

US EPA ARCHIVE DOCUMENT

E-mail exchange between Scott P. Carroll of Carroll-Loye Biological Research and John M. Carley of EPA concerning Repellent Studies EMD-003 and EMD-004 on December 18-19, 2006. The correspondence reads from the bottom up.

From Scott P Carroll <spcarroll@ucdavis.edu> 12/19/2006 03:25 PM
To John Carley/DC/USEPA/US@EPA
cc
bcc
Subject Re: Reports on EMD-003 and EMD-004

Dear John,

I will explain these dates point by point, addressing questions that may be implied in each. Many explanations for 003 will also apply to 004.

Please explain the following date sequences reported for these two studies:

EMD-003:

Subject limb measurement 10/23-11/1

Subject limb measurement dates continue to 1 Nov because the collection of efficacy data extended into November, and included subjects that did not participate in dosimetry and were measured later.

Dosimetry data collection 10/23-25

Self-evident.

Protocol 10/24

This is the revision of the September 8 version (IIRB-approved on September 12), as prepared for the IRB in response to the recommendations of the HSRB. The changes were to §9.1.4.i, "Those who will serve as untreated control subjects are limited to experienced technical personnel, who are screened with the same exclusion criteria as are other subjects," 9.4.1.2, "This freedom is especially re-emphasized in cases in which considerable effort or expense has been required to include a subject (e.g., air travel to a distant site), to discourage the conception that that effort or expense creates any added obligation in the subject.," and §9.5, "On the day of testing, a physician who has read the protocol and discussed the research with the Study Director will be on call."

See also discussion of ICF, below.

QA Protocol review 10/26

This is when the QA completed review of the revised protocol.

Repellency data collection 10/28-30

Self-evident.

QA In-Life Inspection and Audit 10/28

Self-evident

IRB approval of protocol and ICF 11/1/06

Revised protocol and ICF approval. Subjects participating in dosimetry and/or testing lotion and pump spray signed the ICF dated 12 September. The appended revision of 11/1 was used by the subjects who tested aerosol. It includes the statement that the alcohol in the pump spray is not likely to be a serious risk. In addition, it corrects the statement about compensation being a benefit, and eliminates the statement about access to medical records, which does not apply. To each of the 12 September consent forms used for subject enrollment, the latter two corrections were made by hand, and acknowledged by initialing by the subject and Study Director.

The 11/1 ICF is appended to the reports because it was the latest version used in the study, with particular reference to the aerosol portion (which at the time we anticipated would be reviewed concurrently with the lotion and spray reports). In addition, its content reflects the conduct of the study and the content of the ICF as understood by the subjects.

EMD-004:

Subject limb measurement 10/23-11/1

As above.

Dosimetry data collection 10/23-28

Dosimetry data collection concluded on the 25th. It is possible that a date corrected from the 24th to the 25th appears to be the 28th.

Repellency data collection 10/25-11/1
QA Protocol review 10/26
QA In-Life Inspection and Audit 11/1
Protocol 11/1
IRB approval of protocol and ICF 11/1/06

Explanations for these are as for 003, above.

Please also provide complete records of correspondence with IIRB subsequent to the HSRB meeting on October 18, including the "Site Letter of 10/30" and the ICF "Ver. 10/24/06" mentioned in the approval letters from the IIRB.

I'll send the correspondence next.

Thanks,
Scott

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From John Carley/DC/USEPA/US 12/18/2006 03:46 PM
To Amy Morton <amorton@gsblaw.com>
Cc Scott P Carroll <spcarroll@ucdavis.edu>
Bcc
Subject Re: Reports on EMD-003 and EMD-004

Please explain the following date sequences reported for these two studies:

EMD-003:

Subject limb measurement 10/23-11/1
Dosimetry data collection 10/23-25
Protocol 10/24
QA Protocol review 10/26
Repellency data collection 10/28-30
QA In-Life Inspection and Audit 10/28
IRB approval of protocol and ICF 11/1/06

EMD-004:

Subject limb measurement 10/23-11/1
Dosimetry data collection 10/23-28
Repellency data collection 10/25-11/1
QA Protocol review 10/26
QA In-Life Inspection and Audit 11/1
Protocol 11/1
IRB approval of protocol and ICF 11/1/06

Please also provide complete records of correspondence with IIRB subsequent to the HSRB meeting on October 18, including the "Site Letter of 10/30" and the ICF "Ver. 10/24/06" mentioned in the approval letters from the IIRB.

Thank you.

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