

Message

From: Green, Joseph J. [JGreen@KelleyDrye.com]
Sent: 10/26/2017 3:17:29 PM
To: Hebert, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07f9bbcf7c7c4219aa78a9618f7ead54-John D. Hebert]
CC: Knizner, Steve [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3920da14a514463bb691d16bf903ef33-Steve Knizner]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Weiss, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ce04987a3784f21985f65e96c220b84-Weiss, Steven]
Subject: RE: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business Information)

John – Thanks for the update.
Regards,
Joe

JOSEPH J. GREEN
Special Counsel
Kelley Drye & Warren LLP
(202) 342-8849
JGreen@KelleyDrye.com

From: Hebert, John [mailto:Hebert.John@epa.gov]
Sent: Thursday, October 26, 2017 9:06 AM
To: Green, Joseph J. <JGreen@KelleyDrye.com>
Cc: Knizner, Steve <Knizner.Steve@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Weiss, Steven <Weiss.Steven@epa.gov>
Subject: RE: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business Information)

Hi Joe – The charge questions are currently undergoing internal review. We'll definitely provide the questions for CDA's review/comment before they are finalized. As for timing, it will probably be no earlier than the week of November 6.

Regards,
John

From: Green, Joseph J. [mailto:JGreen@KelleyDrye.com]
Sent: Wednesday, October 25, 2017 4:53 PM
To: Hebert, John <Hebert.John@epa.gov>
Cc: Knizner, Steve <Knizner.Steve@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business Information)

Hi John – Checking in again to see about a chance to review the draft charge questions, as noted below.
Thanks
Joe

From: Green, Joseph J.
Sent: Friday, October 13, 2017 11:06 AM
To: 'Hebert, John' <Hebert.John@epa.gov>
Cc: Knizner, Steve <Knizner.Steve@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business Information)

John – Thanks for the response. We appreciate the agency's efforts to keep this moving. As discussed during our call in June, CDA would like to review the charge questions to ensure that they properly frame the issues that we think will be paramount as we look towards future registration of claims. Let me know when we might be able to see a draft.

Thanks again and have a great weekend.
Joe

JOSEPH J. GREEN
Special Counsel
Kelley Drye & Warren LLP
(202) 342-8849
JGreen@KelleyDrye.com

From: Hebert, John [<mailto:Hebert.John@epa.gov>]
Sent: Thursday, October 12, 2017 6:20 PM
To: Green, Joseph J. <JGreen@KelleyDrye.com>
Cc: Knizner, Steve <Knizner.Steve@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business Information)

Hello Joe – I apologize for not getting back to you earlier. The current status is that we are close to finalizing the letter that we will share with our federal partners that will include a request for a reviewer, the charge questions and the criteria for the review. I ensure you that we are still focused on this issue and I will let you know as soon as I have any updates on our progress.

Thanks,
John

John Hebert, Chief
Registration Management Branch I
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6249
hebert.john@epa.gov

From: Green, Joseph J. [<mailto:JGreen@KelleyDrye.com>]
Sent: Wednesday, October 11, 2017 10:20 AM
To: Hebert, John <Hebert.John@epa.gov>
Cc: Knizner, Steve <Knizner.Steve@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business Information)

Hi John and all –

From our discussions in June, CDA was encouraged that a panel to review the clinical trial studies would be formed promptly and in an open and cooperative manner. CDA provided the data to EPA on August 8, and recommendations on potential panel members for consideration on September 12. We understand that the agency is seeking appropriate reviewers, but it is unclear what kind of progress has been made in terms of panel formation or other aspects of the review process, such as developing draft panel questions. It is vital that we maintain momentum and focus on the issue.

Please let us know where things stand and the schedule for moving forward. CDA also is happy to initiate drafting of questions for the panel, or to discuss development of the questions with EPA.

