OPPT-2003-007/-0059



To: David.Menotti@shawpittman.com

cc: Robert.J.Giraud@USA.dupont.com, Gautam

Srinivasan/DC/USEPA/US@EPA

Subject: Re: 1) Section IX language and 2) QA R5

Two points:

1) Thanks for the "space holder" text. I have faithfully replaced the [] text with your space holder. EPA believes that it is necessary to include the original text that is under discussion. I have put the original text in red to highlight that this is what the drafting committee is discussing. Here's what it looks like:

*** FOLLOW-ON DISCUSSION POINT FOR DRAFTING COMMITTEE:

[SUMMARY: Discussions are continuing on: (a) appropriate tailoring of GLP requirements to meet the special needs of this test program, and (b) a table providing guidance for the development of quality assurance project plans.]

{original text under discussion}

C. All testing required by this ECA must be conducted in accordance with the EPA Good Laboratory Practice Standards (GLPS) found at 40 CFR part 792.

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01/21/04 12:06 PM

To: Rich Leukroth/DC/USEPA/US@EPA

cc: Robert.J.Giraud@USA.dupont.com

Subject: Section IX language

Rich:

Here is the language that we want as the "space holder" in Section IX for the GLP and QAPP basket of issues:

"[Discussions are continuing on: (a) appropriate tailoring of GLP requirements to meet the special needs of this test program, and (b) a

table providing guidance for the development of quality assurance project plans.]"

This "space holder" would appear after line 21 on page 9 of the current draft, in place of everything that appears thereafter in that draft, up to the beginning of Section X.

As we explained in the call, we will not agree to the inclusion of the language currently in the draft after line 21 in any consensus document for distribution to the Technical Working Groups at the end of this week.

David

David E. Menotti 202-663-8675

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