

ROUTING SLIP
GENERATED BY: HF-40
DATE: JUN 19, 2001

FDA CONTROL NUMBER: 01 3128

TRACER #: OS #:

DATE OF CORRESPONDENCE: 06/11/01

DATE INTO FDA: 06/19/01

TO: BERNARD A SCHWETZ HF-1

FROM: RICHARD J ZAZENSKI, LUZENAC AMERICA

SYNOPSIS: MEETING REQUEST FOR FDA. EXPRESSES CONCERN THAT AN ASSUMPTION THAT COSMETIC TALC USED IN THE U.S. MAY STILL BE CONTAMINATED WITH ASBESTOS. LUZENAC BELIEVES THE ASSUMPTION IS UNWARRANTED AND WOULD LIKE TO DISCUSS THE SPECIFICS OF THOSE CONCERNS WITH FDA.

LEAD OFFICE: HF-1

HOME OFFICE: HF-40

CONTACT/PHONE#: KRISTINE M MORAN 301-827-4446

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HFS-1 JOSEPH A LEVITT

COORDINATION: HF-40 ANNE B CRAWFORD
HF-40 WANDA G RUSS

SIGNATURE REQUIRED:

REFERRALS FROM HF-40

ASSIGNED TO	ACTION	DUE DATE
HF-1 CRIMC	NECESSARY ACTION	
REMARKS: PLEASE ADVISE WRUSS OF DECISION.		
HF-40 CRAWFORA	PREPARE RESPONSE FOR SIGNATURE	
REMARKS: WRUSS WILL ADVISE.		

**PLAINTIFF'S
EXHIBIT
CAM-253**

Stewart, ShearIdene

From: Russ, Wanda
Sent: Thursday, June 21, 2001 11:32 AM
To: OC Invitation Reviewers; Levitt, Joseph A; Dennis, Donna A
Cc: Wheeler, Renee J; Stewart, ShearIdene; Crawford, Anne
Subject: BAS Invitation Request #01-3128

Importance: High

Attached is a MEETING request for the Acting Principal Deputy Commissioner to meet with Luzenac America to discuss their concerns regarding the assumption that cosmetic talc in the U.S. may be contaminated with asbestos and it is driving the proposal to list talc not containing asbestiform fibers as a "reasonably anticipated human coarcinogen" in the 10th Report on Carcinogens. They have been in contact with our Office of Cosmetics and Colors regarding these concerns. I suggest that the CFSAN meet with them (Office of Cosmetics and Colors) as well as a senior staff person from the Center - Joe Levitt or Janice Oliver or who ever Joe may want to recommend.

Please indicate the priority for the Commissioner accepting this request:

☒ LOW ☐ MEDIUM ☐ HIGH

If this is important to FDA but it would be more appropriate for another Agency representative to accept in the Commissioner's place, who would you recommend?

CFSAN/OCAC and a Center-level scientific expert.

Rationale/What other information is relevant to this decision?

Please provide your input to me by COB 6/25.

Thanks,

Wanda

Joe Levitt

cc: Oliver, Dennis



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June 11, 2001

Via FedEx, and/or E-mail

Dr. Bernard Schwetz
Acting Commissioner - Food and Drug Administration
U. S. Department of Health and Human Services
Parklawn Bldg., Rm. 14-71
5600 Fishers Ln.
Rockville, MD 20857

Dear Dr. Schwetz:

We are writing to express our concern that an assumption that cosmetic talc used in the United States may still be contaminated with asbestos is driving the proposal to list talc not containing asbestiform fibers as a "reasonably anticipated human carcinogen" in the 10th Report on Carcinogens. While we believe the assumption is unwarranted, we wish to make clear that if there is a genuine concern that cosmetic talc used in the U.S. may be contaminated with asbestos, we would like to meet with FDA and NIEHS to discuss the specifics of those concerns and how we, Luzenac, and other companies producing and selling cosmetic talc, along with FDA, could allay those concerns through measures such as a federal standard or guideline or testing of today's cosmetic talc.

The salient background points are as follows. Two Report on Carcinogen review groups (RG1 and RG2) voted to list talc not containing asbestiform fibers as a "reasonably anticipated human carcinogen" (6 to 1 and 7 to 1, respectively). The basis for their recommendations is set out in the Draft Background Document on Talc. That document states clearly that one of the primary bases for the recommendations is an assumption that "talc" in general "may contain asbestos fibers", and therefore it is prudent to regard talc as likely to cause ovarian cancer.¹ (P. 28) That assumption was made even though the background document acknowledges that industry adopted a voluntary purity standard in 1976 which requires that cosmetic talc be free of asbestos, and even though it is clear that the ovarian cancer studies must have involved use of talc that may well have been contaminated prior to 1976. When the nomination reached the outside peer review group, the RoC Subcommittee, they took note of those two points, among others, and voted 8-2 against listing talc not containing asbestiform fibers in the 10th Report on Carcinogens.

