

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

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In the Matter of:)
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Enrofloxacin for Poultry: Withdrawal)
of Approval of Bayer Corporation's)
New Animal Drug Application)
(NADA) 140-828 (Baytril))
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FDA DOCKET: 00N-1571
DATE: April 25, 2002

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Center for Veterinary Medicine's Response in Opposition to Bayer Corporation's Motion to Amend Schedule of Due Dates

Background

On April 15, 2002, Bayer Corporation ("Bayer") filed a Motion to Amend the Schedule of Due Dates. The Center for Veterinary Medicine ("CVM" or "the Center") opposes Bayer's Motion and urges the Administrative Law Judge to deny it.

Introduction

The Center believes that the schedule, as set out in the April 10, 2002, Scheduling Order, is fair and equitable, consistent with regulations and case law, and in the interest of judicial efficiency. The Administrative Law Judge has the discretion to set the order of presentation of testimony and other evidence at the hearing. There is no reason to set aside any part of the April 10, 2002, Scheduling Order.

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Argument

1. The Regulation Contemplates Simultaneous Submission of Evidence

The Agency's trial-type hearing regulations at 21 C.F.R. Part 12 vest the Administrative Law Judge with discretion to determine the order of presentation of evidence at hearing.¹ These regulations provide for the receipt of evidence, including written evidence and anticipate simultaneous submission of written testimony. See 21 C.F.R. § 12.94. The preamble to the precursor of the Part 12 regulations states, "Section 2.160² relates to the development of evidence at a formal evidentiary public hearing. All participants will be submitting evidence during the same time period, rather than having it developed in sequence..." 40 Fed. Reg. 22950 at 22971.

2. The Administrative Law Judge has Discretion to Set the Order of Evidence

It is black letter law that judges have the ultimate discretion to determine the order of presentation of evidence in a civil proceeding. See 2 Am Jur 2d §342.³

Bayer cites to Anheuser-Busch v. John Labatt Limited, 89 F. 3d 1339 (8th Cir. 1996), for the proposition that the Administrative Procedures Act (the "APA") requires the Center to present all its evidence before Bayer is required to present any evidence.

Anheuser-Busch involved a case where one brewer (Anheuser-Busch) brought a

¹ See 21 C.F.R. §12.92(b)(2), which states that the presiding officer will conduct a prehearing conference "To identify the most appropriate techniques for developing evidence on issues in controversy and the manner and sequence in which they will be used, including, where oral examination is to be conducted, the sequence in which witnesses will be produced for, and the time and place of, oral examination." [Emphasis added.] Moreover, 12 C.F.R. §12.70(f) vests the Administrative Law Judge with broad authority to run the hearing as he deems appropriate, including the authority to "control the course of the hearing..." Also see, 21 C.F.R. §12.92(b)(6), which provides that the presiding officer may hold a prehearing conference "[T]o take other action that may expedite the hearing."

²Section 2.160 was recodified as 21 C.F.R. 12.94 on March 14, 1977, at 42 Fed. Reg. 15553, and revised on April 13, 1979, 44 Fed. Reg. 22318. These revisions do not change the import of the preamble language.

³2 Am Jur 2d §342 states, "An administrative law judge has the power to regulate the course of a hearing, and has broad discretion in conducting the hearings..."[Footnotes omitted.]

declaratory judgment case against another (Labatt) alleging the term "ice beer" and "ice brewed" are trademarks owned by the first company. Various cross claims were filed. On appeal, Labatt argued that "the District Court erred when it refused to grant Labatt's motion to set the order of proof at trial and to realign the parties." Anheuser-Busch at 1344. Labatt argued that it should present its evidence first because it carried the burden of proof on the trademark counts even though Anheuser-Busch originally brought the declaratory judgment action. The Court held that "A district court has wide discretion to set the order of proof at trial." Id at 1344 and in this case, "While Labatt bore the burden of proof on the trademark count in A-B's complaint, A-B bore the burden of proof on the other two counts...In the circumstances of this case, we do not believe that the District Court abused its discretion by denying Labatt's motion..." Id at 1344.

