

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

4196 '02 APR 15 P3:37

In the Matter of:

**Enrofloxacin for Poultry:
Withdrawal of Approval of
New Animal Drug Application
NADA 140-828**

FDA DOCKET: 00N-1571

BAYER'S MOTION TO AMEND SCHEDULE OF DUE DATES

On April 10, 2002, the Administrative Law Judge issued an Order establishing a Schedule of Due Dates (the "Schedule") in the above-captioned hearing. Bayer respectfully requests that the Administrative Law Judge amend the Schedule to provide for a sequential presentation of the evidence, with CVM presenting its evidence first. Bayer is *not* requesting any delay at all in the Schedule. Bayer has limited the instant Motion by only requesting that Bayer's written direct testimony and exhibits be submitted on December 23, 2002, rather than on December 9, 2002, as contemplated in the Schedule. This can be accomplished within the existing framework set by the Administrative Law Judge without extending the total time for the oral phase of the hearing, which still will be concluded by May 9, 2003. The proposed schedule submitted jointly by the parties to the Administrative Law Judge on April 5, 2002, agreed that written direct testimony would be sequenced. The law requires that CVM meet its burden of introducing new evidence that raises serious questions about the safety of enrofloxacin for use in chicken and turkey before Bayer can be required to present any evidence at all. Bayer's proposed Order would recognize that burden, at least in part, while the current Schedule does not.

INTRODUCTION

On March 22, 2002, the Administrative Law Judge issued a Notice and Order directing the parties in the above captioned matter to confer “in order to submit a proposed schedule of pre-hearing and hearing requirements reflecting consideration of, *inter alia*, those matters set forth in 21 C.F.R. §12.92.” Notice and Order, March 22, 2002, at 1. The Notice and Order specifically directed that “the proposed schedule include due dates for submission of all written direct evidence (including testimony), and for the filing of requests for cross-examination of specified witnesses for the oral phase of the Hearing.” *Id.* at 1-2 (footnote omitted). The Order directed the parties to file a proposed schedule on or before April 5, 2002.

The parties met on March 21, April 2, and April 3 to discuss (among other matters) the hearing schedule. Bayer advanced the position that CVM should put its case into evidence *before* Bayer was required to establish the safety of enrofloxacin. Bayer’s position, set forth in writing to CVM, was based on what it viewed as the controlling legal principle, *to wit*, CVM has the initial burden of demonstrating that *new evidence* raises serious questions about the safety of enrofloxacin *before* Bayer is required to demonstrate the safety of enrofloxacin. It was further Bayer’s position that fairness as well as conservation of judicial and party resources dictated that CVM first present its written direct testimony, followed by Bayer’s cross-examination, after which Bayer would either file a dispositive motion (if it concluded that CVM had not met its burden) or present Bayer’s evidence (if it concluded that CVM had met its burden) supporting the safety of enrofloxacin for use in chickens and turkeys.

Ultimately the parties reached agreement, and the parties jointly submitted a proposed schedule. Under the agreed schedule, CVM would respond to certain discovery *before* Bayer and, further, that CVM would present its written direct testimony, with Bayer having an

opportunity to cross-examine CVM's witnesses (assuming the Administrative Law Judge allowed cross-examination) *before* Bayer would present its written direct testimony. In order not to unduly delay the submission of this matter to the Administrative Law Judge for ultimate decision any further than established in the initial schedule discussed between Bayer and CVM, Bayer offered to have some matters proceed concurrently, and/or to provide Bayer with less time to respond than CVM was given for similar actions.

The Administrative Law Judge's Order dated April 10 requires the parties concurrently to present written direct testimony. Bayer brings this Motion to modify this part of the schedule. Not wanting to delay this matter, Bayer requests only that the April 10 Order be modified so that Bayer's written direct testimony is not due to be filed until two weeks after CVM, i.e., until December 23, 2002. This modification of the schedule will allow Bayer to evaluate CVM's case and to file its written direct testimony or dispositive motion *without* any extension of time in the overall Schedule.

ARGUMENT

Presentation of evidence in this hearing must be sequential. CVM should present its case first. Bayer should then present its case. If at any point the Administrative Law Judge determines that CVM cannot meet its initial burden, the hearing should be concluded. Bayer's position, to which CVM has previously consented in the jointly proposed schedule, is supported by applicable case law, the Notice of Hearing in this matter, the Administrative Procedure Act, the Federal Rules of Evidence, and hundreds of years of Anglo-American jurisprudence.

