

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

In the Matter of:

**Enrofloxacin for Poultry:
Withdrawal of Approval of
New Animal Drug Application
NADA 140-828**

FDA DOCKET: 00N-1571

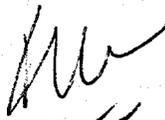
6068 02 JUL 26 04:20

**RESPONDENT BAYER CORPORATION'S
MOTION FOR A PROTECTIVE ORDER**

RESPONDENT Bayer Corporation hereby moves for a Protective Order to protect confidential materials submitted in the course of the above captioned hearing. Pursuant to Judge Davidson's scheduling Order dated April 10, 2002, Bayer and CVM have exchanged written interrogatories and requests for production. By agreement, responses to these interrogatories and requests are due July 26, 2002. In response to these interrogatories and requests, Bayer is prepared to submit certain confidential documents and information, but only pursuant to the proposed Protective Order attached hereto. Certain interrogatory answers and responsive documents include highly confidential commercial information that Bayer has not made publicly available and will not make available in the public portions of this Administration Hearing.

Bayer moves that the Court enter the proposed Protective Order to govern the submission of confidential materials pursuant to the discovery conducted in this Administrative Hearing.

Respectfully submitted,



Robert B. Nicholas
James H. Sneed
Gregory A. Krauss
M. Miller Baker
MCDERMOTT, WILL & EMERY
600 13th Street, N.W.
Washington, D.C. 20005-3096
(202) 756-8000

CERTIFICATE OF SERVICE

I hereby certify that a copy of Respondent Bayer Corporation's Motion for a Protective Order was sent via e-mail and hand-delivered this 26th day of July 2002, to:

Nadine R. Steinberg, Esquire
Food and Drug Administration
Office of General Counsel (CGF-1)
5600 Fischers Lane, Room 7-77
Rockville, MD 20857

and was mailed, via first-class mail, postage pre-paid to:

Kent D. McClure
Animal Health Institute
1325 G Street, N.W., Suite 700
Washington, D.C. 20005

and was sent via facsimile and hand-delivered this 26th day of July 2002, to:

Honorable Daniel J. Davidson
Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, Maryland 20857

and was hand delivered this 26th day of July 2002, to:

Dockets Management Branch (HFA - 305) - FDA
5630 Fishers Lane
Room 1061
Rockville, Maryland 20857



Robert B. Nicholas

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

In the Matter of:

**Enrofloxacin for Poultry:
Withdrawal of Approval of
New Animal Drug Application
NADA 140-828**

FDA DOCKET: 00N-1571

ORDER

Bayer's Motion for a Protective Order in the above-captioned matter is hereby
GRANTED.

It is ORDERED that:

1. Except as otherwise provided in paragraph 4 herein, each of the parties, Bayer Corporation ("Bayer") and the Center for Veterinary Medicine ("CVM") shall permit the inspection of documents and things otherwise discoverable but which contain or comprise confidential business information and/or trade secret information in accordance with the provisions of Paragraph 4 of this Protective Order.
2. Any of the parties herein may designate any confidential document or thing hereafter produced by the party pursuant to Paragraph 1 as "CONFIDENTIAL" by stamping or otherwise applying the above designation on the document or thing. In the event it is not practical to affix a sticker or to stamp "CONFIDENTIAL" on an object or document(s) produced,

the party seeking protection will take reasonable steps to notify the party(ies) inspecting the object or document(s) that the object or document(s) is deemed confidential.

3. 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).

4. With respect to any documents or things designated "CONFIDENTIAL," access to such documents and things and the material contained therein shall be limited to the 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 CVM non-attorney employees and to such outside independent persons, e.g., persons not employees of or consultants to or otherwise contractually related to either party, who are retained by the attorneys for any party to furnish technical or expert services and or give testimony with respect to the subject matter of the hearing 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 the work requested by the attorneys.

"CONFIDENTIAL" information will not be disclosed to any such person until after a period of seven (7) business days after service on all parties of information regarding the identity of the person, including name, address and job title, the name and address of the person's employer and a current curriculum vitae including a list of all companies for which such person has consulted during the last year. If, within seven (7) business days of such notice, another party objects to the provision of "CONFIDENTIAL" information to the person or to his or her employment, then, unless the parties otherwise agree, the objecting party shall have seven (7) business days to file

an appropriate motion to preclude the employment of the person and/or disclosure of “CONFIDENTIAL” information to him or her, and no “CONFIDENTIAL” information will be disclosed until the motion is decided. Each such 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.

5. Control and distribution of all confidential material covered by this Protective Order shall be the responsibility of the attorneys of record and all persons shall be enjoined from disclosing confidential material received from another party, publicly or otherwise. Each individual who receives any “CONFIDENTIAL” information hereby agrees to subject himself/herself to the jurisdiction of this Court for the purpose of any proceedings relating to the performance under, compliance, with or violation of, this Protective Order even after the conclusion of this hearing (including any appeals).

6. 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.

7. All documents hereinafter produced by either party, including pleadings filed in this action, and designated “CONFIDENTIAL”, if filed with the court, shall be held *in camera*, shall not be made a part of the public record herein, and shall be returned to the respective parties promptly upon completion of the hearing (including any appeals).

8. Promptly upon completion of the hearing, each party shall return to the other party, or destroy, all documents and things designated as “CONFIDENTIAL” and all copies

thereof, and shall destroy all extracts of data and other information from such documents and things. Counsel for each party shall thereafter confirm to the producing party that the return or destruction of all such documents and things has been completed. However, nothing herein shall be construed to prevent counsel for each party from retaining a file of pleadings and correspondence even if such files contain "CONFIDENTIAL" material for a reasonable length of time following conclusion of this dispute.

9. The parties shall refrain from referring during the public portions of this hearing to the information contained in the "CONFIDENTIAL" documents and things and, upon motion of either party, any testimony regarding such information shall be heard by the Court *in camera*.

10. "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.

11. No party or its attorneys shall in any manner, directly or indirectly, transfer any other party's documents or things designated "CONFIDENTIAL" or copies of the documents or things or communicate orally or in writing any of the information contained in the documents or things to any person, except as permitted by paragraph 4 above for purposes directly related to this hearing.

12. 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.

13. 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 any other party that any such testimony, document, thing or response to an interrogatory is in fact confidential, and such party shall not have waived its right to challenge any such designation as provided herein.

14. In the event that either party disagrees at any stage of these proceedings with a designation by a person 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 this 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 Court.

15. Any party herein may request a change in the designation of any information designated as "CONFIDENTIAL." Such request shall be by notice served on the attorneys for the other party. Any such document or thing shall be treated as "CONFIDENTIAL" until the change is completed.

16. 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 printed publication;
- b. is a matter of public knowledge;
- c. was or shall be 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.

17. Any party for good cause shown may apply to the Court for a modification of this Protective Order.

18. The provisions of this Order shall also apply to answers to interrogatories which are designated as containing or comprising confidential information.

19. 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 this the ____ day of July, 2002.

Daniel J. Davidson
Administrative Law Judge

WRITTEN ASSURANCE

_____ declares that:

I reside at _____, in the City of _____,
County of _____, State of _____.

I have read the Stipulated Protective Order dated _____ and of record in
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 purposes 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 subject me to sanctions by the Court; and

I declare under penalty of perjury that the foregoing is true and correct.

EXECUTED this ____ day of _____, 20__.

Printed Name Here