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** **Date: April 21, 2003**

RESPONDENT BAYER CORPORATION'S REPLY TO CVM'S OPPOSITION TO BAYER'S REQUEST FOR CROSS-EXAMINATION AND REVISED REQUEST FOR CROSS-EXAMINATION

Pursuant to the ALJ's April 16, 2003 Order, Bayer hereby replies to CVM's Motion in Opposition to Bayer's Request for Cross-Examination. Bayer also provides herein a revised request for cross-examination by way of "additional information in support of [Bayer's] request for cross-examination" as permitted by the April 16, 2003 Order.

Bayer's Request For Cross-Examination, as modified herein, should be granted because (i) oral cross-examination is the most effective and efficient means to clarify the matters at issue in this case; (ii) alternative means of developing the evidence are insufficient for a full and true disclosure of the facts; and (iii) Bayer will be prejudiced by denial of its request for oral cross-examination.

The standard for permitting cross-examination in this proceeding is clear; 21 C.F.R. § 12.87(b)(1)(ii) provides that:

> Oral cross-examination of witnesses will be permitted if it appears that alternative means of developing the evidence are insufficient for a full and true disclosure of the facts and that the party

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> requesting oral cross-examination will be prejudiced by denial of the request or that oral cross-examination is the most effective and efficient means to clarify the matters at issue.
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> 21 C.F.R. § 12.87(b)(1)(ii).

It is noteworthy that § 12.87 is written in the disjunctive. That is, oral cross-examination of witnesses will be permitted: (1) if it appears that alternative means of developing the evidence are insufficient for a full and true disclosure of the facts and that the party requesting oral cross-examination will be prejudiced by denial of the request; ***or*** (2) if it appears that oral cross-examination is the most effective and efficient means to clarify the matters at issue. In the present matter, Bayer's request to conduct oral cross-examination qualifies under both criteria. Finally, contrary to CVM's assertions otherwise, considerations of travel and cost do not directly bear upon the need to (or a request to) conduct oral cross-examination in an administrative hearing.

I. Bayer's Request Should Be Granted Because Oral Cross-Examination Is The Most Effective And Efficient Method Of Challenging Written Direct Testimony In An Administrative Hearing

FDA has long recognized that in administrative hearings where there is a substantial amount of information in the evidentiary record already, such as here, the most effective and efficient method of challenging written direct testimony is through oral cross-examination. As explained by FDA in the preamble to the regulation (21 C.F.R. § 12.87(b)(1)):

> Experience since part 12 regulations were issued has shown that written direct examination is a valuable means of expediting the oral phase of formal hearings, of presenting factual evidence clearly, fully, and concisely, and of focusing cross-examination on key issues. *Experience has also shown that oral cross-examination is usually the most effective and efficient method of challenging written direct testimony, because participants can organize their cross-examination before the oral hearing, and*

> *exclude irrelevant or unproductive questions. Oral cross-examination is therefore quicker than it would be if direct testimony were not submitted in writing, and probably requires less time than other methods of challenging direct testimony, such as written rebuttal or written cross-examination through interrogatories.*

43 Fed. Reg. 51966, 51969 (Nov. 7, 1978) Administrative Practices and Procedures Proposed Amendments; Food and Drug Administration; Proposed rule (emphasis supplied).

In its Motion, CVM recognizes that "[t]he parties have spent an enormous amount of time and resources amassing the docket in this hearing, and developing a comprehensive evidentiary record" and that there is a "huge amount of information already in the evidentiary record." CVM Motion at 2. Therefore, in accordance with the guidance provided by FDA above, allowing oral cross-examination to proceed (rather than written rebuttal or written cross-examination through interrogatories) would be the most effective and efficient method of challenging written direct testimony.[1]

II. Bayer's Request Should Be Granted Because No Alternative Means To Permit A Full And True Disclosure Of The Facts Is Available Is Available

The lack of an alternative means to permit a full and true disclosure of the facts is informed, first and foremost, by the undisputed benefits of oral cross-examination in an administrative hearing where, as here, there is a substantial amount of information in the evidentiary record already. As FDA has previously recognized, these benefits include but are by no means limited to the following:

1) Unlike other means, participants can organize their cross-examination before the oral hearing, and exclude irrelevant or unproductive questions;

[1] A sudden departure from this standard would also raise concerns under section 706(2)(A) of the Administrative Procedure Act (APA) regarding "arbitrary" and "capricious" agency action. *See* 5 U.S.C. § 706(2)(A).

2) Oral cross-examination is quicker if direct testimony has been submitted in writing;

3) Oral cross-examination requires less time than other methods of challenging direct testimony, such as written rebuttal or written cross-examination through interrogatories.

