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The Cosmetic, Toiletry and Fragrance Association, Inc.

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October 11, 1973

MINUTES

CTFA SUBCOMMITTEE OF SAC ON ASBESTOS IN TALC

The first meeting of the CTFA Subcommittee of the Scientific Advisory Committee, on Asbestos in Talc, was held on October 4, 1973 at the Colgate Palmolive Research Center, Piscataway, N.J. Those in attendance were:

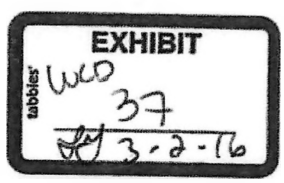
Mr. George Sandland, Bristol-Myers Products (Chairman)
Dr. Murray Berdick, Chesebrough-Ponds, Inc.
Dr. George Cohen, Bristol-Myers Products
Dr. Christopher Costello, Colgate Palmolive Company
Mr. Salvatore Di Bianca, The Mennen Company
Mr. John Facq, Colgate-Palmolive Company
Dr. David Hamer, Johnson & Johnson
Mr. Ray R. Krammer, Whittaker, Clark and Daniels
Dr. DeWitt Petterson, Johnson & Johnson
Dr. Robert Rolle, Johnson & Johnson
Mr. Fred Roesch, Whittaker, Clark and Daniels
Dr. Joseph P. Simko, Jr., Colgate-Palmolive Company
Dr. John Travers, Avon Products, Inc.
Mr. Ronald Yakupcin, Kolmar Laboratories, Inc.

The meeting began with a discussion of the optical microscopic method for detecting asbestos in talc, which was published in the Federal Register of September 28, 1973.

The method, as written, is not completely reliable and discriminatory, since fibers other than chrysotile might fall within the critical range of refractive indices used. Cellulose fibers, for instance, would be counted according to the method guidelines.

It is estimated by at least two academic sources, that the running of a single sample would take at least six hours for a count and a tentative identification. The tedium effect on the person counting is obvious.

Several experts including Walter McCrone agree that there are probably a total of 20 microscopists in the United States who would be sufficiently qualified to do the analysis.



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It was generally agreed that with some modification the methodology could be strengthened to yield a more reliable identification and measurement.

A major consideration in the method is the extremely small sample, one milligram in size, which one must pore over for several hours, then based on the nature of this miniscule sample, make a judgment on a 20 ton lot. Bearing in mind the fact that most talc is produced by a continuous process, the reliability of a one milligram sample is poor, even if taken from a composite of several samples, since homogeneity of the sample is extremely difficult to achieve without changing fiber length.

A discussion of the step scanning X-ray diffraction procedure followed with a description by Joseph Simko of the method which was developed at Colgate. In contrast to optical microscopy, the X-ray method has a lower limit of detection of 0.5%. It is considerably more reliable for discriminating chrysotile and tremolite and uses a 500 milligram sample, thus providing much greater statistical assurance that the sample is representative. It takes about 3 hours to run including manual computation of results.

It was agreed that we run a "round robin" test using six samples of talc from several sources in the United States and including Italian talc. Bob Rolle agreed to furnish a set of samples which will be "seeded" with tremolite and chrysotile using a special technique to assure homogeneity. These are intended to assist in optical recognition and to estimate reproducibility of procedure.

The following eight volunteered to test (or have tested) samples by optical microscopy (Fed. Reg. 9/28/73) and those designated by asterisk will also test by the X-ray diffraction step scanning method used by Colgate.

Dr. Murray Berdick, Chesebrough Ponds
Dr. George Cohen, Bristol-Myers Products
*Dr. Christopher Costello, Colgate-Palmolive Company
Mr. Salvatore diBianca, The Mennen Company
*Dr. DeWitt Petterson, Johnson & Johnson
Mr. Fred Roesch, Whittaker, Clark and Daniels
Dr. John Travers, Avon Products, Inc.
Mr. Ronald Yakupcin, Kolmar Laboratories, Inc.

George Sandland will prepare, code and distribute the samples to the above list of persons.

It was also agreed that George Cohen will contact Pfizer to encourage participation in the work of the Committee.

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The Committee wishes to approach the evaluation of the FDA proposed optical microscopic with an open mind and recommends withholding the critical commenting in these notes until a fair evaluation through the "round robin" is completed.

Following the meeting, several members of the Committee visited the instrument facilities at Colgate to see the X-ray and optical units.

We wish to thank Dr. Costello and Colgate for permitting us to use their facilities for this meeting. Dr. Costello also offered to accomodate us for future meetings.

Respectfully submitted to the
Scientific Advisory Committee,

George W. Sandland

George W. Sandland, Chairman

GWS:dd
cc: P. Reisberg - Carter Products