Thanks and best regards,
Joe

JOSEPH J. GREEN
Special Counsel
Kelley Drye & Warren LLP
(202) 342-8849
JGreen@KelleyDrye.com
Counsel to the Copper Development Association

From: Green, Joseph J.
Sent: Wednesday, October 04, 2017 12:36 PM
To: 'Hebert, John' <Hebert.John@epa.gov>
Cc: Knizner, Steve <Knizner.Steve@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business Information)

Hi John – Any further update on the review panel?
Thanks
Joe

JOSEPH J. GREEN
Special Counsel
Kelley Drye & Warren LLP
Ex. 6
JGreen@KelleyDrye.com

From: Hebert, John [<mailto:Hebert.John@epa.gov>]
Sent: Wednesday, September 13, 2017 5:43 PM
To: Green, Joseph J. <JGreen@KelleyDrye.com>
Cc: Knizner, Steve <Knizner.Steve@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business Information)

Hello Joe – Thank you for CDA's list of potential candidates. We will take your recommendations in consideration as we continue to work on finding appropriate agencies and institutions to review the clinical study. We'll be in touch when we have more information to share with you on this.

Thanks,
John

John Hebert, Chief
Registration Management Branch I
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6249
hebert.john@epa.gov

From: Green, Joseph J. [<mailto:JGreen@KelleyDrye.com>]
Sent: Tuesday, September 12, 2017 12:53 PM
To: Hebert, John <Hebert.John@epa.gov>
Cc: Knizner, Steve <Knizner.Steve@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business Information)

Hi John --

Following up on my message last week, attached please find a list of potential candidates for potential inclusion on the review panel. CDA attempted to identify candidates with relevant expertise in the field that have not previously been involved or associated with the clinical trials.

We look forward to working with EPA on the panel selection process and in developing the charge questions. Thanks again for your continued attention to this matter.

Regards,
Joe

JOSEPH J. GREEN
Special Counsel
Kelley Drye & Warren LLP
(202) 342-8849
JGreen@KelleyDrye.com

From: Green, Joseph J.
Sent: Tuesday, September 05, 2017 4:45 PM
To: 'Hebert, John' <Hebert.John@epa.gov>
Cc: Knizner, Steve <Knizner.Steve@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business Information)

Hi John --

Thanks for the response and the information on the status of the panel selection process. During our June call, EPA offered to consult with CDA regarding selection of the panel members and we would like to do so. In particular, given CDA's detailed knowledge of the clinical trials, we think it would be helpful to review and provide feedback on the draft panel questions, as well as in identifying potential panel members. CDA is developing a list of potential reviewers who have not previously been involved or otherwise associated with the

trials but have expertise and standing that would be relevant to potential participation in the panel. We will send that list to you in short order for consideration.

After we have a chance to consider the panel review questions, perhaps a follow up conference call with EPA would make sense at that point.

Thanks again for your continued attention to this matter.

Regards,
Joe

JOSEPH J. GREEN
Special Counsel
Kelley Drye & Warren LLP
(202) 342-8849
JGreen@KelleyDrye.com

From: Hebert, John [mailto:Hebert.John@epa.gov]
Sent: Tuesday, September 05, 2017 11:40 AM
To: Green, Joseph J. <JGreen@KelleyDrye.com>
Cc: Knizner, Steve <Knizner.Steve@epa.gov>
Subject: RE: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business Information)

Hello Joe – The update on where we are since our last meeting is that the Antimicrobials Division has assembled a task group that meets weekly to work on the review process for the clinical study. This group is in the process of drafting questions and criteria for review of the clinical study. The group is also working to identify appropriate agencies/institutions to review the study, and specific qualifications needed for reviewers. We have engaged with the EPA Office of the Science Advisor to facilitate outreach to reviewers and are coordinating with the Human Research Ethics and Oversight staff.

This is where we currently are so if we have a call, I don't think we'll have anything more substantive to add. But let me know if you would still like a call or if you have any questions.

Regards,
John

John Hebert, Chief
Registration Management Branch I
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6249
hebert.john@epa.gov

From: Green, Joseph J. [mailto:JGreen@KelleyDrye.com]
Sent: Wednesday, August 30, 2017 4:27 PM
To: Hebert, John <Hebert.John@epa.gov>
Subject: RE: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business Information)

Hi John –

I believe you are out of the office for the remainder of the week, but wanted to touch base to set up a call with CDA/EPA regarding the panel selection process. (per our letter with the data submission, excerpted below) Let me know what you think on possible dates for such a call.

