

*A Partnership Including
Professional Corporations*
600 Thirteenth Street, N.W.
Washington, D.C. 20005-3096
202-756-8000
Facsimile 202-756-8087
www.mwe.com

Boston
Chicago
London
Los Angeles
Miami
Moscow
New York
Orange County
Silicon Valley
Vilnius
Washington, D.C.

Robert B. Nicholas
Attorney at Law
rnicholas@mwe.com
202-756-8170

MCDERMOTT, WILL & EMERY

December 9, 2002

VIA HAND DELIVERY

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

Re: In the Matter of Notice of Hearing: Proposal to Withdraw
Approval of New Animal Drug Application for Enrofloxacin
for Poultry ("Enrofloxacin Hearing")
FDA Docket: 00N-1571
Bayer Submission Of Response To December 3, 2002 Order

Dear Sir/Madam:

Enclosed for filing to docket number 00N-1571, please find two copies of Respondent Bayer Corporation's Letter in response to Judge Davidson's December 3, 2002 Order.

Please call with any questions.

Sincerely,



Robert B. Nicholas

Enclosures

CERTIFICATE OF SERVICE

I hereby certify that a copy of the Letter in Response to the December 3, 2002 Order was sent via e-mail and via first-class mail, postage pre-paid this 9th day of December 2002, to:

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

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

Honorable Daniel J. Davidson
Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, Maryland 20857

and was hand delivered this 9th day of December 2002, to:

Dockets Management Branch (HFA - 305) - FDA
5630 Fishers Lane
Room 1061
Rockville, Maryland 20857



Robert B. Nicholas

*A Partnership Including
Professional Corporations*
600 Thirteenth Street, N.W.
Washington, D.C. 20005-3096
202-756-8000
Facsimile 202-756-8087
www.mwe.com

Robert B. Nicholas
Attorney at Law
rnicholas@mwe.com
202-756-8170

Boston
Chicago
London
Los Angeles
Miami
Moscow
New York
Orange County
Silicon Valley
Vilnius
Washington, D.C.

MCDERMOTT, WILL & EMERY

December 9, 2002

VIA EMAIL AND FIRST CLASS MAIL

Honorable Daniel J. Davidson
Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, Maryland 20857

Re: Enrofloxacin for Poultry: Withdrawal of Approval of
New Animal Drug Application
NADA 140-828; FDA Docket: 00N-1571
Response to December 3, 2002 Order

Dear Judge Davidson:

Enclosed please find Respondent Bayer Corporation's ("Bayer") response to your December 3, 2002 Order, requiring Bayer to provide a "detailed explanation of how and when Bayer first became aware of Dr. Harris as a potential witness." Order at 1.

As noted in Bayer's *Motion To Add Witnesses Under 21 C.F.R. § 12.92* dated November 22, 2002, 21 C.F.R. § 12.92(a)(2)(ii), permits additional witnesses to be added with the approval of the presiding officer:

on a showing that the witness was not reasonably available at the time of the prehearing conference or the relevance of the witness' views could not reasonably have been foreseen at that time.

See 21 C.F.R. § 12.92(a)(2)(ii).

As described in Bayer's Motion, the relevance of Dr. Harris' testimony was not foreseen at the time of Bayer's initial May 20, 2002 witness list, when Bayer was still in the process of framing the issues. Motion at 1. As explained in the Motion, Dr. Harris will testify as to the environmental risks relative to the posed removal of enrofloxacin, and correspondingly, how those risks affect human health. Motion at 3.

As stated in Bayer's Motion, Bayer raised the issue of environmental risks related to the withdrawal of enrofloxacin at the beginning of this hearing. Motion at 4-5. At the time of submission of Bayer's initial witness list, Bayer intended Steven Woodruff to be the primary witness related to environmental affects. For purposes of this administrative hearing, Bayer requested that Woodruff identify and quantify the environmental benefits associated with enrofloxacin usage in the poultry industry and the adverse environmental impacts that would occur if enrofloxacin were withdrawn.

