

Joint Exhibit 23

From: Jonynas, Ann
Sent: Thursday, March 25, 2021 12:14 PM
To: Douglass, James
Cc: Wood, Jon; Britton, Cathryn; Bloom, Jill
Subject: RE: DCPA CTA update?
Attachments: 8441782 Pre_Final Toxicology report 22 Mar 2021.pdf; DCPA 8432592 Final Study Plan.pdf

Hi James

Good news! Please find attached the following:-

1. Dose Range Finding QA'd Draft Report (Covance:PM86YP/8441728). This draft report (pre-final) is undergoing finalization and will then be submitted formally via CDX portal, in the latter half of April. I will update you again at that time.
2. Protocol: DCPA Main Pre and Post Natal Developmental Comparative Thyroid Study in CD Rats by Oral Administration (Covance:8432592). Please can EPA review this protocol, provide any comments and their approval to proceed. We now have a proposed schedule in place at the CRO for this study, with animal order in mid May (time-mated females) and animal arrival in late June. Outstanding study dates can then be confirmed by an Amendment.

Please let me know if you have any questions or if anything is unclear. I'll keep you updated as to our progress at the CRO i.e. study dates and report finalization.

Regards
Ann

From: Douglass, James <douglass.james@epa.gov>
Sent: Wednesday, March 24, 2021 1:48 PM
To: Jonynas, Ann <AnnJ@amvac.com>
Cc: Wood, Jon <JonW@amvac.com>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Bloom, Jill <Bloom.Jill@epa.gov>
Subject: RE: DCPA CTA update?

Thank you for the clarification, Ann. Would it be possible to get a courtesy copy of the draft just emailed to us? The final version and the protocol could still be submitted through CDX when ready, but we would be interested in seeing the draft as soon as possible.

Thank you again,
James Douglass
Chemical Review Manager, RMIB 5/PRD/OPP/OCSPP/U.S. EPA
703-347-8630
douglass.james@epa.gov

From: Jonynas, Ann <AnnJ@amvac.com>
Sent: Wednesday, March 24, 2021 4:09 PM
To: Douglass, James <douglass.james@epa.gov>
Cc: Wood, Jon <JonW@amvac.com>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Bloom, Jill <Bloom.Jill@epa.gov>
Subject: RE: DCPA CTA update?

Hi James,

There shouldn't be any factual differences between the audited draft and final report. But the pagination, signatures and finalization details would be different. We really don't need two slightly different reports formally submitted into EPA, but the audited draft would be helpful to EPA, if HED wanted start their review of the main CTA protocol, in order to allow us to proceed? The interval however between draft and final DRF report is just less than 4 weeks. So, I'm thinking it might be better to wait for the finalized DRF report now. A copy can then be sent with main CTA protocol to assist EPA's review and then also formally submitted through the CDX portal, as is routine.

Regards
Ann

From: Douglass, James <douglass.james@epa.gov>
Sent: Wednesday, March 24, 2021 12:37 PM
To: Jonynas, Ann <AnnJ@amvac.com>
Cc: Wood, Jon <JonW@amvac.com>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Bloom, Jill <Bloom.Jill@epa.gov>
Subject: RE: DCPA CTA update?

Thank you for the update, Ann. Can you explain to me what the main differences are expected to be between the draft and finalized reports? Would receiving the draft report help us expedite things, or will it serve to confuse our review?

Sincerely,
James Douglass
Chemical Review Manager, RMIB 5/PRD/OPP/OCSPP/U.S. EPA
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From: Jonynas, Ann <AnnJ@amvac.com>
Sent: Wednesday, March 24, 2021 3:26 PM
To: Douglass, James <douglass.james@epa.gov>
Cc: Wood, Jon <JonW@amvac.com>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Bloom, Jill <Bloom.Jill@epa.gov>
Subject: RE: DCPA CTA update?

Hi James,

We are still working on this although our proposed dates have slipped a little, as the CRO has been late on their promised delivery. The Dose Range Finding QA'd Draft Report (Covance:PM86YP/8441728) was just received this week and is now being fully reviewed. The final report is still expected in April for EPA submission. The protocol for the main CTA study is having the study schedule planned and should be ready next week.

Would EPA want to see the Dose Range Finding QA'd Draft Report (Covance:PM86YP/8441728) ahead of the finalized report or wait a couple more weeks for the full finalized DRF report and our formal submission?

Regards
Ann

From: Douglass, James <douglass.james@epa.gov>
Sent: Wednesday, March 24, 2021 9:42 AM
To: Jonynas, Ann <AnnJ@amvac.com>

Cc: Wood, Jon <JonW@amvac.com>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Bloom, Jill <Bloom.Jill@epa.gov>
Subject: RE: DCPA CTA update?

Hello Ann,

I wanted to check on the progress of the CTA work. It looks like a few deadlines in the email thread below are either upcoming or have lapsed. I appreciate any updates you have for us.

Thank you,
James Douglass
Chemical Review Manager, RMIB 5/PRD/OPP/OCSPP/U.S. EPA
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From: Jonynas, Ann <AnnJ@amvac.com>
Sent: Friday, February 19, 2021 12:54 PM
To: Douglass, James <douglass.james@epa.gov>
Cc: Wood, Jon <JonW@amvac.com>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Bloom, Jill <Bloom.Jill@epa.gov>
Subject: RE: DCPA CTA update?

Hi James,

I have been in contact with the CRO (Covance UK) several times this week and can update you on progress. The Dose Range Finding draft report (Covance:PM86YP/8441728) has been delayed but is coming together now and we will have a full draft at the beginning of March, with a final report ready for EPA submission, planned for early April. We are currently reviewing all the data and will be preparing a draft protocol for the definitive CTA assay by mid-March for EPA's review.

