

# **Petitioner AMVAC**

## **Exhibit 27**

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**From:** Wood, Jon  
**Sent:** Thursday, August 6, 2020 1:47 PM  
**To:** Douglass, James  
**Cc:** Jonynas, Ann; Britton, Cathryn; Bloom, Jill  
**Subject:** RE: DCPA DCI-Quarterly Update (July 2020)  
**Attachments:** AMVAC DCPA Update July 2020.pdf; 8441782 Amendment 2.pdf  
**Categories:** DCPA - US

Hi James,

Please see attached our quarterly update for the CTA including scheduling just received from the lab for the Dose Range Finding study.

On a related note, I will be sending our DCI Status summary to you under separate cover shortly.

Please let me know if you need clarification.

Stay safe!

*Jon*

Office: (949) 221-6109

Mobile: (714) 651-7541



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**From:** Page, Jordan <Page.Jordan@epa.gov>  
**Sent:** Tuesday, June 23, 2020 2:41 PM  
**To:** Wood, Jon <JonW@amvac.com>; Bloom, Jill <Bloom.Jill@epa.gov>; Douglass, James <douglass.james@epa.gov>  
**Cc:** Jonynas, Ann <AnnJ@amvac.com>; Britton, Cathryn <Britton.Cathryn@epa.gov>  
**Subject:** RE: DCPA DCI-Quarterly Update (April 2020)

Hi Jon,

Thank you for the interim timeline update here. While I've got you, I'd like to introduce you to James Douglass, a new review manager in our division. James will be taking over coordination of the DCPA registration review going forward. Jill Bloom is remaining as team lead on the case.

Thank you very much, and it's been a pleasure working with you Jon!

Jordan

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**From:** Wood, Jon <[JonW@amvac.com](mailto:JonW@amvac.com)>  
**Sent:** Tuesday, June 23, 2020 4:06 PM  
**To:** Page, Jordan <[Page.Jordan@epa.gov](mailto:Page.Jordan@epa.gov)>  
**Cc:** Jonynas, Ann <[AnnJ@amvac.com](mailto:AnnJ@amvac.com)>  
**Subject:** DCPA DCI-Quarterly Update (April 2020)

Hi Jordan,

Thank you for the estimate. Attached is our most recent Quarterly update. We are still waiting for the lab's scheduling department to provide confirmed study dates, but in the interim we can offer the following:

**DRF CTA study (PM86YP / 8441782)**

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.

The following study dates are still planned:

- Animals arrive: 12 August 2020
- End of life: late September 2020
- Draft report: late November 2020
- Final report: end December 2020

We will pass along confirmed scheduling to you as soon as possible.

Please let me know if you need further clarification.

Best regards,

*Jon*

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Mobile: (714) 651-7541



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**From:** Page, Jordan <[Page.Jordan@epa.gov](mailto:Page.Jordan@epa.gov)>

**Sent:** Monday, June 22, 2020 12:49 PM

**To:** Wood, Jon <[JonW@amvac.com](mailto:JonW@amvac.com)>

**Subject:** RE: DCPA DCI- Response to Protocol EPA comments dated 17-Sep-2019

Hi Jon,

Generally, we assume the review time will be 3 months, depending on the workload of the health effects team. We will be able to provide a better estimate once we know when they can expect to get started.

Do we have anything lately in terms of a schedule update?

Thanks!

Jordan

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**From:** Wood, Jon <[JonW@amvac.com](mailto:JonW@amvac.com)>

**Sent:** Thursday, April 16, 2020 2:26 PM

**To:** Page, Jordan <[Page.Jordan@epa.gov](mailto:Page.Jordan@epa.gov)>

**Subject:** RE: DCPA DCI- Response to Protocol EPA comments dated 17-Sep-2019

Hi Jordan,

I hope this finds you doing well and virus-free!....

Thank you for the DRF protocol review. The lab is reviewing the Agency's comments and we expect to provide you with a Quarterly update/schedule soon. Meanwhile, can you provide a (very rough) estimate of time EPA will need to review the final definitive CTA study once we submit?

Thanks and stay safe!

*Jon*

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Mobile: (714) 651-7541



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**From:** Page, Jordan <[Page.Jordan@epa.gov](mailto:Page.Jordan@epa.gov)>

**Sent:** Tuesday, April 14, 2020 8:30 AM

**To:** Wood, Jon <[JonW@amvac.com](mailto:JonW@amvac.com)>

**Cc:** Bloom, Jill <[Bloom.Jill@epa.gov](mailto:Bloom.Jill@epa.gov)>; Jonynas, Ann <[AnnJ@amvac.com](mailto:AnnJ@amvac.com)>

**Subject:** RE: DCPA DCI- Response to Protocol EPA comments dated 17-Sep-2019

Good Morning Jon,

Please see the attached Protocol review for an updated range-finding comparative thyroid assay for DCPA. I understand the lab has been awaiting this review to proceed, so please provide an updated schedule as soon as you can. Thanks,

Jordan

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**From:** Wood, Jon <[JonW@amvac.com](mailto:JonW@amvac.com)>

**Sent:** Thursday, March 05, 2020 8:30 PM

**To:** Page, Jordan <[Page.Jordan@epa.gov](mailto:Page.Jordan@epa.gov)>

**Cc:** Bloom, Jill <[Bloom.Jill@epa.gov](mailto:Bloom.Jill@epa.gov)>; Jonynas, Ann <[AnnJ@amvac.com](mailto:AnnJ@amvac.com)>

**Subject:** FW: DCPA DCI- Response to Protocol EPA comments dated 17-Sep-2019

Hi Jordan,

Please let me know when we can expect the Agency to review/approve the attached proposed study protocol for Phase I of the DCPA range-finding CTA. Note that in-life study work cannot begin until we have received comments from the Agency.

Thank you for your consideration and please don't hesitate to contact me if you need additional information.

Best regards,

*Jon*

Jon C. Wood

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**From:** Wood, Jon  
**Sent:** Friday, December 13, 2019 5:01 PM  
**To:** Page, Jordan <[Page.Jordan@epa.gov](mailto:Page.Jordan@epa.gov)>  
**Cc:** Bloom, Jill <[Bloom.Jill@epa.gov](mailto:Bloom.Jill@epa.gov)>; Jonynas, Ann <[AnnJ@amvac.com](mailto:AnnJ@amvac.com)>; Baumgartner, Carol <[CarolB@amvac.com](mailto:CarolB@amvac.com)>  
**Subject:** DCPA DCI- Response to Protocol EPA comments dated 17-Sep-2019

Hi Jordan,

Please find attached a copy of our response to the Agency's comments (per below) on the draft study plan for the Dose Range Finding study. The complete documents were submitted today via the CDX portal (CDX Tracking Receipt attached). Please contact me if you need additional information.

*Happy Holidays!*

Best regards,

*Jon*

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**From:** Page, Jordan <[Page.Jordan@epa.gov](mailto:Page.Jordan@epa.gov)>  
**Sent:** Tuesday, September 24, 2019 11:40 AM  
**To:** Wood, Jon <[JonW@amvac.com](mailto:JonW@amvac.com)>  
**Cc:** Bloom, Jill <[Bloom.Jill@epa.gov](mailto:Bloom.Jill@epa.gov)>  
**Subject:** Emailing - 078701\_2019-09-17\_TXR0057935.pdf

Hi Jon,

Please see the review of the DCPA protocol review dor Range-Finding and CTA attached here. Thanks!

Jordan