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DRAFT MINUTES

TALC INTERESTED PARTY TASK FORCE.

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

July 21, 1993

A meeting of the Talc Interested Party Task Force was held at CTFA on Wednesday, July 21, 1993 beginning at 10:00 a.m. Those in attendance were:

- Dr. Lauren MacEachern - COLGATE-PALMOLIVE
- Ms. Kate Trammell - MAYBELLINE
- Mr. William Ashton - JOHNSON & JOHNSON (Guest)
- Mr. Mike Chudkowski - JOHNSON & JOHNSON
- Mr. Richard Zazenski - LUZENAC AMERICA
- Dr. Martin Roddy - NOXELL
- Ms. Marjorie McTernan - JOHNSON & JOHNSON (Guest)
- Dr. Stephen Gettings - CTFA (Liaison)

I. OPENING REMARKS

1. SGettings opened the meeting and apologized for calling it at such short notice. He noted that the purpose of the meeting was to discuss the outcome of a meeting SGettings held with members of the Planning Committee of the International Society of Regulatory Toxicology & Pharmacology (IS RTP), held at the ToxForum meeting on July 14th, 1993. The minutes of the last meeting were approved with no changes.

II. INFORMATION EXCHANGE/GENERAL DISCUSSION

1. SGettings noted that IS RTP have been asked by FDA to organize a 1-2 day symposium on talc safety and related issues (93-TA-10). The Task Force was alerted as to this possibility in February, 1993 (93-TA-07).

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2. At the ISRTP Planning Committee meeting SGettings was apprised of the following:

The intended target audience are regulatory specialists, toxicologists, food/drug/cosmetic/medical device manufacturers, academicians and medical professionals. At least 100 attendees are anticipated.

From the meeting, FDA hope to gain insight into the relevance of recent toxicological and epidemiological studies to the safety of regulated products. FDA would like participants to address not only the validity of experimental approach but also risk "under conditions of use." FDA does not anticipate that they will be able to develop a regulatory decision from this program alone.

The meeting will be held in the Washington, DC area, possibly at the NIH auditorium. It will be scheduled for late fall (probably November) or for early 1994 (January).

The symposium will relate principally to ingredient use and safety as it applies to consumer products. (FDA anticipate that scientific studies relating to occupational uses of talc will contribute to the program as it relates to consumer products). Relative to OTC drug use of talc, FDA feel that someone from USP should at least serve on the panel for discussion and possibly make a presentation on USP specifications. Apparently, the OTC group thinks there should be a discussion of product labeling as it applies to OTC products, i.e., diaper rash could be discussed for adequacy and possible suggestions. FDA feel that this portion of the program would be useful in assessing whether or not the current USP specifications are adequate.

The proceedings of the symposium will probably be published (probably as a meeting summary, by rapporteurs).

FDA is budgeting \$10,000 as financial contribution to the effort; industry has been asked to contribute \$20,000; the remainder will be provided by ISRTP.

The anticipated format is to have some sort of "expert panel" in attendance throughout the meeting. FDA suggest that someone from industry (possibly a member of the CIR Expert Panel) and a consumer representative be invited to sit on the panel. Following the presentations, FDA would like to have ample time for discussions from the floor. The discussion will be led by members of the panel.

3. The following agenda has been proposed following discussions between ISRTP and FDA:

DAY 1 - The first day of the symposium will concentrate on inhalation health considerations, and will take the following format:

Introduction - introduce the topic, present the reasons for holding the symposium and provide some background about studies conducted on the safety of talc (historical perspective). IS RTP have been asked to identify someone who can serve in this capacity.

Manufacture of talc - To discuss (1) how, and where, it is obtained (mineral sources), (2) specifications for talc as used in different products, and (3) quality control including steps to control and monitor asbestos contamination. FDA stress that it is important for this presentation to describe the "specifications" for the material that is actually used in different products (i.e., particle size, impurities, etc). CTFA has been asked to identify a suitable speaker.