43 Fed. Reg. 51966, 51969 (Nov. 7, 1978) Administrative Practices and procedures Proposed Amendments; Food and Drug Administration; Proposed rule.

In addition, oral cross-examination will allow Bayer to effectively probe the basis of each witness's testimony and to assess its significance for purposes of resolving issues in this proceeding. To date, Bayer (and apparently CVM) has been unable to identify a specific alternative means that would permit a similar full and true disclosure of the facts.

III. Disallowing Bayer's Request Would Prejudice Bayer And, Therefore, Irrevocably Taint The Entire Rest Of The Hearing

In the preamble to the regulation (21 C.F.R. § 12.87(b)(1)(ii)), FDA responded to a comment requesting that § 12.87(b)(1)(ii) "be revised to make clear that oral cross-examination is a matter of right, citing 5 U.S.C. § 556(d)." 44 Fed. Reg. 22318, 22321 (April 13, 1979) Administrative Practices and Procedures Amendments; Food and Drug Administration; Final rule. In response to the comment, FDA stated:

> [FDA] believes that the regulation accurately reflects the standard for cross-examination in 5 U.S.C. § 556(d): "A party is entitled * * * to conduct such cross-examination as may be required for a full and true disclosure of the facts."
>
> *Id.*

FDA's response is telling in light of the weight accorded the right to conduct oral cross-examination in administrative proceedings under 5 U.S.C. § 556(d). As explained by the Fifth Circuit, even though evidentiary procedures are "somewhat relaxed" in administrative proceedings, "*cross-examination of witnesses is basic to due process of*

law". Texas-Capital Contractors, Inc. v. Abdnor, 933 F.2d 261, 269 (5th Cir. 1990) (emphasis supplied) (citing *Southern Stevedoring Co. v. Voris* 190 F.2d 275, 277 (5th Cir. 1951)).

The statute also memorializes the specific importance of *oral* cross-examination in administrative proceedings in addition to a party's right "to conduct such cross-examination as may be required for a full and true disclosure of the facts." In pertinent part, the statute provides that:

> Any *oral* or documentary evidence may be received...
>
> A party is entitled to present his case or defense by *oral* or documentary evidence...
>
> 5 U.S.C. § 556(d) (emphasis supplied).

Disallowing Bayer's request to orally cross-examine CVM's witnesses would irrevocably prejudice Bayer and, therefore, taint the entire rest of the hearing. It would effectively nullify the protections offered by 5 U.S.C. § 556(d) and 21 C.F.R. § 12.87(b)(1)(ii), and would undercut Bayer's ability to probe the basis of each witness's testimony and to assess its significance for purposes of resolving issues in this proceeding. Indeed, if this were to happen, the hearing as a whole would suffer, as would the parties and participants.

IV. Considerations Of Travel And Cost Do Not Directly Bear Upon The Need (Or A Request) To Conduct Oral Cross-Examination In An Administrative Hearing

CVM complains that it "should not be required to bear the costs of presenting twenty-seven of its witnesses for cross-examination" and that "of the twenty-seven witnesses that Bayer seeks to cross-examine, seven currently live in Europe."

CVM Motion at 2, n. 2 and n. 3. CVM also points out "of the twenty-seven CVM witnesses that Bayer seeks to cross-examine, Bayer has planned only one to two hours to cross- examine nineteen CVM witnesses (including four witnesses residing in Europe), thus signaling there are few issues that could possibly be in contention and that they can likely be addressed in ways other than through cross-examination." *Id.* at 2.

Bayer recognizes the reality and logistical difficulties of bringing witnesses to the United States from Europe, but also feels compelled to underscore the following points. First, CVM selected its own witnesses, knowing that oral cross-examination in the United States would be a distinct possibility, if not a certainty. Bayer plainly should not be criticized for seeking to exercise its rights to cross-examine CVM's witnesses just because they hail from Europe. Secondly, the regulation (21 C.F.R. § 12.87(b)(1)(ii)) does not cite cost or travel as relevant to assessing the need (or a request) for oral cross-examination in an administrative hearing. Nor has CVM pointed to any source of authority that does.

Finally, the fact that Bayer has allocated one to two hours to cross-examine nineteen CVM witnesses says absolutely nothing about the issues "in contention" or whether "they [the issues] can likely be addressed in ways other than through cross-examination." Make no mistake, Bayer's intent with respect to each CVM witness is to conduct a specific and focused oral cross-examination, not an unbounded fishing expedition. Moreover, contrary to CVM's assertions otherwise, Bayer believes numerous issues *can* be probed in detail within the time requested, particularly where (as here) every witness is an expert in the field and numerous substantive issues can be immediately discussed at the outset of the cross-examination. Nevertheless, since Bayer

has now reviewed CVM's critique to the proposed findings of fact Bayer has revised its request for cross-examination, as Bayer stated it would in its April 14 request for cross-examination. Accordingly, CVM's criticisms are moot.