I. D.C. Circuit Caselaw Requires that CVM Present Its Case First.

In *Hess & Clark v. FDA*, 495 F.2d 975 (D.C. Cir. 1974), the D.C. Circuit found that FDA, as the proponent of withdrawal, has the statutory burden of making the first showing (i.e., that the drug is no longer shown to be safe):

The Secretary, or Commissioner, may withdraw the approval if this 'new evidence . . . evaluated together with the evidence available . . . when the application was approved shows that such drug is not shown to be safe for use . . .

The statute plainly places on the FDA an *initial burden* to adduce the 'new evidence' and what that new evidence 'shows.' *Only when the FDA has met this initial burden of coming forward with the new evidence is there a burden on the manufacturer to show that the drug is safe. Only at this later stage must the manufacturer produce 'adequate tests' of safety.*

Id. at 992 (emphasis added) (quoting 21 U.S.C. § 360b(e)(1)(B)). This standard was also adopted by the Commissioner in his final decision following a formal evidentiary public hearing on Nitrofurans; Withdrawal of Approval of New Animal Drug Applications, 56 Fed. Reg. 41902, 41903 (Aug. 23, 1991).

II. The Notice of Hearing Requires that CVM Presents Its Case First.

The Notice of Hearing in this matter adheres to the *Hess & Clark* rubric, in placing on CVM an initial burden to adduce the "new evidence" and what that new evidence "shows." Only when CVM has met this initial burden of coming forward with the new evidence is there a burden on Bayer to show that the drug is safe:

CVM must provide a reasonable basis from which serious questions about the ultimate safety of the drug may be inferred... *Once CVM provides a basis for questioning the safety of enrofloxacin, the sponsor will have the ultimate burden of showing the drug's safety.*

Notice of Hearing, 67 Fed. Reg. 7700 (Feb. 20, 2002) (emphasis added and citations omitted). In other words, CVM must first present new evidence that shows that serious questions exist. *Only*

after CVM shows that serious questions exist must Bayer present evidence to prove enrofloxacin's safety.

FDA's regulations further support this conclusion. 21 C.F.R. § 12.87(d) states that the party who is contesting a withdrawal of approval of a drug has the burden of proof in establishing safety. Bayer does not dispute that it has the ultimate burden of proof regarding the safety of the labeled use of enrofloxacin in chickens and turkeys. Indeed, it is Bayer's position that it has met that burden since, by approving NADA 140-828, FDA of necessity must have concluded that enrofloxacin, as labeled, is safe for use in chickens and turkeys. 21 U.S.C. § 360b, 21 C.F.R. § 520.813. However, FDA has acknowledged that 21 C.F.R. § 12.87(d) is not intended to change the requirement that "the Commissioner is first required to show that there is new evidence or new information about a drug that leads him to conclude that it can no longer be regarded as safe." 41 Fed. Reg. 51706, 51717 (Nov. 23, 1976). Therefore, it is incumbent on CVM to establish that new evidence raises serious questions about the safety of enrofloxacin before Bayer need present evidence establishing the safety of enrofloxacin in chickens and turkeys.

III. The Administrative Procedure Act Requires That CVM Present Its Case First.

CVM's obligation to go first is also confirmed by the Administrative Procedure Act ("APA") and case law interpreting the APA. *See, e.g., Anheuser-Busch, Inc. v. John Labatt Ltd.*, 89 F.3d 1339, 1344 (8th Cir. 1996). CVM has proposed the withdrawal of approval for enrofloxacin. As the proponent of action by the FDA, CVM has the burden of proof in the upcoming hearing. Under Section 7(c) of the Administrative Procedure Act, which governs the hearing, "[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. § 556(d). Section 7(c) does not merely impose a substantive burden

on CVM; it imposes a procedural burden as well. As the Supreme Court has observed, “[b]urden of proof was frequently used to refer to what we now call the burden of persuasion—the notion that if the evidence is evenly balanced, the party that bears the burden of persuasion must lose. But it was also used to refer to what we now call the burden of production—a party’s obligation to come forward with evidence to support its claim.” *Director, Office of Workers’ Compensation Programs v. Greenwich Collieries*, 512 U.S. 267, 272 (1994).

