The Cosmetic, Toiletry and Fragrance Association, Inc.

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James H. Merritt
President

Norman F. Estrin, Ph.D.
Vice President—Science

TALC TASK FORCE

M I N U T E S

A meeting of the Talc Task Force was held on February 7th, 1975. After a pre-meeting at the CTFA Offices, the Task Force reconvened at the office of Dr. Robert Schaffner at the Food and Drug Administration, 200 C Street, SW, Washington, DC. Those in attendance were:

Mr. George Sandland, Bristol-Myers (Chairman)
Dr. Murray Berdick, Chesebrough-Pond's
Mr. George Lee, Johnson & Johnson
Dr. Robert Rolle, Johnson & Johnson
Dr. Norman Estrin, CTFA

Those in attendance from the Food and Drug Administration were:

Dr. Robert Schaffner
Mr. Henry Davis
Mr. Heinz Fitzmann
Dr. William Horwitz
Mr. Ronald Yates

Mr. Sandland opened the meeting stating that the objective of the Task Force meeting was to give a status report on its activities and at the same time ascertain the status of work at FDA in this area. Dr. Schaffner responded FDA was still interested in development of satisfactory methodology and Dr. Horwitz noted briefly his work in this area.

Mr. Sandland called upon Dr. Rolle to give a report on CTFA progress. Dr. Rolle reported on the development of a Differential Thermal Analysis procedure for serpentine followed by an optical microscopy procedure, with detection limits between 0.5 and 1%. For amphiboles like tremolite, an x-ray diffraction method, followed by dispersion staining optical microscopy has been developed; this procedure allows determination of whether the

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material is fibrous or not. Dr. Rolle noted successful completion of round robin tests with detection levels between 0.5 and 1%. Dr. Rolle observed that he has been unable to obtain a single naturally occurring sample containing chrysotile.

Dr. Berdick questioned the need for a regulation on chrysotile since no sample has yet to be confirmed as containing this material.

Mr. Eiremann responded that he sees no problem with a regulation covering both amphiboles and chrysotile, since "if chrysotile is not there, you should have no problems."

Dr. Estrin and Dr. Berdick objected, stating that Mr. Eiremann was proposing regulations for the sake of regulation, and has not considered the wasteful tax on resources that would arise from inclusion of a standard for chrysotile. Dr. Berdick and Dr. Estrin concluded that if a regulation is not necessary, it should not be proposed.

Dr. Schaffner responded with a suggestion that CTFA send in a letter with documentation, showing the extent of tests and results which would support a recommendation about the inappropriateness of a regulation for chrysotile.

It was noted that Professor Lewin was the only scientist to ever have mentioned chrysotile in his report and the lack of confirmation of his results by other scientists.

Dr. Schaffner asked for a progress report on Professor Lewin's activities, and stated that he will speak to Dr. Lewin shortly concerning his progress.

Mr. Sandland noted that CTFA specifications for Talc published as part of the CTFA Standards, are up for revision. He reported that the new specifications will add a tremolite specification and the methodology for continuous scanning x-ray diffraction, but added that CTFA would not expect to include a specification for chrysotile. He added that chrysotile has never been found in cosmetic talcs from either European or dosmetic sources.

FDA was asked for its present timetable, and responded, it is ~~are~~ awaiting results from the Franklin Institute and have arrived at no definite time schedule for either a food or a cosmetic regulation.

Mr. Sandland proposed limits of 1% for tremolite, stating that based on the OSHA limit of 2 fibers per cc in an 8-hour day proposed for 1976, one would arrive at a safety factor of 48,000 if such a limit were adopted.

Mr. Eiermann questioned this calculation on the basis of his understanding of the OSHA limits for short and long-term exposures.

Dr. Schaffner added the political inadvisability of citing mine-worker standards for cosmetic talcs, and advised that it would be more meaningful to have animal studies with talc than statistical estimates.

Mr. Lee responded by noting animal work in progress.

Mr. Eiremann then proposed "non-detectable" terminology rather than numerical limits.

Mr. Yates noted briefly that there was no progress yet on enrichment for chrysotile and that he was pessimistic about the possibilities in this area.

Mr. Lee offered participation of the CTFA Talc Subcommittee in evaluating any methods developed by FDA.

There being no further business, the meeting adjourned.

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