Message

From: Willis, Kristen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B437BEE32204A51AED37522B09153F3-WILLIS, KRI]
Sent: 4/4/2018 9:23:58 PM
To: 'Green, Joseph J.' [JGreen@KelleyDrye.com]
CC: Pease, Anita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbbef4b4951144499885d4cdf88d46d0-Anita Pease]; 'adam.estelle@copperalliance.us' [adam.estelle@copperalliance.us]; 'RStewart@TSGUSA.COM' [RStewart@TSGUSA.COM]; Hilbert, John [jhilbert@khaconsultants.com]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: RE: Antimicrobial Copper Clinical Trial Expert Panel Review - BioBurden Claims and Panel Review of Infection Related Claims
Attachments: Bioburden draft questions 4-4-2018docx.docx

Hi Joe,
Thanks for a productive call today. I wanted to provide you with a copy of the revised charge questions for the bioburden paper based on our conversation. We'll keep you posted on the progress on our end.

Best,
Kristen

From: Green, Joseph J. [mailto:JGreen@KelleyDrye.com]
Sent: Wednesday, April 04, 2018 3:31 PM
To: Willis, Kristen <Willis.Kristen@epa.gov>
Cc: Pease, Anita <Pease.Anita@epa.gov>; 'adam.estelle@copperalliance.us' <adam.estelle@copperalliance.us>; 'RStewart@TSGUSA.COM' <RStewart@TSGUSA.COM>; Hilbert, John <jhilbert@khaconsultants.com>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Antimicrobial Copper Clinical Trial Expert Panel Review - BioBurden Claims and Panel Review of Infection Related Claims

Anita and Kristen –

Thanks again for the call today and for reiterating the agency's commitment to moving the panel review along quickly going forward.

I think it was very useful today to walk through the questions and address the comments and questions we had, which we feel were resolved sufficiently to finalize the materials and package for the prospective reviewers.

We look forward to seeing the draft cover letter and list of materials to be sent to the reviewers, and will look for by the end of next week as indicated on the call. We recognize that the letter needs to go through management review, but anticipate that that can happen readily, with issuance of EPA's communication to the panel candidates to follow promptly thereafter. It appears that we are very close to finalizing everything and appreciate your efforts to get the panel review finally moving.

Thanks again and please let us know if you need any additional information.

Regards,
Joe

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Counsel to the Copper Development Association

From: Green, Joseph J.
Sent: Wednesday, April 04, 2018 12:40 PM
To: 'Willis, Kristen' <Willis.Kristen@epa.gov>
Cc: Pease, Anita <Pease.Anita@epa.gov>; adam.estelle@copperalliance.us; RStewart@TSGUSA.COM; Hilbert, John <jhilbert@khaconsultants.com>
Subject: RE: Antimicrobial Copper Clinical Trial Expert Panel Review - BioBurden Claims and Panel Review of Infection Related Claims

Hi Kristen –

Thanks again for sending the draft questions related to the bioburden claims. In advance of our call at 3:00 this afternoon, I thought it would be useful to provide our feedback to tee up issues for discussion and hopefully resolution. The attached redline includes our comments and suggestions.

As an initial matter, we are most interested in moving this process along quickly, and far more expeditiously than has been the case to date. In that spirit, we offer the recommendations you see in the attached document, but do not want these comments to hold up the process any further.

In particular, we believe that the methodological issues raised in questions 1-5 do not seem necessary for review by an outside expert panel. These issues are clearly answered in the study paper and its supporting materials, and the study methodology already has been validated by independent third party reviewers from both the participating hospitals and the journals in which the study articles were published. If EPA feels it is nonetheless necessary to include these questions, it underscores the need to ensure that the panel reviewers are provided the "data roadmap" and other supporting materials that already have been provided to EPA (and which we suggested previously be provided to the panel). These materials are critical to make sure that the reviewers have all appropriate materials related to the study so that they can answer the questions efficiently and with full information.

Finally, regarding next steps, we still need to receive a draft of the cover letter and the list of charge materials that will be sent to the panel reviewers, as we discussed several months ago. We request to be provided those materials by the end of next week (April 13), after which we will turn around any comments by middle of the following week (April 18).

