Luzenac

June 11, 2001

Via FedEx, and/or E-mail

PLAINTIFF'S EXHIBIT CAM-252

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

[1]We 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.

**Luzenac America, Inc.**
8985 E. Nichols Ave., Ste. 300 • Englewood, CO 80112 USA • (800) 525-TALC (8252) • (303) 643-0451 • Fax: (303) 799-8926

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

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.

**Luzenac America, Inc.**
8985 E. Nichols Ave. • Englewood, CO 80112 USA • (800) 525-TALC (8252) • (303) 643-0451 • Fax: (303) 799-8926