTIAL information or documents obtained pursuant to said Order;

I am employed by _____ whose address is

_____;

I realize that any violation of said Order may be subject to sanctions.

If executed within the United States: I declare under penalty of perjury that the foregoing is true and correct.

EXECUTED this _____ day of _____, 20__.

Signed: _____

Printed Name Here: _____

If executed outside the United States: I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

EXECUTED this _____ day of _____, 20__.

Signed: _____

Printed Name Here: _____

CERTIFICATE OF SERVICE

I hereby certify that an original and two copies of the foregoing Center for Veterinary Medicine's Opposition to Bayer's Motion for a Protective Order, and Motion for a Limited Protective Order was hand delivered this 5th day of August, 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 5th day of August, 2002, to:

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

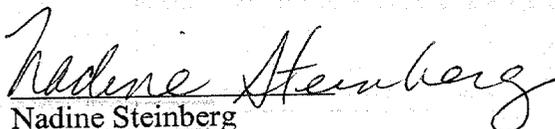
I also certify that a copy pleading was e-mailed and mailed by First Class U.S. mail, this 5th day of August, 2002, to:

Robert B. Nicholas
McDermott, Will & Emery
600 13th Street, NW
Washington, DC 20005

and

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

Dated: 8/5/02


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