Bayer's Revised Request For Oral Cross-Examination

By way of advancing the discussion on scheduling witnesses for cross-examination and, and in accord with the April 16, 2003 Order's invitation that Bayer may include additional information in support of their request for cross-examination, Bayer hereby provides a revised list or CVM witnesses requested for oral cross-examination in this case, as follows:

CVM Witness	Estimated Time
Dr. Frederick J. Angulo	4.0 hours
Dr. Mary J. Bartholomew	4.0 hours
Marja-Liisa Hänninen	3.0 hours
Heidi Kassenborg, DVM, MPH	4.0 hours
Kirk Smith	4.0 hours
RADM Linda Tollefson, DVM, MPH	4.0 hours
Robert D. Walker, M.S., Ph.D.	2.0 hours

The purpose of Bayer's intended oral cross-examination is to probe the basis of each witness's testimony and to assess its significance for purposes of resolving disputed issues in this proceeding.

Specifically, Bayer believes that oral cross-examination is appropriate to elicit a full and true disclosure of the facts as follows:

Dr. Frederick J. Angulo - Bayer believes that Dr. Angulo's written direct testimony needs clarification because: the testimony is selective in its use of FoodNet, NARMS and other data; the testimony ignores certain critical aspects of the scientific literature; the testimony is not fully evocative of the issues discussed; the testimony's reliance on certain data is unfounded and misleading.

Dr. Mary J. Bartholomew - Bayer believes that Dr. Bartholomew's written direct testimony needs clarification because: the testimony presents an inaccurate view of the

development of the *Campylobacter* risk assessment and its application; the testimony is not fully evocative of the issues discussed; the testimony's reliance on certain data is unfounded and misleading.

Marja-Liisa Hänninen - Bayer believes that Dr. Hänninen's written direct testimony needs clarification because: the testimony is selective in its use of the scientific literature and data; the testimony is not fully evocative of the issues discussed; the testimony's reliance on certain data is unfounded and misleading.

Heidi Kassenborg, DVM, MPH - Bayer believes that Dr. Kassenborg's written direct testimony needs clarification because: the testimony is selective in its use of data and contains factual inaccuracies; the testimony is not fully evocative of the issues discussed; the testimony's reliance on certain data is unfounded and misleading; the testimony draws conclusions not supported by the evidence.

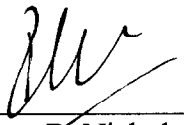
Kirk Smith - Bayer believes that Dr. Smith's written direct testimony needs clarification because: the testimony is selective in its use of data; the testimony is not fully evocative of the issues discussed; the testimony's reliance on certain data is unfounded and misleading.

RADM Linda Tollefson, DVM, MPH - Bayer believes that Dr. Tollefson's written direct testimony needs clarification because: the testimony contains factual inaccuracies as relates to the development and application of NARMS; the testimony is selective in its use of data; the testimony is not fully evocative of the issues discussed; the testimony's reliance on certain data is unfounded and misleading; the testimony draws conclusions not supported by the evidence.

Robert D. Walker, M.S., Ph.D. - Bayer believes that Dr. Walker's written direct testimony needs clarification because: the testimony is selective in its use of data; the testimony is not fully evocative of the issues discussed; the testimony's reliance on certain data is unfounded and misleading; the testimony draws conclusions that are unsupported by the evidence.

Live cross-examination of these witnesses will permit efficient and effective exploration of these problems to elicit a full and true disclosure of the facts.

Respectfully submitted,



Robert B. Nicholas
James H. Sneed
Gregory A. Krauss
M. Miller Baker
McDERMOTT, WILL & EMERY
600 Thirteenth Street, N.W.
Washington, D.C. 20005
(202) 756-8000
Counsel for Bayer

CERTIFICATE OF SERVICE

I hereby certify that an original and one copy of Respondent Bayer Corporation's Reply to CVM's Opposition to Bayer's Request for Cross-Examination and Revised Request for Cross-Examination was hand-delivered this 21st day of April, 2003 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 foregoing Respondent Bayer Corporation's Reply to CVM's Opposition to Bayer's Request for Cross-Examination and Revised Request for Cross-Examination was e-mailed this 21st day of April 2003 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 foregoing Respondent Bayer Corporation's Reply to CVM's Opposition to Bayer's Request for Cross-Examination and Revised Request for Cross-Examination was e-mailed and mailed via first-class mail, postage pre-paid, 21st day of April 2003 to:

Nadine Steinberg
Counsel for the Center for
Veterinary Medicine
5600 Fishers Lane (GCF-1)
Rockville, MD 20857

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

Robert B. Nicholas
Counsel for Bayer