

August 30, 1972

Mr. C. W. DeLoach

TALC-ASBESTOS CONTENT
EVALUATION

Dear Larry:

This will serve as the report on the current situation regarding talc contamination evaluation.

On August 9 we received a call from Mr. James H. Merritt, President of the CTFA in Washington, D.C. He advised that Dr. Robert Schaffner of the Food and Drug Administration called him stating that they were going to publish in the Federal Register this week that talc with a contamination of more than 1%, as tested by X-ray Diffraction, will not be permitted for use in cosmetics and baby powders. His information was based on the results of a report prepared for his department by Prof. Seymour Z. Lewis of the New York University. The report stated that out of 102 products on the shelf (mostly duplication) were tested and out of this number only 23 were found free of asbestos. Of the 43 remaining they evaluated in contamination from 1 to 8%, many being in the 1 to 5% range. A number of customers had been notified that their products were so contaminated, which included customers such as Johnson & Johnson, Chesebrough-Pond's, Avon, Avon, Estee, etc.

Mr. Merritt set up a conference call with people from Johnson & Johnson, Waco and himself to work out a method of approach. It was decided that the way to handle such a situation was to arrange a meeting with Dr. Schaffner regarding his proposal.

Dr. Schaffner agreed to a meeting of people from industry to meet with his group at the F&D Administration offices in Washington, D.C. This meeting was scheduled for 11 A.M. on August 16. The ADHCC cancelled it.

James H. Merritt, President of the CTFA
Dr. Murray Burellak (Chairman) Chesebrough-Pond's
Dr. Harold Schwartz, Merck
Dr. Robert Ciombarini, Glaxo
Dr. Gil Sack, Avon
Dr. Nedra (T) Johnson & Johnson
Dr. Ian Stewart, Walter G. McCann Associates, Inc.
Several other people from Johnson & Johnson as technical experts
Miguel from Whitaker, Clark & Daniels, Inc.

EXHIBIT

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The group from the Food & Drug Administration (including Dr. Robert Schaffer and Dr. A. Waksler, plus several technical people Prof. Seymour Z. Levin of the New York University who had prepared the report and acted as the technical expert for the Food & Drug Administration

The meeting was opened by Jim Morris who indicated the reason for calling this meeting was that it was felt that the report made was not complete or a true evaluation of the products involved; that it would be very unfair to the industry and to companies involved to the degree that, if it were released to the public, industry would go to court against the FDA Administration.

The meeting was then turned over to Prof. Levin, in defense of his test methods and report. He had very little time to prepare his defense (?) however, he did have his charts and verification of analyses used.

Dr. Ian Stewart of McCrone Associates had done work for Johnson & Johnson over the past years and appeared as their expert on X-ray Diffraction, crystallography and electron microscopy evaluation. Before the meeting he had arranged for a sample of material tested by Prof. Levin and indicated that he did not confirm the same result. He had electron microscope photographs to prove his point. At this time Prof. Levin admitted before his group that the percentage reported was $\pm 10\%$ on the basis of 3 to 25 accuracy and it would be necessary at this point to run further tests by the step method of X-ray Diffraction rather than by the continuous scanning method used. Dr. Stewart commented that in addition to this, it would be necessary to run the electron microscopy evaluation and identify the particles. This was an open meeting and helped the situation immeasurably, where we all had an opportunity to add our views.

Dr. Waksler stated that chrysothrix was always found in a fibrous form, whereas he agreed that trematite could be found both in a fibrous and massive form and he was only concerned with the fibrous form. He further clarified this statement by saying that if a material identified with 9% of trematite (massive) scanning method of X-ray Diffraction, would have to be further tested by the step method and then by electron microscopy to determine the percentage of fiber. If this was found to be less than 1%, the material would be non-potable. (This was a most significant statement and could help us in any future situations on the subject.)

Dr. Schaffer further stated that even though their proposal for the Federal Register was already at the Printing Office, it would not be released. He ordered a further study by Prof. Levin to reevaluate on the 43 samples involved, first by X-ray scanning method, then by the step method, and then

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Mr. C. U. Brinson

by electron microscopy. He is to get this report back to the F&D Administration's hands by the end of September, at which time the proposal will be released. Some question as to whether it will be at a 1% or a 3% level to the Federal Register. We will get some adverse action. At this time the second report will be open for public inspection, which means that Ralph Hader of the newspapers can observe it on demand.

Our group and the F&D Administration seemed to be very well satisfied with the outcome of the meeting because it was felt that the publication of the report now in their hands could be very detrimental to the field. It was suggested by Dr. Scheffner that none of the above information be released to anyone outside of the group, that they would hold in confidence the information they have other than advising the 48 people on the list that their product was in evaluation because of possible contamination.

In answer to my inquiry as to how we can be better wary of those 48 companies who are going to approach us (industrially) for guidance in the future, Dr. Scheffner said that if we continue in the same manner as we have over the past years, that if our test methods and complete evaluation were similar to what will later be published, we can't see how we can be wrong; in fact, he indicated that we might end up by becoming a monopoly in the field---at which point I said, "we'll be in more trouble than we are now!"

I would predict that the final results will be less than 10% of the products evaluated will still be in trouble, but it won't be as serious as it could have been.

Fred Kneech

FFR:mjz

cc: G. J. Diggold