



For purposes of these Requests for Production of Documents:

- A. "Bayer" means Bayer Corporation, any previous or successor corporations, subsidiaries, affiliates, branches, and divisions, wherever located, and each of its present or former directors, officers, employees, agents, and representatives, and any other person acting or purporting to act on behalf of Bayer.
- B. "Agent" or "agents" means any person employed by Bayer or working under Bayer's supervision, direction, or control, or acting on Bayer's behalf, including but not limited to employees, contract manufacturers and their employees, distributors, laboratories, consultants, independent contractors, trade associations, veterinarians, physicians, and attorneys.
- C. "And" and "or" shall be interpreted liberally, as conjunctive, disjunctive, or both, depending on the context, so that the fullest disclosure of information is achieved.
- D. "Document" or "Documentation" means handwritten, typed, printed, or visually, electronically, or orally reproduced material of any kind in which information, facts, thoughts, or expressions of any kind are in any way preserved or recorded, whether or not privileged, in the possession, custody, or control of Bayer or Bayer's agent or agents. "Document" includes every copy of every document where the copy is not identical in every respect to the original (e.g., because of any addition to, deletion from, alteration of, or notation on the copy).
- E. "Fluoroquinolone-resistant *Campylobacter*" means *Campylobacter* isolates exhibiting ciprofloxacin MICs of 4  $\mu\text{g}/\text{mL}$  (micrograms per milliliter) or greater.
- F. "Fluoroquinolone-susceptible *Campylobacter*" means *Campylobacter* isolates exhibiting ciprofloxacin MICs of less than 4  $\mu\text{g}/\text{mL}$  (microgram per milliliter).
- G. "Including" means "including without limitation."
- H. "Poultry" means both chickens and turkeys. When a Request asks about "poultry," Bayer should provide responses to the Request for chickens and turkeys separately, if such information is available.
- I. "Relating to" and "regarding" mean consisting, containing, embodying, reflecting, identifying, stating, dealing with, or in any way pertaining to, either directly or indirectly.
- J. Use of the singular includes the plural, as appropriate, and vice versa. Use of any tense of any verb includes within its meaning all other tenses of the verb.

- K. If Bayer objects to any Request or any part of a Request, state the reasons for the objection and respond to all parts of the Request to which Bayer does not object.
- L. If Bayer asserts a claim of privilege (including work product) in responding or objecting to any Requests herein and does not provide information on the basis of such assertion, state in response or objection the nature of the privilege (including work product) that is being claimed. For any privilege claimed, indicate, as to the information requested, whether any such information exists.
- M. If Bayer believes there to be any ambiguity in construing a Request, definition, or instruction, answer the Request as completely as possible and state the matter decreed ambiguous and the construction selected in responding to the Requests.
- N. If Bayer does not have information with the requested precision or specificity, so state and answer the Request with the best available information.

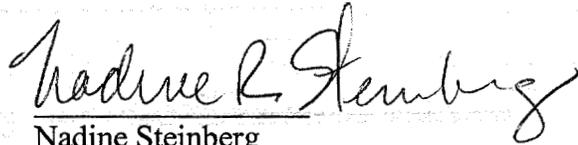
#### Requests for Production of Documents

1. 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.
2. Provide any information on fluoroquinolone-resistant *Campylobacter* (as opposed to fluoroquinolone-susceptible *Campylobacter*) in surface water, drinking water, sewage, feedlot runoff or agricultural land runoff, including the specifics in Request number 1.
3. Provide any data that Bayer has relating to plasmid-mediated fluoroquinolone resistance in *Campylobacter*.
4. 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.
5. Provide any data on treatment alternatives for *E. coli* (colibacillosis) in chickens and *E. coli* (colibacillosis) and *P. multocida* (fowl cholera) in turkeys, including the proportion of use of enrofloxacin versus other specific treatments for the same disease by country, from 1985-present.

6. Provide any mortality data (by number and by percentage) for broilers and growing turkeys in the United States due to *E. coli* (colibacillosis) and/or *P. multocida* (fowl cholera) by year from 1990 - present.
7. Provide any information on fluoroquinolone-resistant *Campylobacter* that is not a result of the selective pressure of fluoroquinolone drug exposure.
8. Provide any information on human to human transmission of *Campylobacter*.
9. 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.
10. Provide empirical data that exist to select values for the following parameters (specify by organism if known):
  - the initial microbial load on chicken leaving the farm (by season)
  - effects on microbial load of transportation from farm to processing plant
  - effect of processing (including cross-contamination) on microbial load
  - effect of storage and preparation prior to consumption on microbial load
11. Provide any available documentation that the U.S. poultry industry cannot provide safe and healthy poultry to consumers without the use of enrofloxacin.
12. Provide a list of all poultry producers in the United States that no longer use fluoroquinolones.
13. Provide a list of all poultry processors in the United States that no longer accept poultry for slaughter that have been treated with fluoroquinolones.
14. Provide a list of all poultry food retailers in the United States that no longer purchase or sell poultry that have been treated with fluoroquinolones.
15. Provide any risk assessments conducted on the impact of fluoroquinolone-resistant *Campylobacter* on human health, other than the one completed by CVM. Specifically, provide the Harvard Risk Assessment on *Campylobacter* and any drafts thereof.
16. 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.

17. Provide all documents relating to costs associated with fluoroquinolone-susceptible *Campylobacter* infections in humans, including but not limited to medical and hospital costs, lost wages and lost productivity.
18. Provide all documents relating to costs associated with fluoroquinolone-resistant *Campylobacter* infections in humans, including but not limited to medical and hospital costs, lost wages and lost productivity.

Submitted this 24th day of June, 2002, by:



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Enrofloxacin Hearing  
Docket No: 00N-1571

### CERTIFICATE OF SERVICE

I hereby certify that an original and one copy of the foregoing Center for Veterinary Medicine's Request for Production of Documents to Bayer Corporation was hand delivered this 24th day of June, 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 Request has been hand delivered and e-mailed, this 24th day of June, 2002, to:

The Office of the Administrative Law Judge (ddavidso@oc.fda.gov)  
Food and Drug Administration  
Room 9-57, HF-3  
5600 Fishers Lane  
Rockville, MD 20857

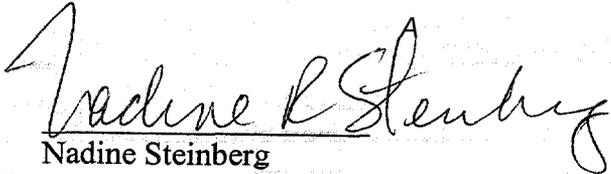
I also certify that a copy of the Request was e-mailed and sent by U.S. mail, postage prepaid, this 24th day of June, 2002, to:

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

and

Kent D. McClure (KmcClure@ahi.org)  
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Washington, DC 20005

Dated: 6/24/02

  
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