Hopefully, we can talk through and resolve all of these issues on the phone today. Again, we emphasize that above all we want the process to move forward rapidly from this point, and do not see the need to delay issuance of the questions after our call.

We look forward to discussing later this afternoon.

Regards,
Joe

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From: Willis, Kristen [mailto:Willis.Kristen@epa.gov]
Sent: Thursday, March 29, 2018 11:53 PM
To: Green, Joseph J. <JGreen@KelleyDrye.com>
Cc: Pease, Anita <Pease.Anita@epa.gov>
Subject: RE: Antimicrobial Copper Clinical Trial Expert Panel Review - BioBurden Claims and Panel Review of Infection Related Claims

Hi Joe,
As promised, attached are the draft questions for the bioburden paper. We look forward to hearing your feedback next week.

Best,
Kristen

From: Green, Joseph J. [mailto:JGreen@KelleyDrye.com]
Sent: Tuesday, March 20, 2018 5:44 PM
To: Willis, Kristen <Willis.Kristen@epa.gov>
Cc: Beck, Nancy <Beck.Nancy@epa.gov>; Pease, Anita <Pease.Anita@epa.gov>
Subject: Re: Antimicrobial Copper Clinical Trial Expert Panel Review - BioBurden Claims and Panel Review of Infection Related Claims

Hi Kristin - thanks for your message. I will check on availability for April 4. I believe that works so we can at least pencil in a call that day.

On timeline, I'm unclear if we are now triggering an additional 2-6 months to the original 15 month timeline (if HSRB review is needed). As I recall, there is an October HSRB meeting we were targeting.

Regards
Joe

On Mar 20, 2018, at 4:35 PM, Willis, Kristen <Willis.Kristen@epa.gov> wrote:

> Good afternoon Joe,
>
> Please see the responses to topics covered in your email:
>
> *(1) Bioburden claims – reference to "clinical trials" and "conducted in ICU rooms"*
>
> The agency stance has been and remains that we don't review clinical studies. The goal of the external review is not to have the reviewers verify that a clinical study was conducted in an ICU which we agree is easily verifiable. Rather the goal is to have reviewers evaluate the conclusions of both of the clinical studies in support of a label claim. It is the combination of the reference to the clinical study and the claim based on the study that necessitates external review.
>
> As such, the agency feels that the bioburden study and a set of questions should go out for external review in order to support the claims desired by CDA. At present, our list includes 15 questions which we will share with you no later than March 30.
>
> We would like to schedule a conference call with CDA to discuss the questions after CDA has had a chance to review the questions. We suggest a target date of Wednesday April 4th depending on how long CDA anticipates needing in order to review the questions.

An amendment to add the claims could be submitted after the external review is complete, if the study does not need to go to HSRB. If the study does need to go to HSRB, the PRIA amendment to add the claims could be submitted after the HSRB review. AD staff is meeting on Monday March 26, 2018 to discuss the appropriate PRIA code. You will receive the appropriate code when the draft charge questions are shared.

(2) Bioburden claims – DoD funding reference

Submission of the requested funding verification documentation with the PRIA application noted above is appropriate.

(3) Status of Panel Review of Infection-Related Claims

We have not yet provided a courtesy copy of the final cover letter as the letter has recently been modified to include both the HAI review and the bioburden reduction review. We were waiting to determine the path forward for review of the bioburden reduction study before modifying the letter and getting signature. Once signed, we will provide a courtesy copy to CDA.

With regard to the timeline, please note that option 2 under Bioburden reduction claims was as follows: "Option 2 (external review with HAI claims): **Additional 2-6 months** onto time line designated above for HAI claims (15 months) depending on HSRB schedule

- EPA drafts charge questions specific to bioburden reduction and shares with CDA (4-6 weeks)
- Both sets of questions would go out at the same time with a target date of mid-late March to send out the request to review to federal partners."

While we had hoped to have the questions to CDA in 4-6 weeks, we will be slightly past that timeframe (~8 weeks) by the time we share the questions with CDA. The request for review will be sent out to reviewing external agencies as soon as it is cleared by agency senior management.

