

Joint Exhibit 11

From: Wood, Jon
Sent: Monday, August 14, 2017 7:22 PM
To: Page, Jordan (Page.Jordan@epa.gov)
Cc: Bloom, Jill (Bloom.Jill@epa.gov); Jonynas, Ann
Subject: FW: FW: Call with AMVAC on DCPA CTA
Attachments: Amvac DCPA plan for completion of thyroid studies 18 January 2017.pdf; Amvac DCPA update 11 April 2017.pdf; Amvac DCPA Update 18 July 2017 (3).pdf; HLS0980_EPA_Validation_Final_Report.pdf; XJ05HV Toxicology Report.pdf; Update on DCPA developmental thyroid studies 23 May 2017.docx; BDG0204 Phase Ia TSH data.xlsx

Categories: DCPA - US

Jordan,

As requested, please find attached the following reports and updates pertaining to the ongoing thyroid testing with Dacthal:

- Three Quarterly Updates - Dated January, April, and July 2017.
- Validation Report for Immunoassay Method - [Envigo Study Number [HLS0980](#) - Dated 3 May 2016].
- PTU - positive control report - [Envigo Study Number [XJ05HV](#) - Dated 27 April 2017]. Note that this report is also being submitted concurrently through Document Processing Desk.
- Study Update: Dose Range Finding Pre and Post Natal Developmental Thyroid Study in Sprague-Dawley Rats by Oral Administration - [Envigo Study Number [BDG0204](#) - Phase 1 - Dated 23 May 2017]. This was provided to the Agency via email on 30-May-2017 with a request for confirmation of proposed dose levels and timings for hormone measurements. It is important to note that EPA's confirmation is still needed (by Sept 1) in order to proceed with Phases II and III.

In addition, later this week we expect to provide the following summary report:

- Validation for GC-MS/MS - No final report yet, but Envigo will provide a summary with Protocol, Method, Calibration Curves and Results - [Envigo Study Number [FF58YR](#)].

I hope this information addresses your needs. Please let me know if further details are required before our conference call (date & time TBD).

Best regards,

Jon

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From: Page, Jordan [<mailto:Page.Jordan@epa.gov>]
Sent: Thursday, August 10, 2017 12:32 PM
To: Wood, Jon
Cc: Jonynas, Ann
Subject: RE: FW: Call with AMVAC on DCPA CTA

Jon, thanks for that. I see Ann will be available, so looking forward to talking next week. Sorry for all the information requests, but I am getting several inquiries on background info for this study in advance of the call. If you could help me address these, it will help ensure that we can have the most productive call possible. See below:

In the Update on DCPA developmental thyroid studies, it states that updates on this study (presumably Phase 1) were submitted on January 18, 2017 and April 11, 2017. Do you have these submissions? Do those submissions indicate whether they have performed a positive control (PTU) study (to gain expertise in blood sampling of young animals, as stated in 2015 protocol review), and whether there are data to show if direct dosing of pups will be necessary (as stated in the 2015 protocol review)?

(Please forward me 1/18/17 and 4/11/17 submissions referenced here if available)

Did Envigo send in the protocol for the new LCMS method as well as the calibration curves and stability data that they mention in the Update on DCPA developmental thyroid studies letter? We need to know the sensitivity of the new method.

(Please forward me the LCMS method protocol and stability data referenced here if available)

Thanks for your all your help!

Jordan

-----Original Appointment-----

From: Wood, Jon [<mailto:JonW@amvac-chemical.com>]
Sent: Thursday, August 10, 2017 1:13 PM
To: Page, Jordan
Cc: Jonynas, Ann
Subject: Tentative: FW: Call with AMVAC on DCPA CTA
When: Wednesday, August 16, 2017 3:30 PM-4:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomPYS9621/Potomac-Yard-One

Hi Jordan,

I can make this meeting but I'm not sure of Ann's travel schedule so I replied *tentative* until she responds - however, I note that the email you have used for Ann is older and might not get through so please forward your invite to her again at her current annj@amvac-chemical.com address.

In response to your email yesterday, I can offer the two attached EPA documents that I believe answer your question regarding the need for the thyroid study. If this doesn't address your inquiry then please clarify further.

1. 2011 Human Health Scoping Document that discussed the need to further evaluate thyroid toxicity, which then led to,
2. The Reg. Review Final Work Plan that outlined data that would be listed/required in the subsequent 2013 DCI, including this Special Study (non-GL)

I hope this is helpful. I will pencil in the meeting time and then let's see how Ann responds.

Thanks,

