George Lee CTFA

The Cosmetic, Toiletry and Fragrance Association, Inc.

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January 3, 1977

M I N U T E S

INTER-INDUSTRY AEROSOL SAFETY COMMITTEE

A meeting of the Inter-Industry Aerosol Safety Committee was held on Tuesday, December 14, 1976 at Bristol-Myers Company, 345 Park Avenue, New York City, beginning at 1:30 P.M.. Those in attendance were:

Yale Gressel, Avon Products, Inc. (CHAIRMAN)
James McDermott, Procter & Gamble (VICE-CHAIRMAN)
Frank Baker, Procter & Gamble
Richard Bourne, Lehn & Fink
Salvatore DeSalva, Colgate-Palmolive
Paul Finkelstein, Johnson & Johnson
Lester Hardy, Gillette
Joseph Hiddemen, Armour-Dial
James Johnson, Plough, Inc.
John McClement, New York University
Richard Schnetzinger, Revlon
William Troy, Avon Products, Inc.
Leonard Vinson, Lever Bros. Inc.
John Willson, Johnson & Johnson
Richard Witkowski, Faberge, Inc.
George Wolcott, J. H. Breck, Inc.
Ronald Wulf, Carter-Wallace
James McNerney, CTFA

I. Opening Remarks

Chairman Gressel welcomed the attendees and the minutes of the October 19, 1976 meeting were approved.

II. Particulate Testing Program

Dr. Wulf reported on the status of the proposed particulate program including a meeting of the Particulate Testing Protocol Development Subcommittee held on December 13, 1976.

The purposes for this proposed program include determining the inherant toxic potential and target organs in rats, hamsters, and monkeys exposed to three product categories (antiperspirants e.g. aluminum chlorohydrate, hairsprays e.g. resins, and powders e.g. talc) by the inhalation route for 30-days. The resultant data will be used as the basis for developing industry comments on testing methods being proposed by the FDA-OTC Antiperspirant Panel.

II. (Cont'd)

The subcommittee is in the process of preparing an appropriate protocol. A meeting to finalize the protocol will be held early in January and a draft should be distributed to the committee for review prior to the next meeting. Following approval, cost estimates will be obtained and site visits to potential contractors will begin.

Funding for the program probably will be attained through a procedure similar to that employed in the hair color research program i.e. one or more member companies may subscribe to have a specific product component studied.

The risk of testing cosmetic ingredients, heretofore considered safe, by a new, untried protocol was discussed. Although a difference in opinion existed, it was agreed that risks versus benefits of the program should be evaluated by the individual companies in their decision to subscribe or not. An apparent majority of the attendees favored the program.

III. NIEHS Studies on Aluminum Chlorohydrate

Informal reports were presented by several members on aluminum chlorohydrate chronic inhalation studies being conducted by NIEHS. These studies were initiated by Dr. Robert Drew who now is associated with Brookhaven National Laboratory.

Hamsters, rats, and guinea pigs are being exposed 6 hr/day, 5 days/wk to 0.25, 2.5, and 25 $\mu g/m^3$ of 2 micron aluminum chlorohydrate. It has been reported that after 6 months no gross lesions were observed but granuloma were found microscopically in rats and guinea pigs exposed to 2.5 and 25 $\mu g/m^3$. After 12 months of exposure lesions were observed grossly at 2.5 and 25 $\mu g/m^3$, however microscopic examinations were yet to be completed. Dr. Drew will present a paper on these studies at the Society of Toxicology annual meeting in March, 1977.

Mr. McNerney will contact Dr. William Busey, pathologist for the project, and attempt to gain further information.

IV. Lovelace Foundation Program on the Inhalation Biology of Propelled Cosmetic Substances

The Particulate Testing Protocol Development Subcommittee is considering a visit to Lovelace Foundation in conjunction with the next committee meeting. Mr. McNerney will make arrangements with Dr. Jones.

V. University of Washington Epidemiology Study

Mr. McNerney reported that he had contacted Dr. Discher when CTFA had not received the draft of the final report on November 15 as the contractor had informed Drs. Wolcott and Wulf during their October visit to Washington. He was told by Dr. Discher that the "Discussion" and "Conclusion" sections are yet to be written. Dr. Discher will write these sections during the holidays. Apparently it will take most of January to process the report and CTFA should receive it by the end of January.

