

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

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In the Matter of:)	FDA DOCKET: 00N-1571
)	DATE: December 2, 2002
Enrofloxacin for Poultry: Withdrawal)	
of Approval of Bayer Corporation's)	
New Animal Drug Application)	
(NADA) 140-828 (Baytril))	
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**RESPONDENT BAYER'S MOTION TO SUPPLEMENT
DOCUMENT SUBMISSION UNDER 21 C.F.R. § 12.85**

Pursuant to 21 C.F.R. § 12.85(c) Respondent Bayer Corporation ("Bayer" or "Respondent") respectfully requests approval to supplement its document submission under 21 C.F.R. § 12.85(a). The subject documents numbered B-1508 through B-1849 have been filed with the Dockets Management Branch. (As a courtesy, Bayer has also sent today by courier a complete copy of the documents to the Center for Veterinary Medicine.) Under separate Motion dated today, Bayer has also sought to withdraw its Motion to Supplement Document Submission Under 21 C.F.R. § 12.85 dated November 29, 2002.

21 C.F.R. § 12.85(a) requires Respondent to submit to the Dockets Management Branch documents in Respondent's files containing factual information which relate to the issues (§ 12.85(a)(2)) as well as all other documentary data and information relied upon (§ 12.85(a)(3)).

In accordance with 21 C.F.R § 12.85(c) and the July 17, 2002 Order entered in this matter, Bayer seeks to supplement its 12.85 document submission. 21 CFR § 12.85(c) states:

Submissions required by ... this section may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material contained in the supplement was not reasonably known or available when the submission was made or that the relevance of the material contained in the supplement could not reasonably have been foreseen.

Furthermore, the July 17, 2002 Order in this matter states that:

21 C.F.R. § 12.85(c) indicates that the required submissions "... may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material ... was not reasonably known or available ... or that the relevance of the material contained in the supplement could not reasonably be foreseen (sic)." (Emphasis added). It appears that the use of the word "may" allows the submissions to be voluntary and that the parties may therefore voluntarily limit their Section 12.85 supplements to relevant material.

Order at 1.

The subject documents each fall in one or more of the following categories:

- i) documents not reasonably known to Respondent at the time of its April 22, 2002, or its September 13, 2002 filings pursuant to § 12.85¹;
- ii) documents not reasonably available to Respondent at the time of its April 22, 2002, or its September 13, 2002 filings pursuant to § 12.85;
- iii) documents whose relevance was not reasonably foreseen by Respondent at the time of its April 22, 2002, or its September 13, 2002 filings pursuant to § 12.85.

The subject documents are now known by and available to Respondent and Respondent believes that each is relevant to the issues set for hearing herein. Respondent anticipates relying

¹ Bayer recently discovered that CVM's document G-219, which according to the first page is a transcript copy of the May 11, 2002 Joint Meeting of the Veterinary Medicine Advisory Committee and Anti-Infective Drugs Advisory Committee is actually a transcript of the second day of the meeting, May 12, 2002. As such, Bayer has included a copy of the transcript of this meeting from May 11, 2002, as part of today's submission.

on the data and information contained in the subject documents at the hearing in this matter. As such, it is reasonable and appropriate that the documents be added to the docket as part of Respondent's § 12.85 filing.

In conclusion, these documents are relevant to the issues of the hearing and have been published, acquired, or come to the attention of Bayer, since its last submissions.

Respectfully submitted,



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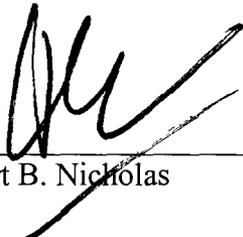
Attorneys for Bayer

CERTIFICATE OF SERVICE

I hereby certify that a copy of Respondent Bayer's Motion To Supplement Document Submission Under 21 CFR § 12.85 was e-mailed and also mailed, postage pre-paid, this 2nd day of December, 2002 to:

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

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

By motion filed December 2, 2002, Respondent Bayer Corporation seeks to supplement its documentary submission pursuant to 21 C.F.R. § 12.85(c).

Bayer states that the documents subject to its motion are related to the issues and have been published, acquired or come to the attention of Bayer since its September 13, 2002 submission.

Accordingly, the motion will be granted.

It is ORDERED, that Respondent Bayer's Motion to Supplement Submission Under 21 CFR § 12.85 is GRANTED.

DATED this the ___ day of December, 2002.

Daniel J. Davidson
Administrative Law Judge