

US EPA ARCHIVE DOCUMENT

From: John Carley/DC/USEPA/US 09/13/2007 03:24 PM
 To: Scott P Carroll <spcarroll@ucdavis.edu>, "Metzger, Bill" bill.metzger@spectrumbrands.com
 cc: Clara Fuentes/DC/USEPA/US@EPA, Todd Peterson/DC/USEPA/US@EPA, Linda Hollis/DC/USEPA/US@EPA, William Jordan/DC/USEPA/US@EPA
 Subject: Re: Missing Correspondence with IIRB concerning final revisions to consent documents for WPC-001

In reviewing the submitted report on the field test of OLE (WPC-001) I found references in the correspondence from IIRB to two "Sponsor letters" which I cannot find. The approval letter from IIRB dated 10 July 07 (p. 139) cites a Sponsor letter of 4 July 07, and the approval letter from IIRB dated 13 July 07 (p. 158) cites a Sponsor letter of 10 July 07.

Have I overlooked these letters? If so, please tell me where they appear. If they were not submitted, please send me electronic images of both letters--as well as of any other correspondence between the sponsor and the IIRB--as soon as possible, and follow up with a hard copy submission, in PR Notice 86-5 format, identified as a supplement to the study report (MRID 47217601).

In addition, please clarify which of the four approved consent documents was signed by each participating subject, and when. A tabular presentation something like this would be ideal:

Subject Number	Date signed CD 16 Jan 07	Date signed CD 19 Jun 07	Date signed CD 10 Jul 07	Date signed CD 13 Jul 07

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From: Scott P Carroll ,spcarroll@ucdavis.edu. 09/20/2007 10:13 AM
To: John Carley/DC/USEPA/US@EPA
cc: bill.metzger@spectrumbrancs.com, billdragonfly@gmail.com
Subject: Re: Missing Correspondence with IIRB concerning final revisions to consent documents for WPC-001

Dear John,

I am glad to respond to your queries. First, regarding the Sponsor Letters: those are within the correspondence appendix (#11). The letter of 4 July 07 is on page 219. The letter identified by IIRB as being of '10 July 07' is one that I in fact dated '9 July 07', and it is the second entry in that correspondence record, beginning on page 220, concluding mid-way on page 221. I can see why IIRB's specific designation of that correspondence as Sponsor Letters (plus their date inconsistency) made it more cryptic.

Second, the attached table in pdf gives the history of consenting and participation for each subject. Only the ICD versions listed in the table were employed (signed). In compiling the information, we noted that for subject #60, we have consenting on the 12th, but participation beginning on the 10th. We do not believe that that subject was consented late, but rather that she inadvertently consented anew during a visit to the lab on the 12th, and that that form was then retained rather than her signed form from the 10th.

Please let me know if you have any additional questions.

Best,
Scott

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WPC-001
Consent Documents

Subject number	Sex	Dosimetry July 10 2007	Dosimetry July 11 2007	Efficacy Testing July 12 2007	Efficacy Testing July 13 2007	Efficacy Testing July 15 2007	Untreated Subjects Consent Document (Version 7/10/07)	Untreated Subjects Consent Document (Version 7/13/07)	Treated Subjects Consent Document (Version 7/10/07)
							Date Signed	Date Signed	Date Signed
6	H	X				Control	July 11 2007	July 16 2007	July 10 2007
8	H	X				X			July 10 2007
13	H			Control	Control	Control	July 11 2007	July 16 2007	July 11 2007
14	H	X		Control	Control		July 11 2007	July 16 2007	July 10 2007
15	H				X	X			July 12 2007
17	F		X			X			July 11 2007
20	F					X			July 11 2007
21	H					X			July 11 2007
24	H	X							July 10 2007
29	H					X			July 11 2007
36	F			X					July 11 2007
37	F	X			X				July 10 2007
38	F			X					July 11 2007
40	F				X				July 12 2007
43	H				X				July 10 2007
52	H			X					July 11 2007
53	F			X					July 11 2007
60	F	X			X				July 12 2007
61	F	X							July 10 2007
62	F	X							July 10 2007
63	H				X				July 12 2007
67	H	X				X			July 10 2007
69	F					X			July 15 2007
71	H					X			July 10 2007
72	H					X			July 10 2007