We are suggesting, that we send EPA the draft DRF report once fully reviewed, together with our draft protocol for the definitive CTA assay together in mid March. We can follow up with the finalized DRF study report in April. This would allow EPA to start their review. We will await EPA's review and acceptance prior to scheduling and commencing the definitive CTA assay. Dates etc. for the definitive CTA study will have to be coordinated at the CRO, once EPA approval to proceed with the CTA assay is received.

I hope this is sufficient information for you and please let me know if you have any questions.

Regards
Ann

From: Douglass, James <douglass.james@epa.gov>
Sent: Tuesday, February 16, 2021 10:28 AM
To: Jonynas, Ann <AnnJ@amvac.com>
Cc: Wood, Jon <JonW@amvac.com>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Bloom, Jill <Bloom.Jill@epa.gov>
Subject: RE: DCPA CTA update?

Hi Ann and Jon,

Happy Mardi Gras or, as I prefer, Paczki Day. I was hoping to get an update on the status of the dose range finding work from the thread below. Has the draft report been issued (January 27 was the deadline previously specified)? Is AMVAC still on track to provide a final report to the agency at the end of March? Are there any other updates for us?

Thank you,
James Douglass

Chemical Review Manager, RMIB 5/PRD/OPP/OCSPP/U.S. EPA

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From: Jonynas, Ann <AnnJ@amvac.com>

Sent: Wednesday, December 9, 2020 12:57 PM

To: Douglass, James <douglass.james@epa.gov>

Cc: Wood, Jon <JonW@amvac.com>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Bloom, Jill <Bloom.Jill@epa.gov>

Subject: RE: DCPA CTA update?

Hi James,

AMVAC will submit the final report (PM86YP/8441782) to EPA at end March 2021, as soon as it is issued from the CRO. Report titled: DCPA (Chlorthal Dimethyl)- Dose Range Finding Comparative Thyroid Assay Investigating Milk Transfer and Thyroid Hormone Levels in Dams and Pups (Including a PTU Positive Control Group) in Sprague-Dawley Rats by Oral Administration."

In addition, AMVAC intends to provide a study summary with QC'd thyroid hormone and milk transfer data together with a draft protocol for the main definitive CTA assay, for EPA's review and approval in February 2021. This will be sent just ahead of the DRF report submission.

The DRF study (PM86YP/8441782) is completed and all the data are currently being processed, analyzed and QC / QA checked. The report has just started being prepared.

I can update you in the New Year to be sure everything is still keeping to the current schedule.

Regards

Ann

Ann Jonynas MSc DipRCPATH(Tox)

Director of Toxicology



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From: Wood, Jon <JonW@amvac.com>

Sent: Wednesday, December 9, 2020 8:18 AM

To: Jonynas, Ann <AnnJ@amvac.com>

Subject: Fw: DCPA CTA update?

Hi Ann -- can you please confirm this for James?.....thanks!

Jon

Jon C. Wood

Sr. Regulatory Manager

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From: Douglass, James <douglass.james@epa.gov>
Sent: Wednesday, December 9, 2020 8:11 AM
To: Wood, Jon <JonW@amvac.com>
Cc: Britton, Cathryn <Britton.Cathryn@epa.gov>; Bloom, Jill <Bloom.Jill@epa.gov>
Subject: FW: DCPA CTA update?

...Actually, Jon, one clarification while I have your attention: On page 3 it states "QA Audited Draft Report (including QC checked and QA audited thyroid hormone data) to be issued: 27 January 2021." Does this mean the report will be issued to AMVAC, or to EPA? If the former, do you have an estimate of when EPA will receive the report?

Thanks again,
James Douglass
Chemical Review Manager, RMIB 5/PRD/OPP/OCSPP/U.S. EPA
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douglass.james@epa.gov

From: Douglass, James
Sent: Wednesday, December 9, 2020 11:00 AM
To: Wood, Jon <JonW@amvac.com>
Cc: Britton, Cathryn <Britton.Cathryn@epa.gov>; Bloom, Jill <Bloom.Jill@epa.gov>
Subject: RE: DCPA CTA update?

Thank you for the prompt reply, Jon.

James Douglass
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From: Wood, Jon <JonW@amvac.com>
Sent: Wednesday, December 9, 2020 10:56 AM
To: Douglass, James <douglass.james@epa.gov>
Cc: Britton, Cathryn <Britton.Cathryn@epa.gov>; Bloom, Jill <Bloom.Jill@epa.gov>
Subject: Re: DCPA CTA update?

Hi James,

Attached is our Quarterly update on the Comparative Thyroid Assay study as requested. In hindsight I should have forwarded this to you when I received it but was holding for our response to all studies due next week -- my apologies.

Let me know if further clarification is needed at this time.

Thanks, and stay safe!

Jon

Jon C. Wood

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From: Douglass, James <douglass.james@epa.gov>
Sent: Wednesday, December 9, 2020 6:42 AM
To: Wood, Jon <JonW@amvac.com>
Cc: Britton, Cathryn <Britton.Cathryn@epa.gov>; Bloom, Jill <Bloom.Jill@epa.gov>
Subject: DCPA CTA update?

Hi Jon,

I know you are planning to respond to our DCPA data delay letter by next Tuesday, but our Health Effects Division is particularly curious about the status of the CTA work. Is there any way we can provide them with an update this week on just this one study?

Thank you,
James Douglass
Chemical Review Manager
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Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency