UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

March 6, 2012

MEMORANDUM

SUBJECT: Interpretation of the Good Laboratory Practice (GLP) Regulation
GLP Regulations Advisory No. 83

FROM: Francisca Liem. Director
GLP Program

TO: GLP Inspectors

Please find attached an interpretation of the GLP regulations as issued by the GLP Program, Office of Compliance. This interpretation is official policy in the GLP program and should be followed by all GLP inspectors.

For further information, please call 202-564-2365.

Attachment Advisory No. 83

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
GENERAL COUNSEL

Feb. 8, 2012

Re: Inquiry Concerning Retention of Raw Data in Support of Pesticide Registration

Dear Mr.:

Thank you for your August 24, 2011 letter in which you asked for EPA's opinion regarding the retention of copies of raw data rather than original documents, in support of pesticide registration. Specifically, you indicated that the [redacted] wishes to convert the raw data paper records of its members into PDF files and place the files on DVDs in lieu of storing the original records. Your inquiry seeks an opinion as to the authority under the relevant regulations to do so, particularly given a Question and Answer document (Q & A) referenced in your letter that appears on EPA's website (at http://www.epa.gov/oecaerth/monitoring/programs/fifra/glpqanda-definitions.html), which would indicate that original documents must be maintained.

Consultations have taken place involving Francisca Liem, Director of the Good Laboratory Practices (GLP) Program in the Office of Compliance, as well as staff from the Office of General Counsel and the Office of Enforcement and Compliance Assurance. Notwithstanding the Q & A, it is our opinion that paper records that must be retained pursuant to the GLP Regulations, 40 CFR Part 160, may be kept as true copies and must be available for inspection. The format, method and process used to copy and retain those copies will be key in determining whether or not [redacted] has met its obligations to ensure that the copies are "true" and that they will be available in the future for inspection.

Specifically,

- 40 CFR 160.195(i) sets forth, "Records required by this part may be retained either as original records or as *true* copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records." (Emphasis added.)
- 40 CFR 160.3 defines "raw data" as "[a]ny laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of 'Raw data' have been prepared (e.g., tapes which have been transcribed verbatim, dated and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. "Raw data" may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments."
- 40 CFR 169.3(a) requires that "[a]ny producer of any pesticide, device, or active ingredient used in producing a pesticide which is subject to this Act shall, upon request of any officer or employee of the Agency or of any State or political subdivision, duly designated by the Administrator, furnish or permit such person at all reasonable times to have access to and to copy all records required to be maintained by this part, including records in the possession of an independent testing facility or laboratory which performed tests on behalf of the producer."

We believe that allowing the retention of true copies of raw data paper records instead of the original paper records is consistent with the requirements of 40 CFR Parts 160 and 169. 40 CFR 160.195(i) contemplates the retention of "true copies" of raw data rather than the original records. Part 169 establishes requirements for the retention and availability for inspection of various records, including a requirement that registrants maintain records containing all research data relating to registered pesticides, including "*all* underlying raw data" for as long as the registration is valid. 40 CFR 169.2(k) (emphasis in original). While section 169.2(k) clearly requires that all underlying raw data be retained and available for inspection, nothing in Part 169 discusses the form of the data to be retained. Reading Parts 160 and 169 in concert, we see nothing that prevents the retention of accurate and complete copies of raw data paper records rather than the original paper.

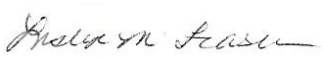
While we understand that [redacted] would like to convert original data into PDF and store it on DVDs, there are certain risks posed by that method and format. The risk is that the method and format may not result in true copies that will be available in the future for inspection. Any such risks are borne by the particular pesticide registrant. Any person transferring paper raw data to PDF format will need to ensure that the PDF files are complete (all pages in the paper document or paper raw data in question are converted to the PDF files), and are clearly legible.

For example, important forensic information can be lost when pen or pencil marks on paper documents (such as signatures) are scanned into PDF. Also, as PDF files can be modified without detection, once the PDF files are loaded onto DVD, a system must be put in place to demonstrably meet the requirement that the PDF is and will remain forever a "true" copy of the original. Such a system might include creating duplicate DVDs that are placed in the safe-keeping of a neutral third party. Another option could be the generation of a mathematical hash of the DVD contents that is generated and stored by a neutral third party. There may be other viable options.

Additionally, to meet the requirements of 40 CFR 160.3, steps must be taken to ensure the unencumbered availability of the raw data in the future even as information storage and retrieval technology evolves. Therefore, care must be taken to ensure that data can be reliably migrated to new formats and that data can be accessed without proprietary software or other technology that may not be readily available to the government without cost or delay.

EPA has removed the referenced Q and A from its website, and will be revising the website further to reflect the position set forth in this letter. If you have any further questions, please contact Robert Perlis in my office at (202) 564-5636.

Sincerely,



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