VI. Propellants - Current Status

Chlorofluorocarbons

1. It was reported that three FDA notices, concerning the phase out of all non-essential uses of fully halogenated chlorofluoroalkanes (such as F-11, 12, 13, 113, 114 and 115), the labeling of products (which contain F-11, 12, and 114) with a warning statement of their potential harm to public health and environment, and the adoption of CTFA nomenclature for seven fluorocarbon propellants, were published in the Federal Register of November 26, 1976.

Hydrochlorofluorocarbons

1. Fluorocarbon 22 has been reported by ICI Ltd. (England) to be weakly mutagenic and potentially carcinogenic based upon positive results in a modified Ames Test. These findings were confirmed by DuPont's Haskell Laboratory and has led DuPont to notify FDA, to initiate animal inhalation carcinogenesis studies, and to recommend to their customers that certain precautions be taken including - "we do not believe it would be advisable to spray FC-22 directly at or onto people during any new product development studies" or "market testing of new products" (See Attachment 1).

2. Fluorocarbon 142b also has been reported by ICI Ltd. (England) to give positive results in the modified Ames Test. DuPont is repeating this test which should be completed by December 22, 1976. However, based upon the ICI findings, both DuPont and Pennwalt allegedly have stopped shipment of this propellant.

3. Reference was made to an article by ICI Ltd. (England) which was to be published in the December 16, 1976 issue of Nature and which would contain the results of screening 120 chemicals including F-142b by a battery of six mutagenicity/carcinogenicity short term tests. This article was obtained subsequent to the meeting (Attachment 2). However, the detailed test results for the 120 chemicals are not included but will be presented at a later date.

Hydrocarbons

Mr. McNerney reported that he had contacted Dr. Richard Stewart, Medical College of Wisconsin, to determine the status of the final report on Propane and Isobutane which was long overdue. Dr. Stewart regretted the delay and promised to submit the report by Christmas.

Methylene Chloride

It was reported by Mr. McNerney that Jessie Norris, Dow Chemical Company, was invited to attend this meeting and report on the status of their toxicity program on methylene chloride. She was not able to attend but will prepare a written report.

VII. Antiperspirant Task Force

The CTFA Antiperspirant Task Force met immediately preceeding this meeting.

During the task force meeting Chairman Giovacchini reviewed his Unofficial Minutes of Meeting XXIII of the FDA-OTC Panel on Antiperspirants which was held on December 2-3, 1976. These minutes had been distributed by mail to the task force members together with the official minutes of Meeting XXI held on August 26-27, 1976.

The Panel Report which is in preparation was the chief topic of discussion. The following developments and plans were noted:

1. The preliminary draft of the Panel report which was prepared by Panel Chairman Rosenberg was rewritten by subgroups during the meeting. It will be retyped by the Executive Secretary and sent to the Panel for review prior to the next meeting. Chairman Rosenberg has rewritten the minority report and the Panel has incorporated their answers into the body of the monograph.

2. The redraft of the report will be polished at the next Panel meeting and then submitted to FDA for review.

3. The next two Panel meetings have been scheduled for February 3-4 and March 31-April 1, 1977.

4. CTFA probably will receive an unofficial copy of the report after the April Panel meeting, most likely in early May.

5. The proposed final monograph probably will be published in the Federal Register by August.

VIII. Next and Future Meetings

Mr. McNerney reported that during the November 23, 1976 meeting of the CTFA Pharmacology and Toxicology Committee it was agreed to hold monthly meetings during 1977 and to hold them jointly with the Inter-Industry Aerosol Safety Committee. The meetings will be held on the third Wednesday of each month as a rule but subject to change due to conflicts with holidays, scientific meetings, etc.. The January meeting will be held in Scottsdale (Phoenix) Arizona at the Armour Research Center where the committee will be the guest of Dr. Hiddemen.

The attendees discussed these plans and agreed that the Inter-Industry Aerosol Safety Committee should cooperate and participate in the joint meetings.

Mr. McNerney will determine the members' preferences for meeting sites during 1977 and these will be discussed and confirmed at the January meeting.

VIII. (Cont'd)
The following meetings were noted:

1. Inter-Industry Aerosol Safety Committee/ CTFA Pharmacology and Toxicology Committees

   January 20, 1977 - Armour Research Center, Scottsdale, Arizona

2. FDA-OTC Antiperspirant Panel

   February 3-4, 1977 Rockville, Maryland

3. CTFA Antiperspirant Task Force

   February 8, 1977 (10:00 A.M.) - Bristol-Myers, New York City

There being no further business, the meeting was adjourned.

Submitted by:

James M. McNerney
Director of Toxicology

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Attachments