Uses of talc in different FDA-regulated products - Specifically, what are the requirements for the use of talc in foods, drugs, cosmetics and medical devices and why they are critical. (FDA suggest that this presentation may be combined with the previous one).

Regulatory status of talc in the different product categories - This topic will be discussed by one (or more) FDA officials.

Health Perspectives - Presentation and critique of the NTP inhalation study by various presenters (eg., Oberdorster, Goodman etc).

Panel/Floor discussion

DAY 2 - The second day will primarily cover ovarian cancer and talc, but epidemiology as it relates to inhalation exposure will also be discussed.

Introduction - historical overview of the various epidemiology studies on talc (possibly in 2 parts):

- a. Epidemiology studies of occupational exposures (inhalation).
- b. Epidemiology studies on ovarian cancer.

Risk factors in ovarian cancer

Harlow's Epidemiology studies of ovarian cancer and perineal exposure.

Meta-Analysis - Discussion of the pros and cons of meta-analysis as a general statistical tool in measuring correlations in epidemiology studies.

Panel/Floor discussion

Moderator wrap-up and close

III. ACTION/NEXT STEPS

1. The Task Force agreed that it was clear that the ISTRP meeting will be held irrespective of industry input, but that such input was important. The Task Force agreed that it was important that, as industry's representative, SGettings continue to participate at the ISRTP Planning Committee meetings and to offer advice and suggestions as outlined by the Task Force.
2. The Task Force agreed that the level of sponsorship requested by industry was not prohibitive. CTFA will send out commitment forms requesting total sponsorship from the Task Force of \$20,000 (depending upon the number of participants, as low as \$1,000 per company).
3. The Task Force agreed that Dr. Bruce Semple (formerly of J&J, now with P&G) should be approached and asked to represent industry on the Panel (both days of the meeting).
4. The Task Force agreed that a representative of one of the talc suppliers should make a presentation on (1) the production, processing and quality control of talc manufacture; and (2) particle size and specifications for different product applications. RZazenski agreed to provide a presentation outline and a suggested speaker within the next few days. The Task Force agreed that all speakers will be representing the industry and that the Task Force will approve the ~~contact~~ ^{content} of each industry presentation.
5. The Task Force agreed that a representative of a finished-product manufacturer should make a presentation on consumer use/risk assessment of cosmetic products containing talc. SGettings will get clarification on whether other speakers will address similar issues as they relate to other talc uses. The Task Force suggested that BSemple would again be the most appropriate industry representative. The Task Force agreed to begin assembling data which might form the basis of such a presentation. It was noted that some of this information (on particle size and product notices) had previously been requested by FDA and that the Task Force had not been successful in collecting such information. Washton

agreed to review, in particular, J&J's published data on exposure to talc. RZazenski noted that a lot of useful information could be derived from the report prepared by JKalse for the Task Force. LMacEachern noted the presentation should reference recent studies on talc (93-TA-12). LMacEachern noted that the presentation should emphasize the safety of talc use.

6. The Task Force agreed to review available information on occupational exposure from inhalation, and to discuss this issue at a follow-up meeting.
7. The Task Force agreed that both Dr. Oberdorster and Dr. Wehner (both co-authors of the BEC Report) should be proposed as speakers (on lung overload mechanisms and the biological implausibility of ovarian cancer from talc exposure, respectively). The Task Force agreed that industry should arrange for their attendance (at cost), even if they are not selected as speakers. It was also suggested that the Task Force may wish to arrange for the attendance of other consultants if necessary.

IV. ADJOURNMENT/NEXT MEETING

1. It was noted that SGettings next meets with ISRTP in early August. The Task Force agreed to hold a follow-up conference call within the next few days and to arrange a Task Force meeting in early September.
2. There being no further business, the meeting was adjourned.

Respectfully submitted,

Stephen D. Gettings, Ph.D., D.A.B.T.
CTFA