Additionally, the Federal Circuit Court of Appeals has ruled that, "The order of presentation of evidence by the parties is a matter of trial management." Lisbon Contractors v. U.S., 828 F.2d 759 (Fed. Cir.1987). Lisbon involved a contract dispute where the government terminated Lisbon for default. The Claims Court found for Lisbon, and the government appealed.⁴ The Federal Circuit Court of Appeals held that the government had the burden of proof, but that "The order of presentation of evidence by the parties is a matter of trial management....[T]he procedural requirements of the court for one party and then the other to come forward with evidence does not shift the ultimate burden of proof or persuasion on an issue back and forth....[O]n the entirety of the record, the trial court must determine if the party bearing the burden of proof has proved its side of the issue..." Lisbon at 765.

3. The Administrative Procedures Act Does Not Require the Center to Submit its Written Direct Testimony First

Bayer cites to Section 7(c) of the APA in support of its claim that "[e]xcept as otherwise provided by statute, the proponent of the rule or order has the burden of proof." 5 U.S.C. 556(d)." [Emphasis added.] (Bayer's Motion at 5).

Bayer's argument based on Section 7(c) is unpersuasive, since the burden of proof is not at issue here.

Bayer points to Director, Office of Workers' Compensation Programs, Department of Labor v, Greenwich Collieries, 512 U.S. 267 (1994) as support for its claim that CVM must present its testimony and other evidence first. But this case does not control here. Greenwich involved a challenge to a Department of Labor rule (the "true doubt rule") which shifted the burden of persuasion to the party opposing benefit claims instead of seeking such claims. The effect of that rule was that if the evidence on both sides were of equal weight, the proponent of the benefit would win. The Supreme Court found that this was inconsistent with Section 7(c) of the APA because the statute under which the rules were promulgated did not provide for shifting the burden of persuasion in this manner. Although the case does contain a lengthy discussion of the burden of persuasion and the burden of production or of going forward, it does not discuss the actual sequence of production of evidence and cannot lead to the conclusion that the Center has the obligation to present its written direct testimony and other evidence first.

⁴ Lisbon also appealed on the amount of the award.

4. The Federal Rules of Evidence Do Not Require the Center to Submit its Testimony and Other Evidence First.

Bayer cites Federal Rule of Evidence 301⁵ to support its claim that the Center must submit its written direct testimony before Bayer submits its written direct testimony. Again, this argument is without merit. While F.R.E. 301 is not a beacon of "plain language," it is clear that its purpose is to assure parties that the burden of proof, in the sense of the risk of non-persuasion, does not shift in light of certain legal presumptions. F.R.E. 301 accordingly has no bearing on the order of presentation of witnesses. In any case, and as Bayer acknowledges, the Federal Rules of Evidence do not bind the Administrative Law Judge in these proceedings. See 2 Am Jur §345, "The technical rules of evidence applicable to judicial proceedings generally do not govern agency proceedings..." See also, Federal Trade Commission v. Cement Institute, 333 U.S. 683 (1948), "...administrative agencies...have never been restricted by the rigid rules of evidence." Cement Institute at 705.

5. Adoption of Bayer's Proposed Modification of Due Dates Would Severely Prejudice CVM

Bayer's Motion is a not-so-veiled attempt to gain a strategic advantage over CVM. Under Bayer's proposal, CVM would have to submit its written direct testimony 14 days before Bayer submits its written direct testimony. However, the delay in the ability to

⁵ F.R.E. 301 is entitled "Presumptions in General in Civil Actions and Proceedings" and reads: "In all civil actions and proceeding 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."