Finally, there is no delay to the external review based on the HSRB process. We are on separate paths.

(4) Ethics-related information

All ethics/HSRB related issues will be dealt with by Michelle Arling who you have been communicating with.

Best,
Kristen Willis

From: Green, Joseph J. [mailto:JGreen@KelleyDrye.com]
Sent: Monday, March 19, 2018 2:52 PM
To: Willis, Kristen <Willis.Kristen@epa.gov>
Cc: Beck, Nancy <Beck.Nancy@epa.gov>; Pease, Anita <Pease.Anita@epa.gov>
Subject: Antimicrobial Copper Clinical Trial Expert Panel Review - BioBurden Claims and Panel Review of Infection Related Claims

Hi Kristen –

Thanks for the response related to the bioburden reduction claims. We have some thoughts on the points raised in your message as well as with respect to the status of the panel review for infection-related claims.

(1) Bioburden claims – reference to "clinical trials" and "conducted in ICU rooms"

As discussed previously and indicated in our correspondence, the ability to reference the facts that the claims are based on the results of a clinical trial, and that those trials occurred in hospital ICUs, are fundamental and critical. They are not optional as we made clear in our prior discussions. We are surprised that it would be necessary to obtain independent expert panel confirmation of these facts. It is indisputable that the study was a "clinical trial" and involved patients in the intensive care units of the three hospitals. These facts are easily verified, including by review of the journal articles published with respect to the study.

If EPA feels it necessary to seek expert confirmation of these facts, it would seem that such verification can be obtained easily in a simple question or two and should not extend the panel review period or time schedule. We do not see the need for expert panel confirmation of the fact that the studies involved evaluation of hospital ICU rooms.

If the review you indicate is more than that, please let us know immediately.

Please send us the draft panel review questions by March 30, as indicated.

We propose that EPA allow CDA to proceed without delay with filing amendments (as discussed previously using the PRIA A570 process with a 4 month review period) to allow for the bioburden reduction claims including reference to the fact that they are based on the results of clinical trials involving hospital ICU rooms. If somehow the expert panel raises questions about the validity of the clinical trial, then we can review those claims at that time. Imposing additional delay, however, to confirm these facts does not seem reasonable.

(2) Bioburden claims – DoD funding reference

With regard to the issue of referencing DoD funding of the study we would submit the requested funding verification documentation with the A570 PRIA application noted above, and would modify the claims to reflect the suggested qualifier.

(3) Status of Panel Review of Infection-Related Claims

When we spoke in January, EPA was preparing to finalize the panel review questions and cover letter/information to send to the panel reviewers. (We also were supposed to receive a copy of that final cover letter.) According to the attached timeline provided on January 31, the package was supposed to be sent to prospective reviewers within 2-4 weeks (during February). Has that occurred? If not, we see no reason why it should not proceed immediately.

While we understand that there remains a question as to the need for HSRB review, referral to the HSRB, according to the attached timeline, was to occur after receiving panel reviewer input. Accordingly, any delays related to obtaining ethics-related information for the HSRB review analysis should not be delaying initiation of the panel review.

(4) Ethics-related information

We understand that the Medical University of South Carolina (MUSC) has compiled most, if not all, of the requested ethics-related information. However, the decision to release the information to EPA now lies with the hospital general counsel and review boards. We believe that Sloan-Kettering also is compiling the information.

Please let me know if you would like to have a call to discuss.

