

Message

From: Krenik, Edward [edward.krenik@bracewell.com]
Sent: 6/12/2018 10:31:47 PM
To: Vandenberg, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]
CC: Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]; Orme-Zavaleta, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c5a111dc377411595e5b24b5d96146b-Orme-Zavaleta, Jennifer]
Subject: DPE meetings

Hi John,

I wanted to followup on the below email since the dates we proposed are coming up next week. I also have a meeting tomorrow at 10 AM with my client and I was hopeful that I could update the group on possible dates for the two meetings.

Please let me know what works best for your team as we would like to get these meetings on the calendar.

Thanks for all you do.

Ed

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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