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

93-TA-11

E. Edward Kavanaugh
President

DRAFT MINUTES

TALC INTERESTED PARTY TASK FORCE

CTFA
Main Conference Room
1101 17th Street, N.W., Suite 300
Washington, DC 20036

February 2, 1993

A meeting of the Talc Interested Party Task Force was held at CTFA on Tuesday, February 2, 1993 beginning at 10:00 a.m. Those in attendance were:

Dr. Kevin Renskers - AVON PRODUCTS, INC.
Dr. Daniel Briggs - PROCTER & GAMBLE
Mr. William Ashton - JOHNSON & JOHNSON (Guest)
Mr. Jim Brown - MINERALS TECHNOLOGIES, INC. (Guest)
Mr. Mike Larson - MINERALS TECHNOLOGIES, INC.
Mr. Ed Davenport - WHITTAKER, CLARK & DANIELS
Dr. Ron Wulf - CARTER-WALLACE, INC.
Mr. Mike Chudkowski - JOHNSON & JOHNSON
Mr. Frank Penta - LUZENAC AMERICA (Guest)
Mr. Richard Zazenski - LUZENAC AMERICA
Mr. George Lessner - MINERALS TECHNOLOGIES, INC. (Guest)
Mr. George Gill - WESTERN MINING, INC. (Guest)
Mr. Patrick Patterson - AMERICAN WESTMIN, INC. (Consultant)
Ms. Mary Ann Nordhauser - AMERICAN WESTMIN, INC.
Dr. John Kelse - R.T. VANDERBILT CO., INC. (Alternate)
Mr. John Tedeschi - COSMAIR, INC.
Mr. Bill Zavadoski - U.S. COSMETICS CORP.
Taizo Miyoshi - MIKI AMERICA, INC. (Guest)
Ms. Marjorie McTernan - JOHNSON & JOHNSON (Guest)
Mr. John Sanzone - ESTEE LAUDER (Guest)
Dr. Stephen Gettings - CTFA (Liaison)

PLAINTIFF'S EXHIBIT
CAM-151

I. OPENING REMARKS

1. SGettings opened the meeting and asked Task Force Members to introduce themselves.

2. SGettings noted that, in the absence of any specific agenda items requested by members of the Task Force, the purpose of the meeting was (1) to facilitate exchange of information; and (2) to decide on any further CTFA action.

II. INFORMATION EXCHANGE/GENERAL DISCUSSION

1. SGettings noted that nothing had been heard from FDA since the informal meeting with the agency on November 9, 1992. SGettings reiterated the outcome of that meeting (see 92-TA-12). A discussion on the issues of talc particle size and determination of respirable particles in talc products ensued. MANordhauser noted the problems associated with the different analytical techniques used to determine talc size, and stressed the importance of agreeing on a standardized method if the Task Force were to conduct it's own determinations.

2. RZasinski referred the Task Force to a paper by Russell et al (1988) The Determination of Respirable Particles in Talcum Powder. *Fd. Cosmet. Toxicol.* 17, 117-122. WAshton discussed further details re. of the conduct of the study. The *Russell* paper reports an average adult exposure concentration of 2.03 mg/m^3 and an average exposure period of 1.23 minutes.

3. The Task Force discussed whether the findings of the *Russell* paper should be expanded and submitted to FDA in the form of a White Paper. The Task Force agreed that (to address some of the concerns raised by FDA at the November meeting) the White Paper should also address other cosmetic products containing talc. It was noted that the product matrix of other talc-containing products made it unlikely that talc particles would be in a physical form which would facilitate respiration (thus the type of study conducted by Russell represented a "worst-case" exposure). The Task Force therefore decided not to conduct any further exposure assessments on any talc containing products at this time. MANordhauser agreed to prepare a review of all talc product applications in the cosmetic industry, and to prepare a brief description of each type of product matrix. Other members of the Task Force will be contacted to provide relevant information. JKelse agreed to provide a first draft of the section on exposure. MANordhauser and JKelse agreed to provide a draft to CTFA within 3 weeks (by February 23, 1993). SGettings was directed to submit the draft to the Task Force for

Action (Nordhauser, Kelse)

review. The decision to submit the document to FDA will be made by the Task Force.

4. SGettings reported that he had contacted NTP and there appears to be no short-term plans to conduct further research on talc or to list talc in the NTP Annual Report on Carcinogens. NTP do intend to submit the results of the study for publication.

5. The Task Force agreed that the flaws in the NTP inhalation study had been adequately critiqued in the BEC report (particularly by Dr. Oberdorster). SGettings reported that both he and Dr. McEwen had emphasized the flawed study design at CTFA's meeting with FDA.

Action (Gettings) (Task Force)

6. The Task Force agreed that it might be prudent to ask Dr. Oberdoster to publish his critique of the NTP study. SGettings was directed to pursue this objective. The Task Force agreed to review the BEC report and to identify anything else which might also be publishable.

7. The Task Force briefly discussed the implications of the NTP study with regard to Proposition 65. Whilst it was noted that the California Department of Health Services may instigate their own review of the safety of talc, the Task Force were of the opinion that this was more likely if talc was listed as a carcinogen by an "authoritative body" such as NTP.

III. FUTURE ACTION

Action (Gettings)

1. In addition to the Action steps identified previously, it was agreed that SGettings should contact FDA and determine the status of their review of the talc issue. SGettings was directed to offer FDA an invitation to discuss the issue with members of the Task Force if considered appropriate.

IV. ADJOURNMENT

There being no further business, the meeting was adjourned.

Respectfully submitted,

Stephen D. Gettings, Ph.D., D.A.B.T.
CTFA
2/24/93