

medicine and specifically to the 1995 approval of sarafloxacin and 1996 approval of enrofloxacin in poultry." (Bayer Motion at 2.) Further, the proffered evidence is irrelevant to the issue of this hearing; namely, whether the use of enrofloxacin under the approved conditions of use in poultry has been shown to be safe. (Notice of Hearing, 67 Fed. Reg. 7700-7701, February 20, 2002).

Bayer states that "Bayer believed that this factual background information on the approval and activities of the Joint Advisory Committee would be addressed through joint stipulations." (Bayer's Motion, page 2). Bayer's counsel was aware of the likely possibility that Bayer and CVM would not reach agreement on every issue that one of the parties presented for stipulation. Bayer should not be allowed to add a witness at this late date by arguing that its unrequited expectations of stipulations justify adding additional witnesses. Bayer's Motion confirms that it considered submitting such testimony prior to stipulation discussion. This means that Bayer could have listed this witness earlier, or at least moved much earlier for permission to add him. Therefore, Bayer's Motion does not meet the requirements of 21 CFR §12.92(a)(2)(ii).

Further, Bayer's Motion states that "Dr. Livingston only recently received confirmation from the Office of the Commissioner, Ethics Staff at FDA that he may provide testimony under oath as to factual matters in this case. Since Dr Livingston only recently received confirmation of this ability to testify, he was not reasonably available at the time of Bayer's initial witness list." (Bayer Motion, page 2). Bayer did not, however, reveal in its Motion the dates of the request to FDA's Ethics Staff. At CVM counsel's request, Counsel for Bayer provided documentation that this request was made by the Animal Health Institute on November 1, 2002, by phone, and November 4, 2002, by e-mail; and, that the FDA Ethics staff responded to the Animal Health Institute, by e-mail on November 7, 2002. Therefore, Bayer's statement that Dr.

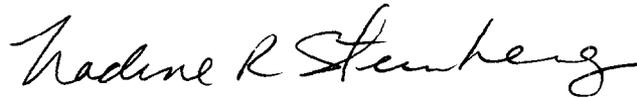
Livingston only recently received confirmation that he was not ethically prohibited from testifying needs the additional disclosure that this confirmation was only recently received because the question was only recently asked. Within this context, it is clear that Dr. Livingston was reasonably available at the time the original witnesses lists were submitted, but that Bayer and AHI did not seek to confirm that availability until very recently. In fact, the question of whether Dr. Livingston could testify should have been asked as Bayer drafted its original witness list in May, 2002. Dr. Livingston's curriculum vitae (filed with Bayer's Motion) confirms that he has not only been available to the parties for some time; he has been an employee of AHI since 2000. Again, Bayer's Motion does not meet the requirements of 21 CFR §12.92(a)(2)(ii).

As to both witnesses, Bayer claims that CVM will not be prejudiced because CVM's original witness list is longer than that of Bayer and AHI, and correctly notes that Bayer did not oppose CVM's motion, dated August 5, 2002, to add an additional witness. (Bayer's Motion, page 5). However, nothing limited Bayer or AHI to the number of witnesses they originally offered on their witness lists, and more importantly, Bayer had four months from the time of CVM's Motion to Add a Witness to determine whether it needed to incorporate testimony responsive to that witness's potential testimony into its Written Direct Testimony, due December 13, 2002. Moreover, the fact that CVM's original witness list contains more witnesses than does Bayer's and AHI's, and the fact that Bayer did not object to CVM's addition of one witness four months prior to the deadline for written direct testimony, does not obviate the clear prejudice involved in Bayer's attempt to add two additional witnesses so close in time to the deadline for CVM to submit its written direct testimony. Even assuming the Administrative Law Judge rules on this Motion immediately, if he were to allow, by Order, the addition to these two witnesses, CVM would have less than one week to evaluate how, and if, its witnesses should incorporate

these issues into their testimony. For example, it is possible that other witnesses have factual information that would place Dr. Livingston's or Dr. Harris' testimony in context. For a great many of CVM's witnesses, especially the ones overseas or out of state, considering and incorporating testimony on these matters, at this late date, is practically impossible.

For all these reasons, CVM opposes Bayer's Motion to Add Two Witnesses, and urges the Administrative Law Judge to deny that Motion.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that an original and a copy of the foregoing Center for Veterinary Medicine's Opposition to Bayer's Motion to Add Witnesses was hand delivered this 2nd day of December, 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 pleading has been hand delivered, this 2nd day of December, 2002, to:

The Office of the Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

I also certify that a copy of the pleading was e-mailed and also mailed, postage prepaid, this 2nd day of December, 2002, to:

Robert B. Nicholas
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Washington, DC 20005

and

Kent D. McClure
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Washington, DC 20005

I also certify that a copy of the accompanying pleading was e-mailed, this 2nd day of December, 2002, to:

Judge Daniel Davidson
The Office of the Administrative Law Judge
Food and Drug Administration
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Dated: December 2, 2002

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