In July 2002, Bayer counsel met with Woodruff for the first time to discuss his preliminary research into these issues and raised questions about whether there were any other environmental issues that should or could be addressed. This session was primarily a discussion of possible theories since Woodruff had very little data or information at the time. As a result of Bayer's discussion with Woodruff, Bayer began to think about the possibility of other environmental affects of withdrawal. While Woodruff continued to gather information, Bayer began to discuss and search for other potential experts who might have specific expertise in deriving human health consequences from environmental impacts.

During the period between late July and August, Bayer was focused on the discovery process including crafting and responding to Interrogatories, Requests for Production and Proposed Joint Stipulations. During this period, ENVIRON's expertise in environmental matters was brought to Bayer counsel's attention. Bayer contacted Dr. Harris of ENVIRON and attempted to set up an initial meeting with Dr. Harris in August, but due to scheduling difficulties was unable to meet with Dr. Harris until mid-September. At this meeting, Bayer and Dr. Harris discussed the issue of linking environmental affects to human health. At the time of this meeting, it was not clear that there would be enough relevant information to be able to perform the necessary analysis. Thus, at this stage it was still necessary for Dr. Harris to begin preliminary research to determine whether any information relevant to the hearing could be developed.

Due to the complexity of obtaining and analyzing many different types of data, Dr. Harris did not provide Bayer with a preliminary draft analysis until mid-November. However, this preliminary analysis appeared to demonstrate a link between environmental affects related to the withdrawal of Baytril and an impact on adverse human health affects. At this point it appeared that Dr. Harris might be able to provide relevant testimony related to an important issue at the hearing (i.e., the risks of withdrawal of enrofloxacin on human health). Around that same time Bayer was also considering the possibility of adding Dr. Robert Livingston as a witness, and did not receive confirmation of Dr. Livingston's availability to testify until sometime shortly after November 7.¹ For the sake of conserving the resources of the Administrative Law Judge and those of the parties, Bayer sought to confirm the availability of both potential witnesses and then began drafting a consolidated motion to address both.

Since Bayer had not opposed CVM's earlier motion to add a witness, Bayer counsel contacted CVM counsel by telephone on November 18 to inquire whether Bayer could present

¹ As described in Bayer's Motion, Dr. Livingston (as an ex-FDA official) contacted the Department of Health and Human Services to assure his compliance with his ethical obligations under the Ethics in Government Act (18 U.S.C. § 207). Dr. Livingston, and his employer AHI, received confirmation on November 7, 2002, of his availability to testify. Bayer counsel received word of this shortly thereafter.

the motion without opposition.² CVM counsel requested to review the motion first, and a draft motion was sent to CVM counsel on November 19. On November 21, CVM counsel indicated they would oppose Bayer's motion. The following day, Bayer submitted its motion.

As described above, Bayer did not confirm that Dr. Harris would have relevant information until shortly before Bayer submitted the Motion to request his and Dr. Livingston's addition. Bayer believes Dr. Harris' testimony is a critical piece in demonstrating Baytril's continued safety and believes that FDA is legally obligated to consider the risks of withdrawal. See Bayer's Motion to Add Witnesses Under 12 C.F.R. § 12.92 at 4; Motion to Reformulate Issues for Hearing at 15-18. Bayer believes that the addition of Dr. Harris meets the requirements of 21 C.F.R. § 12.92 in that Bayer did not confirm the relevance of the witness' testimony until shortly before filing its motion.

Sincerely,



Robert B. Nicholas

cc: Kent D. McClure
Nadine Steinberg

² Bayer has maintained throughout its discussions with CVM that science should dictate the decisions about Baytril. Throughout the hearing process, Bayer has kept abreast of the constant stream of new data and information on this issue and has put all such information coming to its attention into the docket. Bayer's position is that all relevant information should be presented at the hearing. Bayer is puzzled that CVM would object to testimony that is related to human health effects, given that FDA's primary mission is to protect the public health.