Regards,

Joe

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From: Willis, Kristen [mailto:Willis.Kristen@epa.gov]
Sent: Monday, March 19, 2018 9:27 AM
To: Green, Joseph J. <JGreen@KelleyDrye.com>
Subject: RE: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review

Good Morning Joe,

I want to provide an update to you with regard to the bioburden reduction claims. We have finally received a response from our OGC with regard to the proposed claim language for bioburden reduction "[The results of a clinical trial] [sponsored by the Department of Defense] [conducted in the intensive care units of three hospitals][has shown that] Use of Antimicrobial Copper touch surfaces [continuously]…"

1) Study funded by- On our last call we had let you know that "sponsored by the Department of Defense" would not be permitted as a label claim but offered "funded by" or "partially funded by" as a possible alternative. Our OGC said that this would be fine but had the following qualifications:
    i. A copy of the funding agreement or similar documentation should be submitted to demonstrate that the study was funded by/partially funded by the Department of Defense.
    ii. The claim should be qualified with a qualifier similar to that in the published study "The views, opinions, and/or findings presented here are ours and should not be construed as an official position of the U.S. Department of the Army."
2) OGC recommended that for the claim to reference a clinical trial or "conducted in the ICU" we seek external review rather than review internally. If CDA desires these claims we will send a separate set of questions out along with the HAI questions. To that end, we will be prepared to share these questions with you no later than the end of next week (March 30th). Please advise if this is the path CDA would like to pursue. Alternatively, EPA will review internally with the caveat that references to a clinical study or ICU will not be permitted.

Thanks,
Kristen Willis

Kristen Willis, PhD
Senior Scientist
Product Science Branch
Antimicrobials Division, OCSPP
Environmental Protection Agency

Office: 703-347-0515
Cel Ex. 6

From: Willis, Kristen
Sent: Wednesday, February 21, 2018 5:22 PM
To: 'Green, Joseph J.' <JGreen@KelleyDrye.com>
Subject: RE: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review

Hi Joe,
Thanks for checking in. I checked in with OGC yesterday and they said they are still working on the bioburden claim issue and should have a follow up soon. The train is definitely still moving.

Thanks!
Kristen

From: Green, Joseph J. [mailto:JGreen@KelleyDrye.com]
Sent: Tuesday, February 20, 2018 12:39 PM
To: Willis, Kristen <Willis.Kristen@epa.gov>
Subject: RE: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review

Hi Kristen –

Wanted to follow to see, in particular, where the bioburden claims issue stands. We do not want to lose momentum on that issue while we sort out the HSRB issues re: the infection-related claims.

Thanks again,
Joe

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From: Green, Joseph J.
Sent: Wednesday, January 31, 2018 4:54 PM
To: 'Willis, Kristen' <Willis.Kristen@epa.gov>
Subject: RE: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review

Hi Kristen: Thanks for sending the timeline and for the call today. We appreciated the agency providing options for evaluation of the bioburden claims and a timeline for review of the HAI-related claims.
As a follow up, I thought we would send some further information related to the bioburden claims and need for HSRB review.

(1) BioBurden claims: As initially proposed, the basic claims would be preceded by the following statement (bracketed text is optional):

"[The results of a clinical trial] [sponsored by the Department of Defense] [conducted in the intensive care units of three hospitals][has shown that] Use of Antimicrobial Copper touch surfaces [continuously] …" (the full originally proposed claims text is provided below for reference)

We do not object to changing the reference to "clinical trial" to "study" in the first phrase.

We also understood that use of the term "sponsored by the Department of Defense" could be construed as an endorsement by a federal agency. We considered changing the term "sponsored" to "funded" or some similar language that would not connote "endorsement" but would convey the factual information that the study underlying the bioburden claims was conducted under the auspices of and funded by the Department of Defense. Being able to make such a statement is important to convey that the study was conducted and overseen by an independent third party. It also reflects the fact that information provided on the studies that support the claims will clearly indicate that the Department of Defense was involved with the stud (e.g., if the study articles were posted on CDA's website, for example, which would be appropriate if the claims are approved). We are happy to consider alternative language that the agency may suggest, but it is imperative that CDA be able to state that the study was funded and overseen by DoD or, at minimum, an independent third party.

Similarly, it is critical that CDA be able to include in claims a statement about where and how the study was conducted, including that it was "conducted in the intensive care units of three hospitals." This statement provides context for the basic claims language that otherwise would be rendered relatively meaningless given that CDA already has approval for claims that involve greater than 99.9% reduction of bacteria based on laboratory data. The fact that the new claims are based on real world data from a hospital study is the critical element of the claim. Accordingly, we believe it is very important to keep this portion of the bracketed text.