In *Greenwich Collieries*, the government argued that the phrase “burden of proof” in Section 7(c) referred *only* to burden on production—that is, the proponent’s obligation to put on its case first. In other words, *while the government disputed that the APA imposed a substantive burden of persuasion on the government, it conceded that the APA required the proponent of the order to go first*. The Court’s language in rejecting the government’s contention that the government had no burden of persuasion is instructive: “That Congress intended to impose a burden of production does not mean that Congress did not also intend to impose a burden of persuasion.” *Id.* at 279. Applying *Greenwich Collieries* to the instant case, it is clear that Congress intended that CVM must put on its case first. If CVM fails to meet its burden, Bayer need not put on any case at all. The legislative history of Section 7(c) confirms this point: “In other words, this section means that every proponent of a rule or order or the denial thereof has the burden of coming forward with sufficient evidence therefor.” H.R. Rep. No. 1980, 79th Cong., 2d Sess. 36 (1946).

IV. The Federal Rules of Evidence Suggest That CVM Presents Its Case First.

Bayer understands that the Administrative Law Judge will be guided by (although not bound by) the Federal Rules of Evidence in this hearing. The principle that the party with the

burden of proof must present its case first is also supported by Rule 301 of the Federal Rules of Evidence, which states:

In all civil actions and proceedings not otherwise provided for by Act of Congress or by these rules, a presumption imposes on the party against whom it is directed the burden of going forward with evidence to rebut or meet the presumption, but does not shift to such party the burden of proof in the sense of the risk of nonpersuasion, which remains throughout the trial upon the party on whom it was originally cast.

Fed. R. Evid. 301. In the instant case, Rule 301 supports the proposition that CVM has the burden to overcome the presumption that enrofloxacin is safe, the burden of proving that there are serious questions about the safety of enrofloxacin, and the burden of going forward with evidence.

Requested Relief

Statute, caselaw, and hundreds of years of Anglo-American legal tradition dictate that presentation of evidence should be sequential, with CVM making the initial presentation. In every criminal case, the prosecution puts its case on first. In every civil case, the party with the burden of proof puts its case on first. It is axiomatic that CVM has the burden of going first in the instant hearing. Bayer, however, is sensitive to the need to resolve this hearing swiftly, and Bayer does not request any changes with respect to the timelines established by the Administrative Law Judge for the filing of motions to modify the issues for the hearing, the pre-hearing exchange, discovery, stipulations, submission of proposed findings of fact, or cross-examination of witnesses. Bayer's motion is directed *only* to the submission of written direct testimony and exhibits. Therefore, working within the framework of the Administrative Law Judge's April 10, 2002 Order, Bayer requests that entry number 10 on the Schedule of Due Dates should be amended as follows:

Testimony/Exhibits, Cross-Examinations, Dispositive Motions:

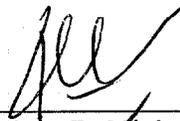
- 10A. Submission of CVM's Written Direct Testimony/Exhibits: 12/09/02
10B. Submission of Bayer's Written Direct Testimony/Exhibits: 12/23/02

The remainder of the Schedule of Due Dates would remain as it appears in the April 10, 2002 Order.

CONCLUSION

Bayer appreciates the Administrative Law Judge's desire to minimize the hearing state of this proceeding. *Indeed, the amendment above would not delay completion of the hearing at all.* The need for a speedy hearing, however, cannot outweigh the law's requirements regarding the burden of going forward with evidence. Bayer respectfully suggests, therefore, that the schedule above, or an approximation thereof, should be adopted.

Respectfully submitted,



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CERTIFICATE OF SERVICE

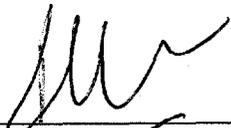
I hereby certify that a copy of Bayer's Motion to Amend Schedule of Due Dates was mailed this 15th day of April, 2002, via first-class mail, postage pre-paid to:

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

Brian Jensen
Royal Danish Embassy
Food, Agriculture and Fisheries Division
3200 Whitehaven Street, N.W.
Washington, D.C. 20008

I hereby certify that a copy of Bayer's Motion to Amend Schedule of Due Dates was e-mailed and also mailed, postage pre-paid, this 15th day of April, 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



Robert B. Nicholas

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ORDER

UPON CONSIDERATION of the Motion of Bayer Corporation to Amend the Schedule of Due Dates, it is hereby

ORDERED that the schedule of due dates be modified to read as follows:

Testimony/Exhibits, Cross-Examinations, Dispositive Motions:

- | | | |
|------|--|----------|
| 10A. | Submission of CVM's Written Direct Testimony/Exhibits: | 12/09/02 |
| 10B. | Submission of Bayer's Written Direct Testimony/Exhibits: | 12/23/02 |

The remainder of the Schedule of Due Dates would remain as it appears in the April 10, 2002 Order.

DATED this the ___ day of April, 2002.

Daniel J. Davidson
Administrative Law Judge