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CTFA/FDA MEETING-August 11, 1972
Washington, D.C.

Subject: ASBESTOS FORMS IN TALC

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August 14, 1972

CTFA/FDA MEETING - August 11, 1972, Washington, D.C.

SUBJECT: ASBESTOS FORMS IN TALC

This meeting was called on behalf of industry by James Merritt of the CTFA. The following members of industry met briefly in Mr. Merritt's office at 10 A.M. prior to the 11 o'clock meeting with the FDA.

Dr. Murray Burdick- Chesebrough -Ponds
Dr. Harold Schwartz - Mennen
Dr. Nashet - Johnson & Johnson
Dr. Robert Giovacchini - Gillette
Mr. Fred Roesch, Vice President, Whittaker, Clark and Daniels
Dr. Ian Stewart - McCrone Associates, Chicago
Mr. Gilbert A.Sprott - Avon

This brief meeting was called to review the results of Dr. Lewin's analyses of 102 samples of finished goods submitted to him by the FDA for asbestos form content analyses. The method used by Dr. Lewin was X-Ray Diffraction and if no indications of asbestos forms were found by this method, the samples were considered to be clean. His results indicated that 59 of the samples showed no asbestos forms. However, 43 showed asbestos content. 35 samples showed from 1-5% and 8 of the samples showed over 5%.

Of the two Avon samples cited, the TAI WINDS samples which were originally submitted by Dr. Colby showed 25% tremolite and also, the FDA had procured a sample of UNFORGETTABLE TALCUM POWDER in the 3-1/2 oz. oval can, which was analysed as being between 1 to 5%.

Samples of Chesebrough-Ponds', Mennen and Johnson and Johnson's loose talcum powders were also identified as having asbestos forms, identified by X-Ray Diffraction and confirmed by other means.

Dr. Stewart of McCrone Associates was representing Johnson & Johnson and indicated in our meeting in Mr. Merritt's office, that although Dr. Lewin showed that their SHOWER TO SHOWER TALC contained 5% chrysotile, that, in fact, he could prove that it did not contain any. A sample of the suspect Johnson & Johnson product had been picked up on Thursday evening from the FDA and sent to Chicago for confirmation of previous results. These results were not available but would be delivered in time for our meeting with the FDA.

We proceeded to the FDA Building and convened at 11 o'clock. We were joined at that meeting by three other members of Johnson & Johnson's technical staff, headed by Dr. Gowdi.

Members of the FDA present were:

Dr. Robert Schaffner
Dr. Alfred Weissler
Dr. John Gowdy
Mr. John Wenninger
Dr. Seymour Lewin , N.Y.U.
Plus two Regulatory personnel

The meeting was convened by Dr. Schaffner indicating that they would publish the results of Dr. Lewin's analyses as soon as possible, in the Federal Register including the names of the cosmetic companies whose products showed an excessive amount of asbestos forms.

Mr. Merritt, on behalf of industry, strongly urged Dr. Schaffner that the names of the companies should not be used in the Federal Register publication. Dr. Schaffner recognized the desire of industry, however, would not commit himself to not publishing company names.

The meeting was then turned over to Dr. Lewin in order that he might present his results. Copies of his paper and the methods used were not available. However, I shall try to procure these through Dr. Weissler who indicated favorably when questioned if he could send them to us.

Dr. Lewin used X-Ray Diffraction as his basic tool. His equipment apparently, is several years old and has as much as 3% background noise. He did, however, indicate that he had had an opportunity to evaluate what he considered one of the newest and best instruments in the field, Philipps A.P.D. 3500 and feels that his present equipment is just as good as anything on the market. He did, however, indicate a slight feeling that his own equipment would be more sensitive for tremolite and might be less sensitive for chrysotile.

As a means of confirming asbestos forms, Dr. Lewin has used Electron Microscopy, as well as Differential Thermal Analysis. He maintained that D.T.A. is a valid method for distinguishing between chlorite and chrysotile. Dr. Lewin went into quite some length in discussing the identification of chrysotile and the difficulties involved in X-Ray Diffraction of distinguishing between that and chlorite.

The Electron Microscopic photographs shown depicted the various forms of chrysotile and tremolite. He was careful to point out the difference between fibrous and non-fibrous tremolite, the implication here being that the amorphous forms of tremolite may not be considered carcinogenic.

It was at this point in his presentation where the example of SHOWER TO SHOWER, Johnson & Johnson's Talc, was used as an illustration of a product containing 5% chrysotile. Dr. Stewart, McCrone, challenged these results and was able to show the analysis of

exactly the same sample which they had conducted. Dr. Stewart maintained that the doublet which Dr. Lewin was separating to show both chlorite and chrysotile, was, in fact, only indicative of chlorite. Dr. Stewart's major position was based upon the fact that Dr. Lewin's equipment had about 3% noise, which did not give him a distinguishing confirmation at approximately 24 degrees of interference. The McCrone curves had less than 1% noise and showed no confirmation of chrysotile.

The meeting was adjourned for lunch at which time, Dr. Stewart and Dr. Lewin conferred on their differences.

Following lunch it was agreed that Dr. Lewin would repeat his analyses on all 43 suspect products. This work is to be paid for by the FDA and Dr. Lewin indicated that he could have these results available in approximately one month. It was also agreed that Dr. Stewart would be allowed to confer with Dr. Lewin as his results were being obtained.

In view of this development, Dr. Schaffner indicated that he would be willing to postpone publication of the Lewin report. If Dr. Lewin's results are confirmed, he still maintained very strongly that he would like to publish these results no later than October 1st.

Following the meeting, I accompanied Dr. Weissler to his laboratory where I was able to obtain approximately three grams of UNFORGETTABLE TALC which by Lewin's results, show 1-5% asbestos forms.

RECOMMENDATIONS:

1. A meeting will be called with Research & Development personnel to review these notes.

2. At that meeting I will strongly recommend a coordinated study involving both our Analytical and Exploratory Product Research Departments.

3. The sample of UNFORGETTABLE TALC will be submitted to one or preferably two laboratories for confirmation of Dr. Lewin's analysis.

4. I will obtain a copy of Dr. Lewin's report including analytical methods, as soon as possible.