(2) HSRB Review: In laying out the proposed 15 month timeline for review and potential approval of the HAI-related claims, at least half of that time is consumed by an HSRB review that we believe is unnecessary and would be duplicative of similar reviews already conducted by the Department of Defense and the institutional review boards (IRBs) of the participating hospitals. The purpose of the HSRB review is to make sure that the testing protocol is appropriate for studies involving intentional human exposure and consistent with the Federal Policy for the Protection of Human Subjects of Research (the "Common Rule"). Such a protocol review was performed by the DoD as well as the hospital IRBs, each of which included evaluation to ensure compliance with the Common Rule and, furthermore, to exclude pregnant or nursing women and children from the study. Requiring a separate EPA HSRB review would be duplicative and is unnecessary in light of past agency practice.

For reference, here is an excerpt from the final DOD study report referencing the IRB approvals:

> Protocols required to initiate Phase III (the Clinical Trial to determine the effectiveness of copper touch surfaces in
> preventing the transmission of the monitored microbes from touch surfaces to patients and from patients to touch
> surfaces in the selected patient care settings) were also developed, approved by each hospital Institutional Review
> Board (IRB) as well as the with the U.S. Army Medical Research and Materiel Command (USAMRMC), Office of
> Research Protections (ORP), Human Research Protection Office (HRPO).

The HRPO log number for the trial was A-14315.3a if that is at all helpful. See this link for a summary of the Army HRPO review process of research protocols that was completed for the trial: https://health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/Protect-Humans-in-Research/HRPO-Review-of-Research-Protocols. In addition, I have attached the IRB review report from the Medical University of South Carolina, which was involved in the study.

In other contexts, including DoD testing of insect repellants, EPA has recognized that DoD protocol review is an adequate substitute in lieu of the EPA HSRB review. The same recognition should be accorded here. This is particularly true given that the evaluation of the

performance of antimicrobial copper surface materials, unlike insect repellants, does not involve application of the copper material to humans (rather, the copper alloys are applied to environmental materials). In fact, EPA also has recognized that HSRB review is unnecessary in situations where people are involved in the study but not the subject to which the pesticidal material is applied. For example, the Antimicrobials Division has found that HSRB review was not necessary in evaluating a study of the efficacy of pool treatment chemicals where people would be in the pool (and a source of contamination). Likewise, with the copper alloy studies, the treatment (copperization of surface materials) is applied to the environment and not the patients themselves. The HAI data from the studies reflect an observation made as a result of people being in an environment where copper alloys are prevalent (similar to the evaluation of bacteria loadings in the pool), but the patients are not being treated with copper directly or intentionally. Accordingly, the copper studies do not involve intentional exposure to humans and, therefore, HSRB review is not necessary.*

> * For example, as EPA described in the *Federal Register* preamble to 2013 amendments to the regulations governing Protections for Subjects in Human Research Involving Pesticides, the rules apply to "research with pesticides involving *intentional exposure* of human subjects and to persons who submit the results of human research with pesticides to EPA." (emphasis added)

In sum, we think that HSRB review is unnecessary given that the copper studies do not involve intentional exposure of human subjects to copper (the pool chemical precedent). However, if such review were deemed necessary, then EPA should recognize that an equivalent review has been conducted by the DoD and hospital IRBs and that these reviews are an adequate substitute for the EPA HSRB process, at least in this case, as the Office of Pesticides has previously determined with respect to prior DoD studies involving insect repellants. To require an extra HSRB review, adding another 6-8+ months to the timeline, is unreasonable.

Thank you for your consideration of these issues. We look forward to resolving these and moving forward as rapidly as possible with the substantive panel review of the copper studies.

Regards,
Joe

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Bio-Burden Reduction Claims

- [The results of a clinical trial] [sponsored by the Department of Defense] [conducted in the intensive care units of three hospitals][has shown that] Use of Antimicrobial Copper touch surfaces [continuously]
  - reduces the level of [Gram +/ Gram -] bacteria in healthcare facilities
  - results in >80% average reduction in the level of [Gram +/ Gram -] bacteria.
  - reduces bacteria by >80%.
  - delivers continuous and ongoing antibacterial action, remaining effective in killing >80% of bacteria.
  - help inhibit the buildup and growth of bacteria between routine cleanings and sanitizing steps.
  - reduces the bacterial load in healthcare settings.
  - delivers [more than][>] 80% reduction of bacteria on this surface [throughout the day].

