

Petitioner AMVAC

Exhibit 35

From: Jonynas, Ann
Sent: Tuesday, February 15, 2022 1:02 PM
To: Douglass, James; Wood, Jon
Cc: Bloom, Jill; Britton, Cathryn
Subject: RE: DCPA CTA update
Attachments: Labcorp TABLE Thyroid Hormone Methods and Control Ranges - February 2022.docx

Hi James,

Please find attached Labcorp's full and updated HC dataset for thyroid hormone measurements. These data have been fully QC checked for accuracy. Some lifestages included here are not relevant to the CTA assay but to prevent further delays the complete HC dataset is attached. All AMVAC's studies were conducted at the same CRO and location (Labcorp / Envigo / Huntingdon Life Sciences). If you have any further questions, then please do let me know.

Regards
Ann

Ann Jonynas MSc DipRCPATH(Tox)
Director of Toxicology



AMVAC Chemical Corporation
4695 MacArthur Court
Newport Beach
CA 92660
Cell:323-717-8122
annj@amvac.com

From: Douglass, James <douglass.james@epa.gov>
Sent: Wednesday, February 9, 2022 2:12 PM
To: Wood, Jon <JonW@amvac.com>
Cc: Jonynas, Ann <AnnJ@amvac.com>; Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: DCPA CTA update

Thank you, Jon. The team appreciates these stability studies.

Earlier today I received another data request from the team that I could use your help fulfilling. Could you please also submit all historical control thyroid hormone data that AMVAC has for all lifestages relevant to this work? To date, AMVAC has submitted serum T4 concentration historical control data for LD 22 offspring (male and female). Please let me know if you require further clarification from the team.

Thank you for your help and your patience,
James Douglass
Chemical Review Manager, RMIB 5/PRD/OPP/OCSPP/U.S. EPA
202-566-2343
douglass.james@epa.gov

From: Wood, Jon <JonW@amvac.com>
Sent: Wednesday, February 9, 2022 2:28 PM
To: Douglass, James <douglass.james@epa.gov>
Cc: Jonynas, Ann <AnnJ@amvac.com>; Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: DCPA CTA update

Hi James,

This is a courtesy copy of the attached documents that were submitted via the CDX portal yesterday. Please let me know if you have questions.

Best regards,

Jon

Office: (949) 221-6109

Mobile: (714) 651-7541



From: Douglass, James <douglass.james@epa.gov>
Sent: Monday, February 7, 2022 10:38 AM
To: Wood, Jon <JonW@amvac.com>
Cc: Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Jonynas, Ann <AnnJ@amvac.com>
Subject: RE: DCPA CTA update

Hi Jon,

Our team was hoping you could provide us with some test substance stability studies that were cited in AMVAC's CTA dose range finding study. Specifically, could you please submit the following:

- Envigo Study Number: BDG0015. Chlorthal dimethyl (DCPA): Validation of an analytical method and liquid formulation preparation, homogeneity and stability.
- Envigo Study Number: BDG0228. DCPA: Validation of an analytical method for the determination of the homogeneity, accuracy and stability of DCPA in aqueous 0.5% w/v methylcellulose formulations.
- Covance Study Number GQ12XG. DCPA: Validation of an analytical method and formulation accuracy, homogeneity and stability.

Thank you,
James Douglass
Chemical Review Manager, RMIB 5/PRD/OPP/OCSPP/U.S. EPA
202-566-2343
douglass.james@epa.gov

From: Wood, Jon <JonW@amvac.com>
Sent: Wednesday, January 26, 2022 2:29 PM
To: Douglass, James <douglass.james@epa.gov>
Cc: Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Jonynas, Ann <AnnJ@amvac.com>
Subject: RE: DCPA CTA update

Hi James,

Here is the latest (~Quarterly) update regarding the DCPA CTA study:

The DCPA CTA assay titled 'DCPA: Main Pre and Post Natal Developmental Comparative Thyroid Study in CD Rats by Oral Administration' (Labcorp Study Number: [8432592](#)) successfully completed the in-life phases during August and early September 2021. The study data are currently being processed and the draft study report is due on 18 February 2022. The final study report is scheduled for EPA submission in June 2022. There have been some delays at the CRO in the reporting schedule but these are the most recent dates we have been given.

We will keep you updated if there are any further changes. If you require further clarification or any additional information, please let us know. Thank you for your patience.

Best regards,

Jon

Office: (949) 221-6109

Mobile: (714) 651-7541



From: Douglass, James <douglass.james@epa.gov>
Sent: Monday, August 23, 2021 9:35 AM
To: Jonynas, Ann <AnnJ@amvac.com>; Wood, Jon <JonW@amvac.com>
Cc: Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: DCPA CTA update

Thank you, Ann. I will pass this along to our team.

Sincerely,
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: Friday, August 20, 2021 1:45 PM
To: Douglass, James <douglass.james@epa.gov>; Wood, Jon <JonW@amvac.com>
Cc: Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: DCPA CTA update

Hi James,

As promised, please find attached AMVAC's response to EPA's review of our CTA Study Protocol (Labcorp:8432592). The study is progressing well and I will keep you updated on progress and our study reporting dates. If there are any further questions or updates required, then please do let me know.

