

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

**RESPONDENT BAYER CORPORATION'S PARTICULARIZED CLAIM
OF CONFIDENTIALITY PURSUANT TO AUGUST 6, 2002 ORDER**

RESPONDENT Bayer Corporation ("Bayer"), pursuant to the August 6, 2002 Order in the above-referenced matter submits the following Particularized Claim of Confidentiality.

The August 6, 2002 Order requires Bayer to:

provide a particularized claim of confidentiality for each document and if the entire document is not claimed as "CONFIDENTIAL," Bayer shall provide a redacted version of that document to CVM and the Dockets Management branch along with a sealed version of the unredacted documents by August 19, 2002.

August 6, 2002 Order at 1-2.

Bayer previously submitted unredacted copies of its confidential discovery documents to the Confidential Docket on or about August 12, 2002. Bayer asserts that each of its confidential discovery documents is confidential in its entirety. For that reason, Bayer is not required under the August 6, 2002 Order to provide redacted versions of the documents.

Bayer submits the following particularized claim of confidentiality for each confidential discovery document below.

1. Bayer Confidential Document B-1155

The Center for Veterinary Medicine's ("CVM") Request for Production #1 requests the following documents:

Provide any data that Bayer has or is aware of relating to enrofloxacin in the environment. This request includes, but is not limited to, information on: runoff from poultry farms; runoff from the land application or spray irrigation of poultry manure/litter on agricultural lands; carry-over of poultry litter to the next flock(s); contamination of groundwater or surface water with antimicrobials (including enrofloxacin); contamination of groundwater or surface water with *Campylobacter*; contamination of groundwater or surface water with fluoroquinolone-resistant *Campylobacter*; leaking drinking water pipes; fate and transport of enrofloxacin in the environment; adsorption of enrofloxacin to the soil; length of antimicrobial and any other activity of enrofloxacin in the environment.

In response, Bayer submitted Confidential Document B-1155. Document B-1155 is confidential pursuant to 21 CFR § 10.20(j)(2)(i)(a), as "safety and effectiveness information, which includes all studies and tests of an ingredient or product on animals and humans and all studies and tests on the ingredient or product for identity, stability, purity, potency, bioavailability, performance, and usefulness." Document B-1155 contains confidential environmental studies and reports on enrofloxacin and ciprofloxacin which have not been made publicly available and have been treated as confidential within Bayer. Additionally, document B-1155 contains confidential commercial or financial information or otherwise protected trade secrets.

Bayer believes that if the studies comprising B-1155 were made publicly available, Bayer's competitors could utilize the studies to support enrofloxacin and ciprofloxacin approval applications in other countries.

2. Bayer Confidential Document B-1156

CVM's Request for Production #4 requests the following documents:

Provide any data that Bayer has relating to the nature, extent and motivation for extra-label use of enrofloxacin in poultry in the United States.

In response, Bayer submitted Confidential Document B-1156. Document number B-1156 is confidential pursuant to 21 CFR § 10.20(j)(2)(i)(a). Document B-1156 contains correspondence between Bayer and CVM specific to Bayer's NADA for enrofloxacin number 140-828. This correspondence describes supplemental applications submitted to the confidential NADA file. This information is not publicly available. Additionally, document B-1156 contains confidential commercial or financial information or otherwise protected trade secrets.

3. Bayer Confidential Document B-1157

CVM's Request for Production #9 requests the following documents:

For each country where enrofloxacin is used in poultry (under approval or otherwise), provide actual use data and sales data beginning on January 1 of the year before enrofloxacin was approved for use in poultry through the present, by month. If this information is not available by month, provide it in the smallest time interval available. This Request includes any information concerning enrofloxacin use in poultry prior to approval and after withdrawal, if applicable, in each country.

In response, Bayer submitted Confidential Document B-1157. Document number B-1157 is confidential pursuant to 21 CFR § 10.20(j)(2)(i)(d), as "production, sales distribution, and similar information, except any compilation of information aggregated and prepared in a way that does not reveal confidential information." Document B-1157 contains quantitative confidential sales information for Baytril® in the United States and thirteen other countries throughout the world. This sales information is highly confidential

and has not been released to the public. Additionally, document B-1157 contains confidential commercial or financial information or otherwise protected trade secrets.

4. Bayer Confidential Document B-1158

CVM's Request for Production #16 requests the following documents:

Provide any documentation (including laboratory data) concerning the effectiveness of approved antimicrobials, other than fluoroquinolones, in the treatment of *E. coli* (colibacillosis) and/or *P. multocida* (fowl cholera) in poultry.