- reduces bacteria in healthcare settings.
- delivers continous antibacterial action.
- inhibits the buildup and growth of bacteria between cleanings.
- inhibits the growth of bacteria during active patient care.

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From: Willis, Kristen [mailto:Willis.Kristen@epa.gov]
Sent: Wednesday, January 31, 2018 4:28 PM
To: Green, Joseph J. <JGreen@KelleyDrye.com>
Subject: RE: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review (bioburden)

Hi Joe,
Thanks again for the call today. While we are working on answers to the follow up questions, attached is the proposed timeline for review of claims that we discussed on our call this afternoon. I will follow up soon.

Thanks,
Kristen

From: Green, Joseph J. [mailto:JGreen@KelleyDrye.com]
Sent: Wednesday, January 31, 2018 1:36 PM
To: Willis, Kristen <Willis.Kristen@epa.gov>
Subject: RE: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review (bioburden)

Hi Kristen –

Here are the issues we would like to discuss (based on last week's call):

- How EPA will handle bioburden claims separately and CDA's request to proceed with a label amendment application
- Status/timing of EPA cover letter to reviewers and CDA request to review draft
- Confirm list of all materials to be sent to reviewers (assumes no bioburden review)
  - Cover letter
  - EPA white paper on standard public health claims AD review process
  - Charge questions
  - Salgado manuscript
  - Raw data file for HAIs and password
  - Raw data roadmap (will need to send revised version that does not include bioburden)
- Review timeline and urgency to get this started

Thanks
Joe

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From: Willis, Kristen [mailto:Willis.Kristen@epa.gov]
Sent: Wednesday, January 31, 2018 12:39 PM
To: Green, Joseph J. <JGreen@KelleyDrye.com>
Subject: RE: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review (bioburden)

Hi Joe,
Confirmed.
Thanks!
-Kristen

From: Green, Joseph J. [mailto:JGreen@KelleyDrye.com]
Sent: Wednesday, January 31, 2018 12:38 PM
To: Willis, Kristen <Willis.Kristen@epa.gov>
Subject: RE: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review (bioburden)

Hi Kristen – Just confirming that we are on for our call at 2:00 today. Call-in below.
Thanks again
Joe

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JGreen@KelleyDrye.com

From: Green, Joseph J.
Sent: Wednesday, January 24, 2018 11:41 AM
To: 'Willis, Kristen' <Willis.Kristen@epa.gov>
Subject: RE: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review (bioburden)

Hi Kristen – 2pm Wednesday 1/31 works best for us. Alternative would be 11am that day. We can use the same call-in info as before if that works for you:

