

CVM provided sworn declarations by its witnesses and counsel proposing changes to the transcript of their respective statements.

2. Bayer submitted proposed changes to its own witness and counsel statements, as well as changes to statements made by CVM witnesses, CVM counsel and even the Administrative Law Judge. CVM understood that only the person whose statements or questions are in error can propose changes to their sworn testimony or to their questions and therefore only provided proposed changes from its witnesses and counsel, each for the declarant's own words.
3. In several instances, Bayer offers proposed corrections for CVM witnesses that differ from those proposed, by sworn declaration, by the witnesses for CVM. CVM's position is that the person making the statement is in the best position to make corrections to that statement and that a sworn declaration is more reliable than a line item matrix signed only by opposing counsel in this case.
4. Bayer's proposed corrections go beyond the Administrative Law Judge's Order and 21 C.F.R. §12.98(d). Bayer appears not to have limited its proposed corrections to transcription errors. Rather, Bayer has proposed grammatical changes and substantive changes well beyond the scope of the Order or regulation. CVM believes that grammatical imperfections and/or misstatements should remain in the record if the record accurately reflects these errors. Only true typographical or transcription errors should be subject to proposed corrections.

While CVM understands that scientific testimony, especially that peppered with scientific terms and acronyms, may be transcribed incorrectly on occasion, CVM notes

¹ If the Administrative Law Judge does not believe clarification is necessary, CVM respectfully requests time to respond to Bayer's proposed corrections to the transcript of the oral hearing.

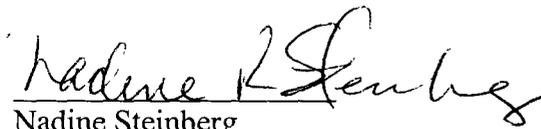
that the purpose of allowing proposed corrections to the record is not to rewrite testimony, or to make the witness or counsel statements clearer than they were at hearing.

Finally, because CVM's proposed corrections were not submitted as a Motion, CVM did not submit a proposed Order. However, if the Administrative Law Judge wishes such a proposed Order from CVM, the Center will promptly submit one.

CVM respectfully requests clarification concerning the extent to which proposed corrections may be permitted under the Administrative Law Judge's May 9, 2003 Order and 21 CFR §12.98(d). Specifically, CVM requests clarification on the following questions:

1. Do proposed changes to a witness' sworn testimony need to be accompanied by an declaration by that witness?
2. Can a party propose changes to any statement in the transcript even if it was not made by that party's witness or counsel?
3. What does the meaning of 'transcription errors' in 21 CFR §12.98(d) include?
4. Does the Administrative Law Judge wish the Center to submit a proposed Order to accompany the Center's proposed corrections to the transcript?

Respectfully submitted,


Nadine Steinberg
Counsel for the Center for Veterinary Medicine

CERTIFICATE OF SERVICE

I hereby certify that an original and one copy of the foregoing Center for Veterinary Medicine's Request for Clarification was hand delivered this 9th day of June, 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 Center for Veterinary Medicine's Request for Clarification has been hand delivered and e-mailed, this 9th day of June, 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 Center for Veterinary Medicine's Request for Clarification was e-mailed and mailed by First Class U.S. mail, this 9th day of June, 2003, to:

Robert B. Nicholas
McDermott, Will & Emery
600 13th Street, NW
Washington, DC 20005

Kent D. McClure
Animal Health Institute
1325 G Street, NW, Suite 700
Washington, DC 20005

Dated: 6/9/03



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