[Letter of proposal to FDA and NIEHS/NIH]

The FDA has legislative responsibility for direct regulation of unsafe ingredients in cosmetics under the Food, Drug and Cosmetic Act. In 1994, as a result of concerns regarding the 1993 NTP animal study and recently published epidemiological studies linking talc and ovarian cancer, the FDA and the International Society for Regulatory Toxicology and Pharmacology co-sponsored a workshop to discuss the issues and to see whether they could arrive at any consensus views on how they should be interpreted. Twenty FDA scientists participated, along with numerous scientists from academia, industry, cancer research institutions, NIEHS, NCI, and other organizations.

At the beginning of the workshop, Dr. John Bailey, Director of FDA's Office of Cosmetics and Colors, presented the "Introduction: Overview - Scope of the Workshop", in which he stated:

> ". . . I think it is reasonable to expect by the end of the workshop to have a discussion or even to reach a consensus of the many scientific and medical experts that are participating in and attending this meeting about the relevance of the recent reports to the safety of talc to human health risks."

At the conclusion of the Workshop, an Executive Summary was prepared by the Rapporteur, Dr. Jelleff Carr (Talc: Consumer Uses and Health Perspectives" in *Reg. Tox. Pharm*. 21(2):211-60 (1995). With regard to the ovarian cancer issue, Dr. Carr explains the consensus that was reached:

> "Following the many issues raised by all presenters, the ensuing discussion generally agreed that while some weak association between talc exposure and ovarian tumors has been reported, it was not sufficient warning for concern."
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> "The possibility of an association of talc exposure and ovarian cancer is an important hypothesis of potential public health importance. However, this association remains a research hypothesis whose verification or falsification needs additional study."

> "[E]pidemiologic studies have provided weak and conflicting risk signals for this association and it is unlikely that further studies may prove adequate to raise concern at a level sufficient to warrant regulatory or public health measures."

Indeed, the prediction by the panel that additional epidemiology studies on this subject would prove inadequate to clearly define an association between the perineal application of talcum powder and an increased risk of ovarian cancer was accurate. When NTP began their review of non-asbestiform talc in 2000, eight additional epidemiologic studies were published and evaluated by NTP. The eight additional studies continued to provide weak and conflicting risk signals with no consistent trend by duration or frequency of talc use. Appropriately, the NTP Board of Scientific Counselors Subcommittee concluded that the listing of cosmetic talc was not scientifically justified and voted 7-3 not to list talc (not containing asbestiform fibers).

Since the conclusion of NTP review in 2000, only one additional case-control study has been published (Central Valley of California). Not surprisingly, this additional epidemiological study provided no new information of scientific utility.

Given all this scrutiny during the last decade of "cosmetic talc" and its association with ovarian cancer, Luzenac cannot imagine that an additional review by NTP would result in a reversal of consensus about the scientific validity of this hypothesized association. But given the sensitive nature of this very serious women's health issue and the lingering suspicions concerning cosmetic talc as a possible risk factor, Luzenac would like to propose a remedy to FDA and NIEHS/NIH that would eliminate the need for any further debate and review of this issue.

We propose:

1. The talc industry in the United States will voluntarily phase-out the production and sale of all cosmetic talc products used specifically for consumer dusting powders, body powders, baby powders, and any other loose powder products that might reasonably be anticipated to be used by women for perineal application.

2. In cooperation with domestic cosmetic and pharmaceutical member companies of the CTFA, this product phase-out will occur within XX months of acceptance of these proposals by NTP and FDA.
3. The voluntary withdrawal would not include such products as medicated foot powders where it would not be reasonably anticipated that the product would be used for perineal dusting; nor would the withdrawal include cosmetic talc products sold for make-up, lipstick, eye-shadow and cream foundations where it would not be reasonably anticipated that the product(s) would be used for perineal dusting.
4. The CTFA will assist the FDA in developing an appropriate cosmetic warning label for any dusting or body powders containing talc which are produced or imported after an established date. The label would warn the consumer the product is not to be used for genital dusting and would report of the possible association between genital dusting and ovarian cancer. The warning label would be mandatory.

The result of these proposed actions would:

1. In very short order, virtually eliminate the exposure potential in the general population to dusting powders containing talc. As more and more dusting powders have already been re-formulated with increased levels of cornstarch, the proposed actions would accelerate these product conversions.
2. Eliminating the perineal exposure potential for women suspends the need for NTP to proceed with a review of cosmetic talc. Given the weakness of the science, it is improbable that a listing recommendation would have resulted – meaning the debate on this theorized association would continue unresolved. These voluntary actions proposed by the talc industry and CTFA member companies would end the debate and allow researchers to focus on other more plausible risk factors.

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