Regards
Ann

annj@amvac.com

Ann Jonynas
Director of Toxicology
AMVAC Chemical Corporation
Cell: 323-717-8122

From: Douglass, James <douglass.james@epa.gov>
Sent: Wednesday, August 18, 2021 7:01 AM
To: Jonynas, Ann <AnnJ@amvac.com>; Wood, Jon <JonW@amvac.com>
Cc: Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: DCPA CTA update

Thank you for the update, Ann, and we look forward to the comments.

Sincerely,
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: Tuesday, August 17, 2021 6:53 PM
To: Douglass, James <douglass.james@epa.gov>; Wood, Jon <JonW@amvac.com>
Cc: Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: DCPA CTA update

Hi James,

The CTA study started on 5 July 2021 and is underway. The completion of the in-life phase is September. As you can appreciate there are many hormonal samples (T3, T4 and TSH) for analysis together with the histopathological evaluations etc. to be conducted. Currently, the CRO has the audited draft report scheduled for January 2022 and the final study report for EPA submission as June 2022.

I am working on our comments back to EPA following EPA's review of our CTA study protocol (dated 15 July 2021) and have just a few points to finalize with the CRO. I will also include our updated amended study protocol with the current study dates included. I anticipate this will be in about a week.

If you need any more study information, then please do let me know.

Regards
Ann

From: Douglass, James <douglass.james@epa.gov>
Sent: Tuesday, August 17, 2021 3:29 PM
To: Jonynas, Ann <AnnJ@amvac.com>; Wood, Jon <JonW@amvac.com>
Cc: Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: DCPA CTA update

Hi Ann and Jon,

I just wanted to check in on the CTA study. Has the study commenced? For our planning purposes, could you provide us with an updated, best-case scenario timeline for the study, including an aspirational date for submission of the final study?

Thank you,
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, July 21, 2021 4:30 PM
To: Douglass, James <douglass.james@epa.gov>; Wood, Jon <JonW@amvac.com>
Cc: Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: DCPA CTA update

Hi James,

Many thanks for sending the finalized CTA protocol memorandum. I can confirm that all the preliminary studies and the main CTA study are all being conducted at the same CRO and lab facility location. This CRO has changed names three times now, going from Huntingdon Life Sciences, to Envigo, then to Covance and now to Labcorp. The most recent name change information is attached. I'll keep you updated on our study progress and we are currently working through all EPA's comments.

Regards
Ann

From: Douglass, James <douglass.james@epa.gov>
Sent: Wednesday, July 21, 2021 11:25 AM
To: Jonynas, Ann <AnnJ@amvac.com>; Wood, Jon <JonW@amvac.com>
Cc: Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: DCPA CTA update

Hi Ann,

Looks like I never responded to this email; I apologize for that. The CTA protocol memorandum was just finalized today, and is attached to this message.

Thank you,
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: Friday, July 9, 2021 5:34 PM
To: Douglass, James <douglass.james@epa.gov>; Wood, Jon <JonW@amvac.com>
Cc: Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: DCPA CTA update

Hi James

Many thanks for the preliminary comments we will start working from here. Can we assume the final response document will have no additional reviews added and will therefore be just be a more formalized version?

Thanks again,
Ann

From: Douglass, James <douglass.james@epa.gov>
Sent: Friday, July 9, 2021 1:39 PM
To: Jonynas, Ann <AnnJ@amvac.com>; Wood, Jon <JonW@amvac.com>
Cc: Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: DCPA CTA update

Hello Ann,

Attached are some preliminary comments on the DCPA CTA protocol, as requested.

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

From: Douglass, James
Sent: Thursday, July 8, 2021 2:51 PM
To: Jonynas, Ann <AnnJ@amvac.com>; Wood, Jon <JonW@amvac.com>
Cc: Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: DCPA CTA update

Hi Ann,

I should have some preliminary commentary for you tomorrow.

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

From: Jonynas, Ann <AnnJ@amvac.com>
Sent: Thursday, July 8, 2021 12:08 PM
To: Douglass, James <douglass.james@epa.gov>; Wood, Jon <JonW@amvac.com>
Cc: Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: RE: DCPA CTA update

Hi James,

I'm just checking back in with you again. Do you have any information to share yet on HED's review of our draft CTA protocol?

Regards
Ann

From: Jonynas, Ann
Sent: Monday, June 28, 2021 1:05 PM
To: Douglass, James <douglass.james@epa.gov>; Wood, Jon <JonW@amvac.com>

Cc: Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>

Subject: RE: DCPA CTA update

Hi James,

Would there be any chance of seeing EPA's informal response ahead of the formalized memorandum, so we can start working on any needed modifications or changes that may be required? There is very tight timeline now before the animal delivery date (7/22) at the CRO to meet our proposed study schedule. As this is such a large, complex study the CRO has stressed it is not possible to delay the start by just a few weeks, the study would have to be fully rescheduled, causing significant delays in our testing program. Any early information you could share with us would be extremely helpful.

