

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: June 6, 2002

916 to JM-6

Center for Veterinary Medicine's Correction of Documents Submitted Pursuant to 21 C.F.R. §12.85 and Request for Clarification Regarding Exhibit G-916

Pursuant to the Administrative Law Judge's Order of June 4, 2002, the Center for Veterinary Medicine respectfully submits corrected versions of the following documents to replace the existing documents previously submitted as part of the Centers document submission under 21 C.F.R. §12.85: Exhibits G-62; G-208; G-415; G-444; G-682, G-691; G-837, G-872, G-876, G-937, and G-962.

Specifically, the Center is correcting copying errors, pagination errors, and other non-substantive errors in Exhibits G-62, G-208, G-415, G-444, G-691, G-876, and G-962, and correcting the citation to Exhibit G-832 in the Center's index of submitted documents. Further, the Center is placing redacted copies of Exhibits G-682, G-837, G-872, and G-937 on the public record and placing these documents, in unredacted form, on the Confidential Docket.

With respect to Exhibit G-916, the Administrative Law Judge's June 4, 2002, Order required that: (1) an unredacted copy of this document be placed on the Confidential Docket, and (2) all Persons having copies of the original Exhibit G-916 return the original and any copies of this document to CVM counsel. However, the Order does not include Exhibit G-916 in the list of documents that the Judge has required CVM to correct and replace. Therefore, CVM requests clarification on whether the Judge's Order provides for CVM to redact this document and place this redacted version on the public docket. CVM is enclosing a redacted version of this document in a sealed

envelope to the Docket's Management Branch for the Judge's consideration. If the Judge so provides, CVM will provide a redacted copy of Exhibit G-916 to Bayer and AHI. CVM is also placing a copy of Exhibit G-916, in unredacted form, on the Confidential Docket.

Additionally, the Center is resubmitting an unredacted copy of Exhibit G-341 to the public docket. CVM has obtained a waiver of the confidentiality agreement with respect to this document.

Further, the Center notes that it now appears that the new Exhibit G-62a is the same document as was already submitted at Exhibit G-65. However we are submitting this document as Exhibit G-62a as required by the June 4, 2002, Order.

CVM is also submitting a corrected index of its submission under 21 C.F.R. §12.85 to reflect the above changes and to ensure that the index contains the proper citation to Exhibit G-832.

Submitted this 6th day of June, 2002, by:



Nadine Steinberg
Counsel for CVM
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
(301) 827-5050

Enrofloxacin Hearing
Docket No: 00N-1571

CERTIFICATE OF SERVICE

I hereby certify that an original and two copies of the foregoing Center for Veterinary Medicine's Correction of the Record was hand delivered this 6th day of June, 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

I also certify that the transmittal pleading was e-mailed and also mailed, postage prepaid, and that the entire submission was hand-delivered this 6th day of June, 2002, to:

Robert B. Nicholas (rnicholas@mwe.com)
McDermott, Will & Emery
600 13th Street, NW
Washington, DC 20005

and

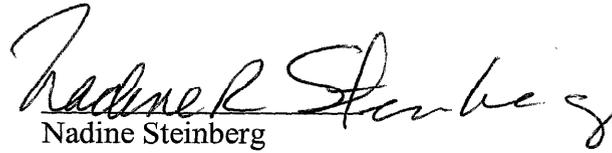
Kent D. McClure (KMcClure@ahi.org)
Animal Health Institute
1325 G Street, NW, Suite 700
Washington, DC 20005

I also certify that the transmittal pleading was e-mailed, this 6th day of June, 2002, to:

Judge Daniel Davidson (ddavidso@oc.fda.gov)
The Office of the Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3

5600 Fishers Lane
Rockville, MD 20857

Dated: 6/6/02



Nadine Steinberg
Counsel for the Center for
Veterinary Medicine
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
(301) 827-5050