Thanks
Joe

JOSEPH J. GREEN
Special Counsel
Kelley Drye & Warren LLP
(202) 342-8849
JGreen@KelleyDrye.com

Finally, as discussed on our call, CDA looks forward to assisting EPA in the review panel selection process. Currently, we are working on identifying experts for EPA's consideration. To ensure continued progress, we believe it would be helpful to have a call to discuss the panel selection process and schedule, including, as noted on our call and follow-up letter of June 26th, areas of expertise and other criteria to ensure that a conflict of interest does not exist for any of the reviewers. **Please let us know your availability for such a call.**

From: Green, Joseph J.
Sent: Sunday, August 20, 2017 1:12 PM
To: Hebert, John <Hebert.John@epa.gov>
Cc: Murasaki, Seiichi <Murasaki.Seiichi@epa.gov>
Subject: Re: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business Information)

Thanks John. We are good with the approach to the data submission as you described below - you have our OK to proceed.

One note: the spreadsheets are rather large and it may be tricky to get it all on a normal size PDF. Just want to make sure the data doesn't get truncated when put in that format.

Thanks again - and hope you are heading off on a good vacation!

Joe

On Aug 19, 2017, at 8:59 PM, Hebert, John <Hebert.John@epa.gov> wrote:

Hi Joe – I just wanted to let you know that I will be out of the office until August 30. Seiichi Murasaki can help you with this while I'm out of the office.

Thanks,
John

From: Hebert, John
Sent: Friday, August 18, 2017 10:57 AM
To: 'Green, Joseph J.' <JGreen@KelleyDrye.com>
Subject: RE: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business Information)

Hi Joe – I talked to the front end about this. We can take the electronic files you submitted and turn them into PDFs and assign that an MRID. We cannot assign MRIDs to electronic files and the data cannot be appended the clinical study (that's why it needs a new MRID). The supporting documents

CBI / Ex. 4

that. There is really nothing for you to do other than give me your OK to go ahead. Sorry, if this seems complicated but I do think it's important for the data to be part of the official record and to link it with the clinical study.

Please let me know if you have any questions.

Thanks,
John

From: Green, Joseph J. [<mailto:JGreen@KelleyDrye.com>]
Sent: Tuesday, August 15, 2017 6:40 PM
To: Hebert, John <Hebert.John@epa.gov>
Subject: Re: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business Information)

Thanks John

On Aug 15, 2017, at 6:03 PM, Hebert, John <Hebert.John@epa.gov> wrote:

Joe – Let me check on this and I'll get back to you.

John

From: Green, Joseph J. [<mailto:JGreen@KelleyDrye.com>]
Sent: Monday, August 14, 2017 1:13 PM
To: Hebert, John <Hebert.John@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Hilbert, John <jhilbert@khaconsultants.com>; 'Thomas Passek' <thomas.passek@copperalliance.us>; adam.estelle@copperalliance.us;
andrew.kiretajr@copperalliance.us; Knizner, Steve <Knizner.Steve@epa.gov>; Jakob, Avivah <Jakob.Avivah@epa.gov>
Subject: RE: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business Information)

Hi John –

Thanks for your message on Friday.

CBI / Ex. 4

CBI / Ex. 4

CBI / Ex. 4

For that reason, the spreadsheets are electronic and password-protected. Is there a way to submit such electronic files through the front end?

Thanks
Joe

JOSEPH J. GREEN
Special Counsel
Kelley Drye & Warren LLP
(202) 342-8849
JGreen@KelleyDrye.com

From: Hebert, John [mailto:Hebert.John@epa.gov]
Sent: Friday, August 11, 2017 2:00 PM
To: Green, Joseph J. <JGreen@KelleyDrye.com>; Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Hilbert, John <jhilbert@khaconsultants.com>; 'Thomas Passek'
<thomas.passek@copperalliance.us>; adam.estelle@copperalliance.us;
andrew.kiretajr@copperalliance.us; Knizner, Steve <Knizner.Steve@epa.gov>; Jakob,
Avivah <Jakob.Avivah@epa.gov>
Subject: RE: Copper Development Association: Review and Approval of Claims for
Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business
Information)

Hi Joe – Thank you for your email. I just wanted to confirm that you are also submitting

CBI / Ex. 4

me know if you have any questions.

Regards,
John

John Hebert, Chief
Registration Management Branch I
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6249
hebert.john@epa.gov

From: Green, Joseph J. [mailto:JGreen@KelleyDrye.com]
Sent: Tuesday, August 08, 2017 11:29 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Hebert, John <Hebert.John@epa.gov>; Hilbert, John
<jhilbert@khaconsultants.com>; 'Thomas Passek' <thomas.passek@copperalliance.us>;
adam.estelle@copperalliance.us; andrew.kiretajr@copperalliance.us
Subject: RE: Copper Development Association: Review and Approval of Claims for
Antimicrobial Copper Products Based on Clinical Trial Results (Confidential Business
Information)

**** Confidential Business Information ****

Dear Deputy Assistant Administrator Beck –

The Copper Development Association (CDA)

CBI / Ex. 4

CBI / Ex. 4

and how to access them, as well as the supporting documents. As noted in the letter, please treat the data files and accompanying information as **Confidential Business Information** and limit distribution and access accordingly.

We also request a call to follow up on the review panel selection criteria and process. Please let us know the availability of you and your team for such a call.

Your continued attention to this matter is greatly appreciated. If you have any questions about the data files or other attachments, please do not hesitate to contact me.

Regards,
Joe

JOSEPH J. GREEN
Special Counsel
Kelley Drye & Warren LLP
(202) 342-8849
JGreen@KelleyDrye.com

From: Beck, Nancy [<mailto:Beck.Nancy@epa.gov>]
Sent: Monday, June 26, 2017 5:01 PM
To: Green, Joseph J. <JGreen@KelleyDrye.com>
Cc: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Hebert, John <Hebert.John@epa.gov>; Hilbert, John <jhilbert@khaconsultants.com>; 'Thomas Passek' <thomas.passek@copperalliance.us>; adam.estelle@copperalliance.us
Subject: RE: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results

Thank you Joe. We look forward to working with CDA to make some progress in this space.

John Hebert will be our main point of contact.

Regards,
Nancy

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273

Ex. 6

beck.nancy@epa.gov

From: Green, Joseph J. [<mailto:JGreen@KelleyDrye.com>]
Sent: Monday, June 26, 2017 1:47 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>

Cc: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Hebert, John <Hebert.John@epa.gov>; Hilbert, John <jhilbert@khaconsultants.com>; 'Thomas Passek' <thomas.passek@copperalliance.us>; adam.estelle@copperalliance.us
Subject: Copper Development Association: Review and Approval of Claims for Antimicrobial Copper Products Based on Clinical Trial Results

Dear Deputy Assistant Administrator Beck –

Please see the attached letter following up on our call last Friday.

Regards,
Joe

JOSEPH J. GREEN
Special Counsel
Kelley Drye & Warren LLP
Washington Harbour
3050 K Street NW, Suite 400
Washington, DC 20007
Tel: (202) 342-8849
JGreen@KelleyDrye.com
Counsel to the Copper Development Association

The information contained in this E-mail message is privileged, confidential, and may be protected from disclosure; please be aware that any other use, printing, copying, disclosure or dissemination of this communication may be subject to legal restriction or sanction. If you think that you have received this E-mail message in error, please reply to the sender.

This E-mail message and any attachments have been scanned for viruses and are believed to be free of any virus or other defect that might affect any computer system into which it is received and opened. However, it is the responsibility of the recipient to ensure that it is virus free and no responsibility is accepted by Kelley Drye & Warren LLP for any loss or damage arising in any way from its use.

The information contained in this E-mail message is privileged, confidential, and may be protected from disclosure; please be aware that any other use, printing, copying, disclosure or dissemination of this communication may be subject to legal restriction or sanction. If you think that you have received this E-mail message in error, please reply to the sender.

