

Moeller, Lisa [CPCUS]

For Bill

From: Mann, Steven [CPCUS]
Sent: Thursday, October 07, 2004
To: Colamarino, Sarah [CPCUS]; Linares, Carlos [CPCUS]; [CPCUS]; O'Shaughnessy, K. [CPCUS]
Cc: Casalvieri, Joan [CPCUS]; Gaetan [CPCUS]; Sinicio, T
Subject: FW: Talc/NTP-Zazenski

[CPCUS]; Hopkins, John;
 Musco, Nancy
 er, Al; Wille, Kathleen
 [CPCUS]; Rouleau,

Some background information on Rich:

Steve

Steven W. Mann, Ph.D., D.A.B.T.
Director, Toxicology
Johnson & Johnson Consumer & Personal Products Worldwide
199 Grandview Road
Skillman, NJ 08558-9418
Tel: (908) 874-1232; Fax: (908) 904-3738

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

From: Zazenski, Rich (LNA) [mailto:Rich.Zazenski@america.luzenac.com]
Sent: Thursday, October 07, 2004 3:11 PM
To: Mann, Steven [CPCUS]
Subject: RE: Talc/NTP

Steve - I understand - no problem. Maybe this will help a little.

Officially my position is Director Product Safety. I've been with Luzenac for 25 years (formerly Cyprus). Prior to that, I worked with Johns-Manville in their talc division for 6 years (chemical engineer). From 1985 through 1999, I was also Director of Quality Assurance and Product Safety for Luzenac operations (including the Windsor, VT operations). Unfortunately, in the last few years, product safety (regulatory issues, litigation, etc) has become a full time job.

In the 1993, I worked with Bill Ashton and Mike Chudkowski to produce the paper "Talc: occurrence, characterization, and consumer applications" in preparation for the 1994 ISRTP/FDA two-day Workshop on Talc. The workshop was arranged to discuss issues with the 1992 NTP Inhalation Study and growing concerns about the association of talc and ovarian cancer. In 1998, I was asked by Dr. Wehner to write a section on talc for his special "talc" issue in *Comments on Toxicology*. Over the years, I have stayed in touch with both Dr. Wehner and Bill Ashton.

Zazenski, R., W.H.Ashton, D.Briggs, M.Chudkowski, J.W.Kelse, L.MacEachern, E.F.McCarthy, M.A.Nordhauser, M.T.Roddy, and N.M.Teetsel. (1995). **Talc: occurrence, characterization, and consumer applications.** *Regul Toxicol Pharmacol* 21:218-229.

Zazenski, R. J. (1998). **The commercial significance of talc.** *Comments Toxicol.* 6, 313-326.

We were obviously very involved in the 10th RoC review of talc. Following the deferral, we completed a comprehensive review and analysis of the literature in an attempt to clarify issues that were raised in the initial Draft Background Document (DBD) and in discussions at the RoC Subcommittee meeting. Our findings included some 85 studies, articles, and commentaries, one-half of which were not referenced in the initial DBD. This "supplemental analysis" was provided to CTFA for submission to Dr. Olden (NTP) under CTFA letterhead. You might note that CTFA just recently re-submitted these comments for the 12th RoC review and they are posted on the NTP website.

I should also note that during the 10th RoC review, the Center for Regulatory Effectiveness (Washington, D.C.) took an active role in ensuring that NTP was conducting a proper review of talc. CRE was instrumental in helping

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Moeller, Lisa [CPCUS]

From: Mann, Steven [CPCUS]
Sent: Thursday, October 07, 2004 4:05 PM
To: Colamarino, Sarah [CPCUS]; Ferguson, John [CPCUS]; Head, Michael [CPCUS]; Hopkins, John; Linares, Carlos [CPCUS]; Moeller, Lisa [CPCUS]; Monseau, Marc [JJCUS]; Musco, Nancy [CPCUS]; O'Shaughnessy, John [JJCUS]; Telofski, Lorena [CPCUS]; Wehner, Al; Wille, Kathleen K. [CPCUS]
Cc: Casalvieri, Joan [CPCUS]; Matheson, J. Neal [CPCUS]; Nettesheim, Susan [CPCUS]; Rouleau, Gaetan [CPCUS]; Sinicio, Telma [CPCUS]
Subject: FW: Talc/NTP-Zazenski

Some background information on Rich Zazenski for our call on Wednesday Oct 13th.

Steve

Steven W. Mann, Ph.D., D.A.B.T.
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- divert an almost guaranteed listing for talc into a "deferral". You can still access some of their many talc papers on their website at <http://www.thecre.com/special-projects/talc.html>. I might point out that in the 10th RoC review, RG1 and RG2 voted 13-2 to list talc (not containing asbestos) as a carcinogen. Up until then, every substance nominated for listing by both RG1 and RG2 went on to be listed.

I look forward to our phone call next Wednesday.

Best regards,
Rich

From: Mann, Steven [CPCUS] [mailto:SMann@cpcus.jnj.com]
Sent: Thursday, October 07, 2004 11:54 AM
To: Zazenski, Rich (LNA)
Subject: Talc/NTP

Rich,

I just had a call, and some of the people internally don't know who you are or your history with J&J on defending talc. Therefore, on the call take a moment at the start to tell everyone who you are. I want everyone to be comfortable to talk in your presence, and not just listen.

Steve

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