

## **Kelleman, Christine B**

**From:** McConagha, William  
**Sent:** Monday, November 03, 2008 9:12 AM  
**To:** Senger, Jeffrey; Cook, Kate; Winckler, Susan; Weinstein, Les S; Warren, Matthew; Torti, Frank  
**Cc:** Chernaik, Beverly; Wion, Ann  
**Subject:** RE: ReGen letter

Thanks. I'll excise the language.

**From:** Senger, Jeffrey  
**Sent:** Saturday, November 01, 2008 4:51 PM  
**To:** Cook, Kate; McConagha, William; Winckler, Susan; Weinstein, Les S; Warren, Matthew; Torti, Frank  
**Cc:** Chernaik, Beverly; Wion, Ann  
**Subject:** Re: ReGen letter

Bill, we are concerned about the draft's statement that "FDA welcomed your input into the structure and composition of this advisory committee." I understand (see below) that we do not give others this opportunity, so it would document special treatment for ReGen.

**From:** Cook, Kate  
**To:** Senger, Jeffrey  
**Cc:** Chernaik, Beverly; Wion, Ann  
**Sent:** Sat Nov 01 16:40:31 2008  
**Subject:** Re: ReGen letter

No, we do not give everyone that opportunity. I think that statement would cause significant problems for the agency.

**From:** Senger, Jeffrey  
**To:** Cook, Kate  
**Cc:** Chernaik, Beverly; Wion, Ann  
**Sent:** Sat Nov 01 16:21:35 2008  
**Subject:** Re: ReGen letter

Hi, Kate. What do you think about the draft's statement that we "welcomed your input into the structure and composition of this advisory committee" – do we give everybody this opportunity?  
Jeff

**From:** McConagha, William  
**To:** Winckler, Susan; Torti, Frank; Schultz, Daniel; Cook, Kate; Senger, Jeffrey  
**Cc:** Chernaik, Beverly; Warren, Matthew; Weinstein, Les S; Norcio, Catherine T.; McConagha, William  
**Sent:** Sat Nov 01 15:13:19 2008  
**Subject:** ReGen letter

Hi, guys. Attached is an updated version of the ReGen letter that includes the Commissioner's edits. He re-organized the letter slightly and added some language, but he accepted virtually all of your prior edits. If possible, please let me know if you have any final edits or concerns by **9:30 am on Monday** so I can forward to Susan for

final clearance through the Commissioner. The hope is to have the letter sent to ReGen by noon on Monday. Thanks for all your help. Sorry to bother you all on a weekend. -bill

<<ReGen-Panel%20(4).doc>>

Dear Mr. Bisbee,

I write regarding ReGen's pending 510(k) for the CS Scaffold.

I am in receipt of the document you sent by e-mail to William A. McConagha, FDA's Assistant Commissioner for Integrity and Accountability, on October 28, 2008, titled, "What we are asking of FDA: A Fair Process." This letter is intended to respond to that document and to clarify our plans for moving forward.

I concur with the decision to refer ReGen's 510(k) to the Orthopedic & Rehabilitation Devices Panel of FDA's Medical Devices Advisory Committee. The meeting of this panel will occur on November 14, 2008. I expect that a notice announcing the meeting will publish in the *Federal Register* early next week. Please note that the panel meeting will begin at 8 a.m., not 8:30 a.m. as stated in the FR Notice. This new time is reflected in the notice that was posted on the FDA Advisory Committee website on October 30, 2008.

FDA has welcomed your input into the structure and composition of this advisory committee in an effort ..... to assure you of its effective and impartial deliberations. We have invited six temporary voting members to participate in the advisory committee, five of whom, per your request, have sports medicine backgrounds. In selecting these temporary voting members, we have been mindful of the criteria you sent us regarding the types of experts that you believe are best qualified to evaluate the CS Scaffold. This is a large number of temporary voting members; because of scheduling constraints and roster limitations, only two of the participants will be permanent members of the committee. As per usual practice, the panel will also include an industry representative and a consumer representative.

The meeting and FDA's preparations for it will proceed according to agency precedent and customary practice. As always, the panel will consist of a diverse group of experts whose identities will be disclosed to you and the public 48 hours before the meeting. The Executive Secretary who conducts the meeting will be a member of CDRH's Office of Device Evaluation (ODE), and FDA will be the final arbiter of the meeting questions to the committee. However, with regard to the latter, I am assured that your company has made ample contribution to their development. I fully expect that the Agency will render a final decision on your 510(k) within two weeks of the meeting, but, until benefitting from the deliberations of the panel, we cannot irrevocably commit the agency to a final decision date of December 1. It is our longstanding policy never to allow industry veto power over our advisory committee participants, but we do take seriously any substantive objections based on concerns about conflict of interest.

With respect to the pre-meeting schedule, we intend to adhere to the timeframes that Mr. McConagha sent to you by e-mail last Wednesday. As a reminder, that e-mail specifies that FDA will mail out panel materials (FDA Executive Summary, FDA Questions, Sponsor Executive Summary, 510(k) Application) to the panel participants by November 5, 2008. In order to meet that deadline, FDA will provide the executive summary of FDA's presentation and our panel questions to ReGen by COB Monday, November 3, 2008. In turn, we need the following from ReGen no later than **noon** on November 5, 2008:

- o Sponsor Executive Summary (.pdf and .doc formats)
- o 510(k) Application (.pdf and .doc formats)
- o Redacted versions of both items above in the same formats for posting on the FDA website.  
Redactions may only include proprietary information, trade secrets, and patient identifiers.

As the schedule above makes clear, FDA will provide ReGen with a draft of its meeting package and the questions before the meeting, and we will carefully consider your feedback before making a final decision with respect to those materials. We continue to evaluate the draft questions you submitted to us for consideration, and I assure you that, consistent with our usual practice, the questions posed to this panel will be legally supportable. CDRH's Ombudsman, Les Weinstein, will work with Mr. McConagha on the panel preparations, and I am confident that the proceedings will meet FDA's highest standards of objectivity and impartiality.

As you know, ReGen has been invited to make the first presentation to the committee. This means you will have an opportunity at the outset to advocate your views directly to the meeting participants. You are free to call on members of your firm to speak, to invite outside experts to present, or both. I respectfully suggest that this represents an important opportunity for ReGen to make its case to neutral experts in a public forum, and it also underscores that your participation is critical if this meeting is to be a success. I assure you that Dr. Frank Torti, FDA's Deputy Commissioner, and I will continue to be personally involved in this matter to be certain that appropriate process is followed in rendering a science-based regulatory decision.

Sincerely,

Andrew C. von Eschenbach  
Commissioner, Food and Drugs

Cc: Sen. Frank Lautenberg  
Sen. Robert Menendez  
Rep. Frank Pallone  
Rep. Steven Rothman  
Dr. Frank Torti  
Dr. Daniel Schultz  
Mr. William McConagha