We firmly believe the assumption that today's cosmetic talc may still be contaminated with asbestos is completely unwarranted, based on many years of testing and the demands of our customers – an assertion we believe we and others have made clear during the Report on Carcinogens review proceedings. We also believe it is completely invalid to propose to list talc not containing asbestiform fibers based on the

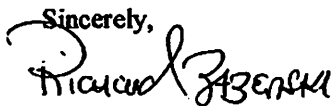
¹We do not believe there is a genuine concern regarding other potential cancer sites. We do not believe cosmetic talc poses any risk (or hazard) of lung cancer to U.S. consumers. It is our understanding that FDA, like us, regards the 1993 NTP rodent inhalation bioassay as not being relevant to real-world consumer exposures, a position that was reflected in the published consensus statement from the 1994 workshop which addressed this issue that was jointly sponsored by FDA and ISRTP and in which numerous FDA scientists participated.

assumption that such talc actually does contain asbestiform fibers. However, we remain concerned that the RG1 and RG2 reviewers, the NTP Executive Committee (which meets June 14), and ultimately the Director and the Secretary, might continue to rely on the contamination assumption and decide that talc not containing asbestiform fibers should be listed as reasonably anticipated to cause cancer. We are also concerned with the potential impact such a listing could have on the petition currently before FDA to label cosmetic talc products as potential carcinogens. Listing of cosmetic talc in the Report on Carcinogens by itself, and certainly if followed by granting of the FDA petition, would likely destroy completely the cosmetic talc industry and market in the United States in short order for no valid reason.

In view of these dire potential consequences, we have approached FDA's Office of Cosmetics and Colors with the proposition that, assuming there are genuine concerns on the part of the responsible federal agencies that modern cosmetic talc may continue to be contaminated with asbestos, we would like to discuss with FDA how those concerns can be resolved.² At this point, we are discussing the matter with other producers and their representatives and the Office of Cosmetics and Colors with a view to submitting a formal request for a meeting to discuss whether there is an adequate basis for FDA action, how we should formally initiate consideration of such action, options that should be discussed, how the agency's deliberative process would proceed, and agency representatives who should be involved.

Since, at this point, it does not appear feasible to organize and take any formal action prior to the NTP Executive Committee meeting on the 10th Report on Carcinogens scheduled for June 14, we wanted you and others involved with the Report on Carcinogens program and the pending FDA petition to be informed concerning these issues and developments. We want U.S. consumers and responsible federal agencies to have confidence in the safety of our products, and we reiterate that we believe that any genuine concerns regarding potential present-day contamination of cosmetic talc can be laid to rest without federal actions detrimental to the industry.

Sincerely,



Richard J. Zazenski
Director Product Safety
Luzenac America

cc: Dr. Adele Dennis, Office of Cosmetics and Colors
Dr. William Allaben, NCTR
Dr. Kenneth Olden, NIEHS
Dr. Christopher Portier, NIEHS
NTP Executive Committee Members

² We may also want to discuss how the term "containing asbestiform fibers", which is essential to the Report on Carcinogens listing proposals (which differentiate talc containing asbestiform fibers from talc not containing asbestiform fibers), should be defined in a scientifically accurate manner.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

June 29, 2001

Mr. Richard J. Zazenski
Director, Product Safety
Luzenac America, Incorporated
8985 E. Nichols Avenue
Englewood, Colorado 80112

Dear Mr. Zazenski:

Thank you for your June 11 letter requesting a meeting to discuss your concerns about cosmetic talc and asbestos fibers. While I am unable to meet with you personally, staff in the Office of Cosmetics and Colors would be pleased to arrange a meeting to address your concerns. Please contact Dr. Adele Dennis, Acting Director of the Office of Cosmetics and Colors, at 202-205-4530 to make the necessary arrangements.

Sincerely,

BA Schwetz

Bernard A. Schwetz, D.V.M., Ph.D.
Acting Principal Deputy Commissioner

docname
drafted:2

(b) (5)

cc:

HF -1 (2)

HF-40 (Russ, Crawford)

HFS-1

HFS-125 (Adele Dennis)

INCOMING

Dennis, Donna A

See Jim
Email Z

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