In response, Bayer submitted Confidential Document B-1158. Document number B-1158 is confidential pursuant to 21 CFR § 10.20(j)(2)(i)(a) & (b)¹. Document B-1158 contains correspondence between Bayer and CVM pursuant to Bayer's Post Approval Monitoring Program ("PAMP") for enrofloxacin and other internal information (including protocols for studies) in Bayer's possession relating to the efficacy of antimicrobials, other than fluoroquinolones, in the treatment of *E. coli* (colibacillosis) and/or *P. multocida* (fowl cholera) in poultry. These PAMP reports were submitted to the enrofloxacin NADA file as confidential documents. The internal Bayer information (including protocols for studies) submitted contains internal Bayer effectiveness comparison information to other antimicrobial products and has not been made public. Additionally, document B-1158 contains confidential commercial or financial information or otherwise protected trade secrets.

5. Bayer Confidential Document B-1159

CVM's Interrogatory #1 requests the following information:

State the quantity (and state the units) of enrofloxacin sold (and if known, the quantity used) worldwide in poultry per month beginning the year before enrofloxacin was approved in each country to the present. Provide this information:

¹ 21 CFR § 10.20(j)(2)(i)(b) provides that "a protocol for a test or study" is confidential.

- by country
- by state, in the United States
- by operation type (i.e., hatchery, breeder, grow-out)
- by operation size
- by species (chicken and turkey)

In response, Bayer submitted Confidential Document B-1159. Document number B-1159 is confidential pursuant to 21 CFR § 10.20(j)(2)(i)(d). Document B-1159 contains quantitative confidential sales information for Baytril® in the United States and thirteen other countries throughout the world. This sales information is highly confidential and has not been released to the public.

6. Bayer Confidential Document B-1160

CVM's Interrogatory #5 requests the following information:

State the quantity (and state the units) of ciprofloxacin used in humans for gastroenteritis and/or diarrhea in each year from 1985 – present in the United States. Also, provide prescription and marketing data for this time period.

In response, Bayer submitted Confidential Document B-1160. Document number B-1160 is confidential pursuant to 21 CFR § 10.20(j)(2)(i)(d). Document B-1160 contains the number of total prescriptions for Bayer's Cipro® related to diarrhea and enteritis from 1990 to the present. This sales information is highly confidential and has not been released to the public. Additionally, document B-1160 contains confidential commercial or financial information or otherwise protected trade secrets.

7. Bayer Confidential Document B-1161

CVM's Interrogatory #13 requests the following information:

When, in what form, and for what indications, was enrofloxacin approved (or other equivalent regulatory mechanism) for use in poultry in each country where it is or was ever approved?

In response, Bayer submitted Confidential Document B-1161. Document number B-1161 is confidential pursuant to 21 CFR § 10.20(j)(2)(i)(d). Document B-1161 contains information with the registration numbers, date of registration, and indication for use for each Bayer enrofloxacin product for over 55 countries throughout the world. Bayer does not believe that such information readily could be obtained from each individual country where the product is registered. Bayer asserts that this list of registration numbers, dates and indications as compiled is confidential. This list was compiled solely for the purpose of responding to Interrogatory #13 and has not been made publicly available. Additionally, document B-1161 contains confidential commercial or financial information or otherwise protected trade secrets.

8. Bayer Confidential Document B-1162

CVM's Interrogatory #16 requests the following information:

When was ciprofloxacin approved (or other equivalent regulatory mechanism) for use in each country, and for what indications?

In response, Bayer submitted Confidential Document B-1162. Document number B-1162 is confidential pursuant to 21 CFR § 10.20(j)(2)(i)(d). Document B-1162 contains information with the dose, indication, approval date, and launch date (where available) for each ciprofloxacin product that Bayer markets throughout the world. Bayer does not believe that such information readily could be obtained from each individual country where the product is registered. Bayer asserts that this list of approval dates, launch dates, dose and indications as compiled is confidential. This list was compiled solely for the purpose of responding to Interrogatory #16 and has not been made publicly available.

Additionally, document B-1162 contains confidential commercial or financial information or otherwise protected trade secrets.

Respectfully submitted,



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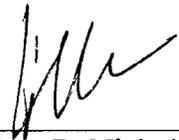
CERTIFICATE OF SERVICE

I hereby certify that a copy of Respondent's Bayer's Particularized Claim of Confidential Pursuant to August 6, 2002 Order was mailed this 19th day of August, 2002, 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

I hereby certify that a copy of Respondent's Bayer's Particularized Claim of Confidential Pursuant to August 6, 2002 Order was e-mailed and also mailed, postage pre-paid, this 19th day of August, 2002, to:

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



Robert B. Nicholas