Message

From: Cowen, Tracey [USA - EMP] [TCowen@versar.com]
Sent: 8/4/2021 3:56:13 PM
To: Schlosser, Paul [Schlosser.Paul@epa.gov]; Hassan Husain (versar) [hhusain@versar.com]; Shams, Dahnish [Shams.Dahnish@epa.gov]; Kapraun, Dustin [Kapraun.Dustin@epa.gov]; Morozov, Viktor [Morozov.Viktor@epa.gov]; Thayer, Kris [thayer.kris@epa.gov]
CC: Bogen, Kenneth [USA - EMP] [KBogen@versar.com]; Williams, Laura [USA - EMP] [lwilliams@versar.com]
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Hi Paul,

Ex. 5 Deliberative Process (DP)

Thanks,
Tracey

Tracey L. Cowen
Environmental Scientist
Environmental Services Group

VERSAR
Your Needs. Our Mission.

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From: Schlosser, Paul <Schlosser.Paul@epa.gov>
Sent: Wednesday, August 4, 2021 11:35 AM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Shams, Dahnish <Shams.Dahnish@epa.gov>; Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Cc: Bogen, Kenneth [USA - EMP] <KBogen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Is Ferguson definitely not available or just unknown right now?

I think the remaining question about the in vitro work (not sure the reviewers really discussed it) is if the sample sizes are adequate. None of them really said, "No, I wouldn't use these results because of that," and because the model uses "A1" to get human lung metabolism (the value for which comes from a pretty good study), this really just devolves to if the sample size was large enough for human liver...

So, maybe we don't need an in-vitro expert now, since we had them in the initial review. EPA/CPAD is doing a huddle on Friday, can discuss more then.

Otherwise I think the expertise we'd want is most likely to be found in pharma (including academics focused on therapeutics). This is an are I don't know well. Rusty Thomas might be able to suggest some names.

-Paul

From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Wednesday, August 4, 2021 11:05 AM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Cc: Bogen, Kenneth [USA - EMP] <KBogen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Dahnish,
The third pool we are referring to is the pool of potential reviewers we had identified previously but not actually contacted yet. This is outside the pool of potential reviewers we had provided previously.

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Let me know if you have any questions. Happy to discuss further.

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Wednesday, August 4, 2021 12:39 AM
To: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Cc: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>; Bottimore, David [USA - EMP] <DBottimore@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Ok thanks Tracey. Do you mind clarifying the pools you are referring to? I thought there really was only one pool from last time (i.e., the candidate reviewers) and then from that pool Versar picked the "final" reviewers who ended up on the panel. Is there another (third) pool?

- Dahnish

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From: Cowen, Tracey [USA - EMP] <TCowen@versar.com>
Sent: Tuesday, August 3, 2021 8:31 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>

Cc: Hassan Husain (versar) <hhusain@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>; Bottimore, David [USA - EMP] <DBottimore@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Hi Dahnish,

Thanks for providing consent of the three selected reviewers we will distribute the review and supporting materials to them.

Ex. 5 Deliberative Process (DP)

Regarding the supplemental analysis it will be sent out as supporting information, but we just wanted to confirm that it had not been updated and the 2020 version that we sent last year will be used.

Thanks,
Tracey

Tracey L. Cowen
Environmental Scientist
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Sent: Tuesday, August 3, 2021 4:50 PM
To: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Cc: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>; Bottimore, David [USA - EMP] <DBottimore@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Hi Tracey – Thanks for the summary. Please feel free to pass on the meeting materials to the three selected reviewers from the previous panel. We have no concerns regarding their selection.

Ex. 5 Deliberative Process (DP)

- Dahnish

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From: Cowen, Tracey [USA - EMP] <TCowen@versar.com>
Sent: Monday, August 2, 2021 4:30 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Cc: Hassan Husain (versar) <hhusain@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>; Bottimore, David [USA - EMP] <DBottimore@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Hi Dahnish and Dustin,

I am writing to provide another update and to request your consent on three selected previous peer reviewers of the revised report on physiologically based pharmacokinetic (PBPK) modeling for chloroprene (Ramboll, 2021).

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The four members of the pool are:

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Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Thanks,
Tracey

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Friday, July 23, 2021 1:14 PM
To: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Cc: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>; Bottimore, David [USA - EMP] <DBottimore@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Great! Thanks for the update Tracey. Let us know when you hear back from the other reviewers.

- Dahnish

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From: Cowen, Tracey [USA - EMP] <TCowen@versar.com>
Sent: Friday, July 23, 2021 11:24 AM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Cc: Hassan Husain (versar) <hhusain@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>; Bottimore, David [USA - EMP] <DBottimore@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>
Subject: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Hi Dahnish and Dustin,

Thanks for sending the updated documents from Ramboll/ Denka.

We already have four candidates who are interested in participating in the re-review (Drs. Portier, Shao, Yang, and Zhu). Drs. Portier and Yang will both need until early September to complete their reviews due to schedule conflicts. We are hoping to hear soon from two of the reviewers (Drs. Louisse and Lumen) who are currently out-of-office. One person has declined (Dr. Benet) and one has not responded (Dr. Smith) but we're hoping to hear from him soon.

We're in the process of re-screening the four people above for COI.

We'll have another update for you early next week and may be able to get some of the reviewers started with their work, in advance of having the charge questions.

Tracey

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Friday, July 23, 2021 9:44 AM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Bottimore, David [USA - EMP] <DBottimore@versar.com>; Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>
Subject: RE: Kick Off for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Hi Hussain/all – Attached to this email are the updated chloroprene files associated with the RFC. EPA's website is currently being upgraded so the documents aren't showing up if you Google them yet, but they will be available shortly at the URL below. Please note that there are two extra files with this submission from DPE, but both I believe are background information only and should not be directly commented on by the reviewers (e.g., the Exhibit B - Epi Data and Studies and the response to comments document). I will follow up asap if anything changes on our end.

EPA will be working to finalize the draft charge questions. However, we don't expect the final version to be complete until Paul S. returns from leave in early August.

Let me know if you have any questions or comments on this.

https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration

- Dahnish

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-----Original Appointment-----
From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Monday, July 12, 2021 3:44 PM
To: Husain, Hassan [USA - EMP]; Shams, Dahnish; Kapraun, Dustin; Schlosser, Paul; Morozov, Viktor; Thayer, Kris; Bottimore, David [USA - EMP]; Cowen, Tracey [USA - EMP]; Williams, Laura [USA - EMP]; Bogen, Kenneth [USA - EMP]
Subject: Kick Off for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance
When: Monday, July 19, 2021 11:30 AM-12:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting

Purpose: To kick-off the follow up peer review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance.

Microsoft Teams meeting

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mistake, please reply to this message and then delete it, so that we can ensure such a mistake does not occur in the future.