

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

July 22, 2003

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RESPONDENT BAYER CORPORATION'S MOTION TO FILE CORRECTED BRIEF

Respondent Bayer Corporation ("Bayer") hereby moves to file a corrected brief to correct minor clerical errors in Bayer's Post-Hearing Brief submitted July 18, 2003.

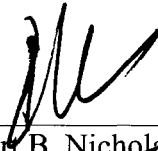
Bayer's corrected brief contains no substantive changes. The corrected brief merely clarifies the record by:

- Correcting internal page citations to the proposed findings of fact. Bayer's proposed findings of fact contain internal citations to portions of its brief and AHI's brief that support each finding. Page number changes from finalizing and printing the Bayer and AHI briefs resulted in minor errors to those internal citations. Because the support for each finding is in the briefs, and the errors were inadvertent, Bayer respectfully requests that it be allowed to make the corrections.
- Correcting other page citations to the AHI brief in the Bayer brief. In certain sections of the brief, (P. 6, 67, 89), Bayer references pages of the AHI Brief. The page number changes described above similarly resulted in minor errors to those citations. These errors were also inadvertent.

- Adding “G” and “B” numbers to the following references cited on pages 76-77: Black (G-67); Rosenquist (G-1788); and Cox (B-1020). Due to a clerical error after the brief was cite-checked, the “G” and “B” numbers were inadvertently omitted from these citations.
- Including initial definitions for two abbreviations used throughout the brief: *Campylobacter* (“CP”) and fluoroquinolone (“FQ”). These also were inadvertently omitted.

Because all of the above errors were inadvertent, no proposed changes are substantive, and allowing corrections will make for a more accurate and more understandable record, Bayer respectfully requests that the corrected brief be accepted and deemed filed as of July 18, 2003.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that an original and one copy of Respondent Bayer Corporation's Motion To File Corrected Brief was hand delivered this 22th day of July, 2003 to:

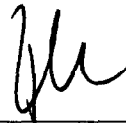
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD 20852

I also certify that a copy of Respondent Bayer Corporation's Motion To File Corrected Brief was e-mailed and also mailed, postage pre-paid, this 22th day of July, 2003 to:

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

I also certify that a courtesy copy of the foregoing Motion was hand delivered and e-mailed this 22th day of July, 2003 to:

Administrative Law Judge Davidson
C/o Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, Maryland 20852



Robert B. Nicholas

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ORDER

UPON CONSIDERATION of Respondent Bayer Corporation's Motion To File Corrected Brief, is hereby

ORDERED that Bayer's Corrected Post-Hearing Brief is to be accepted for filing in the evidentiary record by Dockets Management Branch.

DATED this the ___ day of July, 2003.

Daniel J. Davidson
Administrative Law Judge