VIA FACSIMILE

93-TA-10

MEMORANDUM

DATE: May 26, 1993

TO: Talc Interested Party Task Force

FROM: Stephen D. Gettings, Ph.D., D.A.B.T.
Director - Toxicology

SUBJ: FDA Position (Update)

We have received confirmation from FDA that they have asked the International Society of Regulatory Toxicology and Pharmacology to organize a 1-2 day symposium on talc safety and related issues. FDA anticipate that the meeting will be held in November in the Washington, DC area.

FDA have indicated that they intend to identify speakers who will address issues of ovarian cancer (possibly Harlow?) and pulmonary cancer (someone from NTP/Lovelace). In particular, with regard to the ovarian cancer, FDA seem interested in the validity of meta-analysis.

The agency has identified three areas where they are (provisionally) interested in industry input:

- Regulatory overview - industry perspective.
- Manufacturing/Quality control
- Product applications

I will keep you informed of further developments. I suggest we hold a Task Force meeting to discuss our participation/involvement with the symposium when we receive more specific details from FDA.

93-TA-06

MEMORANDUM

DATE: February 12, 1993

TO: Talc Interested Party Task Force

FROM: Stephen D. Gettings, Ph.D., D.A.B.T.
Director - Toxicology

SUBJ: FDA Position

Please be advised that we expect a communication from FDA sometime next week with regard to the agency's position on talc. We understand that FDA has no immediate intention to regulate talc for cosmetic/personal-care use, however we anticipate that the agency will require some further action (perhaps in the form of additional information) on the part of industry.

I will keep you informed of developments.

C·T·F·A
Representing the personal care products industry

92-TA-14

E. Edward Kavanaugh
President

MEMORANDUM

DATE: December 10, 1992

TO: Talc Interested Party Task Force

FROM: Stephen D. Gettings, Ph.D., D.A.B.T.
Director, Toxicology

SUBJ: Follow-Up to FDA Meeting

As noted in my previous communication (92-TA-12), FDA have expressed an interest in characterizing human exposure to talc in terms of type of product and distribution of particle size. To this end we request that members of the Task Force provide us with the following information:

(1) Breakdown of product type and corresponding distribution of talc particle size.

(2) Market share - estimation of % market share breakdown for your products of a given type and given particle size distribution.

This information will be treated as confidential by CTFA and only summary information will be provided to FDA. We wish to be able to provide FDA with summary information to the effect that only x% of the market comprises products with less than y% respirable particles.

Please provide the requested information by January 3, 1993. Please call me at (202) 331-1770 if you wish to discuss.

The Cosmetic, Toiletry, and Fragrance Association
1101 17th Street, N.W. • Suite 300 • Washington, D.C. 20036-4702 • (202) 331-1770 • Fax (202) 331-1969

VIA FACSIMILE

92-TA-12

MEMORANDUM

DATE: November 10, 1992

TO: Talc Interested Party Task Force

FROM: Stephen D. Gettings, Ph.D., D.A.B.T.
Director, Toxicology

SUBJ: Meeting with FDA

GNMcEwen and I met informally with FDA on Monday, November 9, 1992.

We briefly discussed the content of the critiques prepared by Biomedical & Environmental Consultants, Inc. and discussed the basis of FDA's concerns:

- FDA appears to be less concerned about the significance of the Harlow et al paper on ovarian cancer than the results of the NTP inhalation study.
- We emphasized the datedness of the NTP study and the inadequacy of its design. We emphasized the likelihood of a secondary mechanism (overload of pulmonary clearance) rather than the carcinogenic potency of talc.
- FDA were particularly interested in the characteristics (particularly particle size) of the talc samples used in the NTP study. They did not appear to be particularly knowledgeable about the application of different particle size in different types of product. There appear to be some opportunity here to educate FDA by providing industry data. **FDA specifically requested this information and we agreed to provide it.**
- FDA is particularly concerned about product applications which may result in an opportunity for inhalation exposure (e.g., baby powders, dusting powders etc. "Professional use" (salons, barbershops, etc.) was mentioned as an area of concern(?).
- FDA noted that they were "evaluating several courses of action with regard to talc" (including conducting their own risk assessments), but that no imminent action is anticipated.

Please call me if you have questions. We will make a request for data on particle size/product application in a subsequent communication.

VIA FACSIMILE

92-TA-11

MEMORANDUM

DATE: November 4, 1992

TO: Talc Interested Party Task Force

FROM: Stephen D. Gettings, Ph.D., D.A.B.T.
Director, Toxicology

SUBJ: Meeting with FDA

FDA have requested a "small, informal" meeting with CTFA, at which we will deliver the revised copy of the report prepared by BEC and discuss any present & future concerns they may have with regard to talc.

In view of this request only GNMcEwen and I will deliver copies of the report and meet with FDA (Monday, November 9, 1992).

I will contact you immediately following the meeting. I anticipate a follow-up meeting with the Task Force at CTFA.

A revised copy of the BEC report has been mailed to you.

Please call if you have questions.

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