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Email Z

Dennis, Donna A

From: Zazenski, Rich (LNA) [Rich.Zazenski@america.luzenac.com]
Sent: June 07, 2001 2:17 PM
To: Dennis, Donna A
Subject: Talc Specification

Dear Dr. Dennis:

By way of introduction, my name is Richard J. Zazenski, Director of Product Safety, Luzenac America, Inc. Luzenac is part of the worldwide Luzenac Group, the world's leading producer of talc products. Please visit our website at www.luzenac.com.

I have learned that Mr. Bill Kelly has recently spoken with you about talc and our (talc producers) willingness to work with the FDA to help formulate a cosmetic talc specification. I would like to call you in the next few days to discuss this issue, but let me take this opportunity to "put on the table" some of the options we would like for you to consider:

(1) Assuming talc (non-asbestiform) does not get recommended for NTP listing, we need to re-establish some degree of public confidence in cosmetic talc products. As such, perhaps the FDA might consider requiring cosmetic talc to meet the talc purity standards of USP and/or Food Chemical Codex. Discussing this potential with several other talc producers met with positive feedback.

(2) Additionally, we can discuss an asbestos specification option which requires that cosmetic talc "does not contain detectable asbestos" when analyzed via Transmission Electron Microscopy (TEM). I think we all recognize XRD, PCM, and PLM are simply not sensitive enough to provide complete assurance that the talc is free of detectable asbestos.

As you may know, we supply (b) (4) with all their cosmetic talc requirements. As such, we are required to employ strict quality control protocols in our manufacture as well as use TEM (independent lab analysis) for certification for the absence of asbestos. Although their talc specification is not specifically patterned after USP, their talc meets USP, EP and BP purity specifications. Perhaps their "high-standards" should become the "required" industry standard. If this will help re-establish public (and regulatory) confidence in the purity and safety of talc, then we would all welcome the requirement (I might also add that it is the policy of Luzenac that we will not sell talc products containing asbestos - and we do not entertain the argument advanced by others as to whether or not a particular fiber meets the "technical" definition of asbestos).

With regard to NTP, Luzenac firmly believes that the "science" does not warrant a talc (non-asbestiform) listing by NTP. We particularly object to

NTP's overt disregard of the findings from the 1994 ISRTP/FDA workshop
on
talc. Our "public" comments are posted on the NTP website.

Thank you for this opportunity to consider the "talc" issue. I'll try
to
give you a call either Friday or Monday if that is convenient.

Sincerely,

Rich Zazenski
Luzenac America
303-643-0404