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Dial +1 (877) 472 4353
Guest Dial-in Code: 2418684#
```

Let me now when we are confirmed.

Thanks
Joe

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From: Willis, Kristen [mailto:Willis.Kristen@epa.gov]
Sent: Tuesday, January 23, 2018 2:25 PM
To: Green, Joseph J. <JGreen@KelleyDrye.com>
Subject: RE: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review (bioburden)

Hi Joe,
I looked for a time this week that was good for everyone however unfortunately I couldn't find anything. Haley is out the beginning of next week. As such I would propose the following times:

Wednesday 1/31 at 11am or 2pm
Or
Thursday 02/01 at 11am

Let me know if any of those work for you.

Thanks,
Kristen

From: Green, Joseph J. [mailto:JGreen@KelleyDrye.com]
Sent: Tuesday, January 23, 2018 11:40 AM
To: Willis, Kristen <Willis.Kristen@epa.gov>
Subject: RE: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review (bioburden)

Hi Kristen – CDA is good with the revised charge questions as attached, assuming we come to a satisfactory consensus on how the bioburden reduction claims will be handled. If so, then these questions are appropriate for the panel to consider.

Thanks and let me know what dates/times look good for a call later this week.

Regards,
Joe

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From: Willis, Kristen [mailto:Willis.Kristen@epa.gov]
Sent: Monday, January 22, 2018 4:24 PM
To: Green, Joseph J. <JGreen@KelleyDrye.com>

Subject: RE: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review (bioburden)

Hi Joe,
Thanks for the great call and for the quick turnaround in sending the claims. We also felt it was very productive. As discussed, I have attached a copy of the draft charge questions with the changes we discussed. Please note that former questions 19, 24a, 27 and 28 have been removed from this draft. As discussed, we will revisit the issue of removal of these questions at our follow up call after we have had time to review the information provided. I'm still working on getting some times/dates for our next call. I will follow up with you tomorrow.

Thanks!
-Kristen

From: Green, Joseph J. [mailto:JGreen@KelleyDrye.com]
Sent: Monday, January 22, 2018 3:12 PM
To: Willis, Kristen <Willis.Kristen@epa.gov>
Subject: RE: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review (bioburden)

Hi Kristen –

Thanks again for the call today, which we thought was very productive and helpful. Following up, I'm forwarding the proposed bioburden reduction claims (see "bio-burden reduction" section of attached document and below). As discussed, CDA would be amenable to excluding the bioburden issues from the panel review process, if in fact EPA confirms, as suggested on the call, that these claims can be reviewed and approved by the agency in an expeditious manner. On the call, it was mentioned that EPA already has approved similar claims based on the existing efficacy data that supports the current registration or Antimicrobial Copper Alloys. If EPA confirms that no panel input is needed for EPA review of the bioburden claims, my sense is that we could proceed with a label amendment application at this time.

Such an amendment application presumably would fall under PRIA category A570, with a 4 month review period and application fee of $3831. https://www.epa.gov/pria-fees/a570-pria-fee-category

Please let me know what you think. We look forward to discussing later in the week.

Regards,
Joe

JOSEPH J. GREEN
Special Counsel
Kelley Drye & Warren LLP
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Bio-Burden Reduction Claims

- [The results of a clinical trial] [sponsored by the Department of Defense] [conducted in the intensive care units of three hospitals][has shown that] Use of Antimicrobial Copper touch surfaces [continuously]
  - reduces the level of [Gram +/ Gram -] bacteria in healthcare facilities

- results in >80% average reduction in the level of [Gram +/ Gram -] bacteria.
- reduces bacteria by >80%.
- delivers continuous and ongoing antibacterial action, remaining effective in killing >80% of bacteria.
- help inhibit the buildup and growth of bacteria between routine cleanings and sanitizing steps.
- reduces the bacterial load in healthcare settings.
- delivers [more than][>] 80% reduction of bacteria on this surface [throughout the day].
- reduces bacteria in healthcare settings.
- delivers continous antibacterial action.
- inhibits the buildup and growth of bacteria between cleanings.
- inhibits the growth of bacteria during active patient care.

From: Willis, Kristen [mailto:Willis.Kristen@epa.gov]
Sent: Friday, January 19, 2018 2:38 PM
To: Green, Joseph J. <JGreen@KelleyDrye.com>
Cc: Weiss, Steven <Weiss.Steven@epa.gov>; Hebert, John <Hebert.John@epa.gov>
Subject: RE: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review

Hi Joe,
That is correct. In the event of a shutdown (fingers crossed it doesn't happen) the call will not occur.

Here are a few alternate dates/times that may work depending on how long the shutdown lasts:
Thursday 01/25/2018- 1pm
Wednesday 01/31/2018- 11am or 1pm

Just FYI, once a shutdown commences I won't have access to my work email so won't be able to confirm any of the alternate dates/times until after the shutdown is over.
Hopefully it won't come to that but just in case!
-Kristen

From: Green, Joseph J. [mailto:JGreen@KelleyDrye.com]
Sent: Friday, January 19, 2018 9:03 AM
To: Willis, Kristen <Willis.Kristen@epa.gov>
Cc: Weiss, Steven <Weiss.Steven@epa.gov>; Hebert, John <Hebert.John@epa.gov>
Subject: Re: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review

Hi Kristen - so, figured I'd touch base in case the shutdown goes ahead. If that occurs I assume, obviously, that the call would not occur. (Though correct me if I'm wrong!). With that in mind, are there some alternate dates/times - later in week? Following week? - that we could shift too?
Let me know what you think.
Regards
Joe

On Jan 17, 2018, at 3:16 PM, Willis, Kristen <Willis.Kristen@epa.gov> wrote:

Hi Joe,

The topics you have proposed sound good. We don't have any additional specific issues. If you could provide a call in number that would be great as we are currently going through a revamp of our teleconference system.

Thanks,
Kristen

From: Green, Joseph J. [mailto:JGreen@KelleyDrye.com]
Sent: Wednesday, January 17, 2018 2:58 PM
To: Willis, Kristen <Willis.Kristen@epa.gov>
Cc: Weiss, Steven <Weiss.Steven@epa.gov>; Hebert, John <Hebert.John@epa.gov>
Subject: RE: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review

Hi Kristen –

Monday the 22nd at 2:00 pm works best for us. If there are any specific issues you can point in advance for us to discuss, that would be helpful. In addition, we thought the following topics would be helpful to address:

- Cover letter and other materials to be sent to potential reviewers
- Inclusion of CDA reviewer candidates
- Clarification that both bioburden and infection reduction claims are part of the review
- Schedule/timeline – feedback on schedule proposed by CDA

I can set up a call number if you like, or if there is a system that works better for you, let me know.

Thanks again
Joe

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From: Willis, Kristen [mailto:Willis.Kristen@epa.gov]
Sent: Wednesday, January 17, 2018 1:34 PM
To: Green, Joseph J. <JGreen@KelleyDrye.com>
Cc: Weiss, Steven <Weiss.Steven@epa.gov>; Hebert, John <Hebert.John@epa.gov>
Subject: RE: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review

Hi Joe,
AD would like to set up a call with CDA to discuss the feedback on the questions. In order to expedite this process, would any of the following dates/times work?
Thursday 1/18 at 1pm
Monday 1/22 at 2pm

Alternate date: Friday 1/19 at 11am.

Regards,
Kristen Willis

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From: Green, Joseph J. [mailto:JGreen@KelleyDrye.com]
Sent: Friday, January 05, 2018 10:02 AM
To: Hebert, John <Hebert.John@epa.gov>
Cc: Weiss, Steven <Weiss.Steven@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Hughes, Hayley <hughes.hayley@epa.gov>; Willis, Kristen <Willis.Kristen@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Draft Charge Questions - Antimicrobial Copper Clinical Trial Expert Panel Review

Hi John –

Thanks again for sending the draft charge questions. In the attached letter and red-line document, CDA has a few suggestions on the questions and some recommendations for moving forward, including a suggested timeline to help maintain progress in getting the review of the copper clinical trial underway and completed. We do hope that the process can get started in the next week or so (by January 15) with sending out the initial communication from EPA to prospective panel members, as noted in our letter. To that end, I will be forwarding a suggested cover letter in the next day or so.

Please let us know if you have any questions or need any additional information, and keep us posted on how things proceed.

Also, best wishes with the new posting. We have appreciated working with you and look forward to continuing to do so.

Regards,
Joe

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From: Hebert, John [mailto:Hebert.John@epa.gov]
Sent: Friday, December 15, 2017 3:52 PM
To: Green, Joseph J. <JGreen@KelleyDrye.com>
Cc: Weiss, Steven <Weiss.Steven@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Hughes, Hayley <hughes.hayley@epa.gov>; Willis, Kristen <Willis.Kristen@epa.gov>
Subject: Draft Charge Questions

Hello Joe – Please see the attached draft charge questions. Along with charge questions, we intend to provide our federal partners with a white paper that describes the general registration process including efficacy data requirements for products making public health claims. Please let me know if you have any questions.

Regards,
John

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John Hebert, Chief
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Environmental Protection Agency
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hebert.john@epa.gov

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