This E-mail message and any attachments have been scanned for viruses and are believed to be free of any virus or other defect that might affect any computer system into which it is received and opened. However, it is the responsibility of the recipient to ensure that it is virus free and no responsibility is accepted by Kelley Drye & Warren LLP for any loss or damage arising in any way from its use.

The information contained in this E-mail message is privileged, confidential, and may be protected from disclosure; please be aware that any other use, printing, copying, disclosure or dissemination of this communication may be subject to legal restriction or sanction. If you think that you have received this E-mail message in error, please reply to the sender.

This E-mail message and any attachments have been scanned for viruses and are believed to be free of any virus or other defect that might affect any computer system into which it is received and opened. However, it is the responsibility of the recipient to ensure that it is virus free and no responsibility is accepted by Kelley Drye & Warren LLP for any loss or damage arising in any way from its use.

The information contained in this E-mail message is privileged, confidential, and may be protected from disclosure; please be aware that any other use, printing, copying, disclosure or dissemination of this communication may be subject to legal restriction or sanction. If you think that you have received this E-mail message in error, please reply to the sender.

This E-mail message and any attachments have been scanned for viruses and are believed to be free of any virus or other defect that might affect any computer system into which it is received and opened. However, it is the responsibility of the recipient to ensure that it is virus free and no responsibility is accepted by Kelley Drye & Warren LLP for any loss or damage arising in any way from its use.

The information contained in this E-mail message is privileged, confidential, and may be protected from disclosure; please be aware that any other use, printing, copying, disclosure or dissemination of this communication may be subject to legal restriction or sanction. If you think that you have received this E-mail message in error, please reply to the sender.

This E-mail message and any attachments have been scanned for viruses and are believed to be free of any virus or other defect that might affect any computer system into which it is received and opened. However, it is the responsibility of the recipient to ensure that it is virus free and no responsibility is accepted by Kelley Drye & Warren LLP for any loss or damage arising in any way from its use.

The information contained in this E-mail message is privileged, confidential, and may be protected from disclosure; please be aware that any other use, printing, copying, disclosure or dissemination of this communication may be subject to legal restriction or sanction. If you think that you have received this E-mail message in error, please reply to the sender.

This E-mail message and any attachments have been scanned for viruses and are believed to be free of any virus or other defect that might affect any computer system into which it is received and opened. However, it is the responsibility of the recipient to ensure that it is virus free and no responsibility is accepted by Kelley Drye & Warren LLP for any loss or damage arising in any way from its use.

The information contained in this E-mail message is privileged, confidential, and may be protected from disclosure; please be aware that any other use, printing, copying, disclosure or dissemination of this communication may be subject to legal restriction or sanction. If you think that you have received this E-mail

message in error, please reply to the sender.

This E-mail message and any attachments have been scanned for viruses and are believed to be free of any virus or other defect that might affect any computer system into which it is received and opened. However, it is the responsibility of the recipient to ensure that it is virus free and no responsibility is accepted by Kelley Drye & Warren LLP for any loss or damage arising in any way from its use.

The information contained in this E-mail message is privileged, confidential, and may be protected from disclosure; please be aware that any other use, printing, copying, disclosure or dissemination of this communication may be subject to legal restriction or sanction. If you think that you have received this E-mail message in error, please reply to the sender.

This E-mail message and any attachments have been scanned for viruses and are believed to be free of any virus or other defect that might affect any computer system into which it is received and opened. However, it is the responsibility of the recipient to ensure that it is virus free and no responsibility is accepted by Kelley Drye & Warren LLP for any loss or damage arising in any way from its use.

The information contained in this E-mail message is privileged, confidential, and may be protected from disclosure; please be aware that any other use, printing, copying, disclosure or dissemination of this communication may be subject to legal restriction or sanction. If you think that you have received this E-mail message in error, please reply to the sender.

This E-mail message and any attachments have been scanned for viruses and are believed to be free of any virus or other defect that might affect any computer system into which it is received and opened. However, it is the responsibility of the recipient to ensure that it is virus free and no responsibility is accepted by Kelley Drye & Warren LLP for any loss or damage arising in any way from its use.