Regards

Ann

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

Sent: Wednesday, June 23, 2021 12:10 PM

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

Cc: Jonynas, Ann <AnnJ@amvac.com>; Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>

Subject: RE: DCPA CTA update

Hi Jon,

I received a reply from our team regarding their review of the DCPA CTA protocol. They are scheduled to produce a finalized memorandum by July 15, 2021. I expect I will have information to share with you on or shortly after that date.

Thank you,

James Douglass

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

703-347-8630

douglass.james@epa.gov

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

Sent: Tuesday, June 22, 2021 5:39 PM

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

Cc: Jonynas, Ann <AnnJ@amvac.com>; Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>

Subject: RE: DCPA CTA update

Thank you James!

Jon

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Mobile: (714) 651-7541



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

Sent: Tuesday, June 22, 2021 2:37 PM

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

Cc: Jonynas, Ann <AnnJ@amvac.com>; Bloom, Jill <Bloom.Jill@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>

Subject: RE: DCPA CTA update

Hi Jon,

I just sent a message out to our team regarding their review of the protocol. As soon as I hear back from them, I will send along whatever news I have for you.

Thank you,
James Douglass
Chemical Review Manager, RMIB 5/PRD/OPP/OCSP/US. EPA
703-347-8630
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From: Wood, Jon <JonW@amvac.com>
Sent: Tuesday, June 22, 2021 12:56 PM
To: Douglass, James <douglass.james@epa.gov>
Cc: Jonynas, Ann <AnnJ@amvac.com>
Subject: RE: DCPA CTA update

Hi James,

Hope this finds you well! I'm just checking back to see if any progress has been made with the Agency's review of our protocol? We are set to receive animals at the CRO July 22 so hoping we can stay on that schedule. Thanks!

Best regards,

Jon

Office: (949) 221-6109

Mobile: (714) 651-7541



From: Wood, Jon
Sent: Friday, May 28, 2021 8:29 AM
To: Douglass, James <douglass.james@epa.gov>
Cc: Turnbough, Anne <AnneT@amvac.com>
Subject: RE: DCPA CTA update

Thanks James! – hope you have a great long weekend! 😊

Jon

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Mobile: (714) 651-7541



From: Douglass, James <douglass.james@epa.gov>
Sent: Friday, May 28, 2021 6:06 AM
To: Wood, Jon <JonW@amvac.com>
Cc: Britton, Cathryn <Britton.Cathryn@epa.gov>; Bloom, Jill <Bloom.Jill@epa.gov>; Jonynas, Ann <AnnJ@amvac.com>
Subject: RE: DCPA CTA update

Thank you Jon. I will pass this along to our team and check in with them concerning the draft protocol.

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

From: Wood, Jon <JonW@amvac.com>
Sent: Thursday, May 27, 2021 6:45 PM
To: Douglass, James <douglass.james@epa.gov>
Cc: Britton, Cathryn <Britton.Cathryn@epa.gov>; Bloom, Jill <Bloom.Jill@epa.gov>; Jonynas, Ann <AnnJ@amvac.com>
Subject: RE: DCPA CTA update

Hi James,

The Final Dose Range Finding report for the Comparative Thyroid Assay study was submitted today through the CDX portal [see attached cover letter and CDX confirmation-- report MRID No. [51591701](#)]. Let me know if you also need a copy of the report emailed to your attention.

As noted in the cover letter, we are progressing the main CTA study and would like to receive the Agency's review of the draft protocol (submitted via email March 25, 2021) by the end of June if possible.

Thank you for your consideration. Please contact us if further clarification is needed.

Best regards,

Jon

Jon C. Wood
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From: Wood, Jon
Sent: Tuesday, April 6, 2021 9:34 AM
To: Douglass, James douglass.james@epa.gov
Cc: Britton, Cathryn Britton.Cathryn@epa.gov; Bloom, Jill Bloom.Jill@epa.gov; Jonynas, Ann AnnJ@amvac.com
Subject: RE: DCPA CTA update

Hi James,

Attached is our Quarterly update on the Comparative Thyroid Assay study. Let me know if additional information is needed.

Best regards,

Jon

Office: (949) 221-6109

Mobile: (714) 651-7541



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

Sent: Thursday, March 25, 2021 12:01 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?

Great, thank you Ann. I'll pass these along to our team and will get back to you with any questions they have.

Sincerely,

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: Thursday, March 25, 2021 12:14 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

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
703-347-8630
douglass.james@epa.gov

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
703-347-8630
douglass.james@epa.gov

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
703-347-8630
douglass.james@epa.gov

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

AMVAC Chemical Corporation

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Mobile: (714) 651-7541



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
703-347-8630

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

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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douglass.james@epa.gov

Risk Management and Implementation Branch 5
Pesticide Re-evaluation Division
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency