

FILE NAME: Talc (TALC)

DATE: 2011 Apr 18

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DOCUMENT DESCRIPTION: Email from and to CPCUS Members

From: Nettesheim, Susan [CPCUS]
To: Lemmo, John [CPCUS]; Serbiak, Paul J. [CPCUS]; Mathew, Noble [CONGB]; Jiwrajka, Santosh [CPCUS]
CC: McCarthy, Timothy [CPCUS]; Swei, Homer [CPCUS]; Hicks, Don [CPCUS]; Karaisz, Kenneth [CPCUS]
Sent: 4/18/2011 8:31:05 PM
Subject: RE: URGENT: Talc Monograph Modernization

I will talk to the PCPC to see if they can reach out to the USP team and endorse Drew's nomination.

Susan

(908) 874 -1665

From: Lemmo, John [CPCUS]
Sent: Monday, April 18, 2011 4:16 PM
To: Nettesheim, Susan [CPCUS]; Serbiak, Paul J. [CPCUS]; Mathew, Noble [CONGB]; Jiwrajka, Santosh [CPCUS]
Cc: McCarthy, Timothy [CPCUS]; Swei, Homer [CPCUS]; Hicks, Don [CPCUS]; Karaisz, Kenneth [CPCUS]
Subject: RE: URGENT: Talc Monograph Modernization

In my opinion, we (JNJ Consumer) are best served on this committee by having a knowledgeable talc expert from RJ Lee Group - specifically **Drew Van Orden**. Drew is the person we sent to China recently to directly interact with the SFDA on our behalf (thru Jane Cai as interpreter).

RJ Lee Group are the experts we turn to for analysis of talc from our finished powder products as well as evaluation of potential new mine sources around the world. As experts in the field they are knowledgeable about talc for pharma/consumer use as well as also other industrial grades. No single J&J employee is as well versed in the subject matter.

I just spoke with Drew on this matter; he has submitted an application to be part of the USP talc Expert Panel. He has not yet heard back from USP.

From: Nettesheim, Susan [CPCUS]
Sent: Monday, April 18, 2011 3:41 PM
To: Serbiak, Paul J. [CPCUS]; Mathew, Noble [CONGB]; Jiwrajka, Santosh [CPCUS]
Cc: McCarthy, Timothy [CPCUS]; Swei, Homer [CPCUS]; Hicks, Don [CPCUS]; Karaisz, Kenneth [CPCUS]; Lemmo, John [CPCUS]
Subject: URGENT: Talc Monograph Modernization

The USP is updating the Talc monograph. Key at this point is "USP has approved the formation of an Expert Panel to review, evaluate and generate proposals, procedures and data for the test for Absence of Asbestos in the Talc monograph in support of USP's monograph modernization initiative. The Expert Panel will make recommendations to and work at the direction of the Monographs—Excipients (EXC) Expert Committee". **The deadline for nominations is Friday.**

I called the PCPC. They were unaware of this, as were Tim and I. Were any of you aware of this? I would have thought that our suppliers would have let us know about this earlier....

QUESTIONS: Do we want to recommend someone for this expert panel? I'm not sure we need a J&J person (?), but I would think we certainly would want someone from RJ Lee? Agree? Any other "experts" we'd want to reach out to? Do you want me to lead this, or should it be someone in one of your team?

Also, here is what I got from the website:

Posted: April 1, 2011

Call for Candidates: USP invites qualified candidates to apply to serve as scientific experts on the Talc Expert Panel. The purpose of this Expert Panel is to review, evaluate and generate proposals, procedures and data for the test for Absence of Asbestos in the Talc

monograph in support of USP's monograph modernization initiative. The Expert Panel will make recommendations to and work at the direction of the Monographs—Excipients (EXC) Expert Committee. Candidates interested in sharing their time and expertise should have in-depth knowledge of:

-] Asbestos testing
-] Procedure development and validation
-] Compendial procedures

USP anticipates establishing the Expert Panel by May 1, 2011. Most of the work of the Expert Panel will be conducted via teleconference at a frequency to be determined. It is likely that there will be at least one face-to-face meeting at USP during the lifetime of the Expert Panel.

Apply for this Expert Panel by following the link [here](#). **The deadline for applications is April 22, 2011.** For more information about the role of USP Expert Panels in the standards setting process, click [here](#).

Susan
(908) 874 -1665

-----Original Message-----

From: McCarthy, Timothy [CPCUS]
Sent: Monday, April 18, 2011 1:30 PM
To: Mathew, Noble [CONGB]; Hicks, Don [CPCUS]; Karaisz, Kenneth [CPCUS]; Lemmo, John [CPCUS]
Subject: FW: Talc Monograph Modernization
Importance: High

FYI.

I do not think I am the right person for this from J&J. Should Ken Karaisz or John Lemmo from Analytical be involved?

-----Original Message-----

From: Sharma, Shripal (RTM) [<mailto:Shripal.Sharma@riotinto.com>]
Sent: Monday, April 18, 2011 1:11 PM
To: McCarthy, Timothy [CPCUS]
Subject: FW: Talc Monograph Modernization
Importance: High

Hello Tim,

I am not sure if you are aware of the latest developments with USP re talc. They are planning to modernize the talc monograph and are inviting experts. Are you interested to be part of the panel? Have you considered RJ Lee to be part of the panel? The deadline for an application is April 20th. Julie Pier from RTM plans to apply.

Please let me know your thoughts on this.

I am available for a phone discussion today.

Best regards, Shripal

Shripal Sharma
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-----Original Message-----

From: Kevin Moore [<mailto:ktm@usp.org>]
Sent: Thursday, April 07, 2011 11:22 AM
To: Sharma, Shripal (RTM)
Subject: RE: Talc Monograph Modernization

Dear Shripal,

I just wanted to follow up with you on some progress with regards to the Monograph modernization initiative. USP has approved the formation of an Expert Panel to review, evaluate and generate proposals, procedures and data for the test for Absence of Asbestos in the Talc monograph in support of USP's monograph modernization initiative. The Expert Panel will make recommendations to and work at the direction of the Monographs—Excipients (EXC) Expert Committee. Based on our previous conversations, I would like to extend an invitation to you to apply for participation in the Expert Panel, which can be found at the following link. Please feel free to share this link with some of your colleagues who may also be interested in participating in this panel. Feel free to contact me if you have any questions.

<http://www.usp.org/hottopics/monographs.html>

Kind Regards,
Kevin

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