prepare for the rest of the hearing that CVM will incur is more than a 14-day delay. Since Bayer's proposal would require CVM to wait until 2 days before Christmas to receive Bayer's written direct testimony, it very well may not be able to engage its experts in the review of that testimony until some time after the New Year. This would limit CVM's ability to thoroughly review the testimony to meet the January 27, 2003, deadline to file motions to strike written direct testimony or requests to conduct cross-examination of specific witnesses. As a matter of fundamental fairness, it is not appropriate to treat the parties differently with respect to the time available to prepare their respective cases. Under Bayer's proposal, it would have 14 days more than CVM has to prepare its written direct testimony, and approximately 27 days⁶ more than CVM has to review the opposing participants' testimony and prepare motions to strike testimony and determine which witnesses to request leave to cross-examine. This would be a material disadvantage to the Center and should not be allowed by the Administrative Law Judge.

Additionally, in most civil hearings, if evidence is presented orally, one party presents its testimony and other evidence and rests, and then the other party immediately proceeds to put on its testimony and other evidence.⁷ CVM therefore believes that if the Administrative Law Judge is inclined to grant Bayer's Motion for a sequential submission of written direct testimony, he order Bayer to submit its written direct testimony the day after the Center submits its written direct testimony.

⁶ This is a fair estimation of time since CVM may not be able to engage its experts until January 6, 2003, the first Monday after the New Year.

⁷ In this example, the fact that the opposing party would have already conducted cross examination is not relevant since the administrative rules, at Part 12, do not grant the right of cross examination. Since the Administrative Law Judge may, in his discretion, deny any requests for cross-examination, and since the order of cross-examination is not at issue here, the only issue for decision in this motion is the order of presentation of written direct testimony.

6. Judicial Efficiency Requires Simultaneous Submission of Written Direct Testimony

Judicial efficiency demands that the evidence be submitted simultaneously. The Administrative Law Judge has substantial experience sifting through scientific evidence and determining whether the parties' respective burdens have been met. There is no jury to confuse. In hearings such as this one, where complex scientific testimony will be presented, it is most appropriate to present the Administrative Law Judge all of the information, and allow him the opportunity to review the entire body of evidence together to arrive at an appropriate legal decision.

Conclusion

For the above-stated reasons, the Administrative Law Judge should deny Bayer's Motion to Amend Due Dates in all respects. However, as indicated, if the Administrative Law Judge feels constrained to grant Bayer's Motion to Amend Due Dates, the Center requests that Bayer be required to submit its written direct testimony on December 10, 2002.

Respectfully submitted on this 25th day of April, 2002 by:



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Order

Having considered Bayer Corporation's Motion to Amend Schedule of Due Dates and the Center for Veterinary Medicine's Response in Opposition thereto, Bayer's Motion is hereby DENIED.

The Schedule for Hearing remains as set out in the April 10, 2002 Scheduling Order.

Dated this the ____ day of ____, 2002.

Daniel J. Davidson
Administrative Law Judge
Food and Drug Administration
Rm. 9-57, HF-3
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Enrofloxacin Hearing
Docket No: 00N-1571

CERTIFICATE OF SERVICE

I hereby certify that an original and two copies of the foregoing Center for Veterinary Medicine's Response in Opposition to Bayer's Motion to Amend Due Dates was hand delivered this 25nd day of April, 2002, to:

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

and

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 the foregoing Response was e-mailed and also mailed, postage prepaid, this 25nd day of April, 2002, to:

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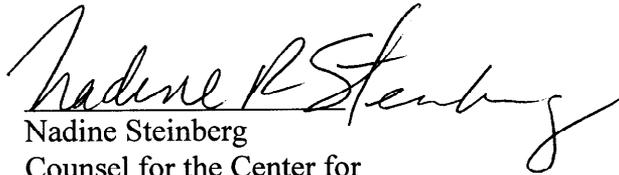
and

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I also certify that the foregoing Response was e-mailed, this 25nd day of April, 2002, to:

Judge Daniel Davidson
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Dated: 4/25/02



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