Message

From: Holden, Bob [BHolden@joneswalker.com]
Sent: 6/13/2018 4:54:45 PM
To: Vandenberg, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]
CC: Orme-Zavaleta, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c5a111dc377411595e5b24b5d96146b-Orme-Zavaleta, Jennifer]; Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]; Fine, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d28c9693c45c41e8a941bc51d2c4914c-Fine, Steve]; Gray, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=881c62b1e54142388c1de2f8e3799c33-Gray, David]; Holloman, Vincia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7e9f8511bc84976ae1eae93e17062fa-Holloma, Vincia]; Idsal, Anne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b1beca8121fb47a08e82b6bf2247a79b-Idsal, Anne]; Thayer, Kris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ce4ae3f107749c6815f243260df98c3-Thayer, Kri]; Quality [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09879eff255940b8951dc434052ea44f-Quality]; Kirby, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbb65672f6f34545be460a66ff6fa969-Kirby, Kevin]; Jorge-Lavastida@denka-pe.com; Henry, Elise [EHenry@joneswalker.com]; Brou, Kelly [KBrou@joneswalker.com]; Bahadori, Tina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7da7967dcafb4c5bbc39c666fee31ec3-Bahadori, Tina]; Rodan, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Rodan, Bruce]
Subject: Re: Chloroprene RFC #17002 and Chloroprene PBPK Model
Attachments: ATT00001.txt

Dr. Vandenberg:

Thank you for your response. We will be back in touch with you shortly about this.

Bob Holden

From: Vandenberg, John <Vandenberg.John@epa.gov>
Sent: Wednesday, June 13, 2018 11:41 AM
To: Holden, Bob <BHolden@joneswalker.com>
Cc: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Fine, Steven <fine.steven@epa.gov>; Gray, David <gray.david@epa.gov>; Holloman, Vincia <Holloman.Vincia@epa.gov>; Idsal, Anne <idsal.anne@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Quality <Quality@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; Jorge-Lavastida@denka-pe.com; Henry, Elise <EHenry@joneswalker.com>; Brou, Kelly <KBrou@joneswalker.com>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>
Subject: RE: Draft Email to Dr. Vandenberg - Privileged and Confidential

Dear Mr. Holden,

Thank you for your letter of June 7 with potential dates for meeting with EPA regarding the development by Dr. Clewell and the Ramboll team of a PBPK model and its subsequent evaluation by EPA. Of the dates you identified, the July 16 and July 18-19 dates will work for us. The key participants are located in Research Triangle Park, NC and it would be

most convenient for us to meet at the EPA facility in that location. Please let me know what dates and times work for you and I will arrange logistics for the meeting.

Attached to this email are EPA comments (dated June 13, 2018) on the DPE workplan to develop a PBPK model (dated March 23, 2018). This set of comments complements the document you received on May 30 from Tina Bahadori titled "An Umbrella Quality Assurance Project Plan (QAPP) for PBPK Models" (also attached). We have provided this information to support an informed discussion in July, and subsequently a more technical discussion, per your suggestion. Please let me know if there are preferred dates for a technical meeting (or, we can determine the need for a technical meeting during our July meeting).

Please contact me if you have any questions.

Best regards,

John

Attachments

From: Holden, Bob [mailto:BHolden@joneswalker.com]
Sent: Thursday, June 07, 2018 11:25 AM
To: Vandenberg, John <Vandenberg.John@epa.gov>
Cc: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Fine, Steven <fine.steven@epa.gov>; Gray, David <gray.david@epa.gov>; Holloman, Vincia <Holloman.Vincia@epa.gov>; Idsal, Anne <idsal.anne@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Quality <Quality@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; Jorge-Lavastida@denka-pe.com; Henry, Elise <EHenry@joneswalker.com>; Brou, Kelly <KBrou@joneswalker.com>
Subject: RE: Draft Email to Dr. Vandenberg - Privileged and Confidential

My apologies, but I hit send on the email below before adding all cc's.

Bob Holden

From: Holden, Bob
Sent: Thursday, June 7, 2018 10:21 AM
To: 'Vandenberg.John@epa.gov' <Vandenberg.John@epa.gov>
Cc: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Fine, Steven <fine.steven@epa.gov>; Gray, David <gray.david@epa.gov>; Holloman, Vincia <Holloman.Vincia@epa.gov>
Subject: FW: Draft Email to Dr. Vandenberg - Privileged and Confidential

Dear Dr. Vandenberg:

As you know, by letter to me dated May 30, 2018, Dr. Tina Bahadori said that I should contact you to arrange a meeting to discuss the path forward on the scientific studies being performed on behalf of Denka Performance Elastomer LLC ("DPE") concerning the development of a physiologically-based pharmacokinetic (PBPK) model to support a recalculation of the inhalation unit risk for chloroprene. Dr. Bahadori said that you would coordinate scheduling a meeting to discuss this, which meeting would include Dr. Kris Thayer and EPA's chloroprene risk assessment team.

Specifically, we would like to discuss the following:

1. The status of PBPK model work being undertaken by Dr. Harvey Clewell and the Ramboll team,

2. Quality assurance issues with the PBPK model,

3. Planned steps for publication and peer review of the PBPK model and underlying data, and

4. The next steps to allow EPA's Integrated Risk Information System (IRIS) to utilize the PBPK information, such as through a new Request for Correction (RFC), and peer review issues in connection therewith.

We would be happy to meet in person at a location of your choice. The first dates on which DPE and its key consultants with Ramboll, Dr. Harvey Clewell and Dr. Ken Mundt, are available would be June 20, 21, or 22 (Wednesday, Thursday or Friday).

Although we would prefer to schedule this meeting as soon as possible, the DPE team and its consultants are also available from July 11-13, and July 16-20.

Please let us know which of these dates would work from EPA's perspective and if EPA has additional objectives for this initial meeting. We will be happy to coordinate on the schedule and attendees in advance

Drs. Harvey Clewell and Jerry Campbell with Ramboll have suggested that it would be beneficial to hold a purely technical meeting with Dr. Paul Schlosser and his associates to discuss the proposed PBPK model for chloroprene. A representative of DPE would also attend to provide assistance as needed. This meeting would involve a discussion of in-depth details such as computer code and data validation.

We look forward to working with you and the chloroprene assessment team. Please feel free to contact me or Patrick Walsh, DPE's SHE Manager, patrick-walsh@denka-PE.com, 985-536-7573, to discuss this.

Sincerely,

Bob Holden

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