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Johnson-Johnson
Asbestos in talc

SEP 27 REC'D

New Brunswick, N.J.
September 25, 1972

Subject: SHOWER-TO-SHOWER/Asbestos
FDA Meeting, September 21, 1972

Memo to File

Drs. Fuller, Hildick-Smith, and I met with Dr. Schaffner before the formal meeting. We requested that other industry representatives and CTFA not be present at our meeting. Dr. Schaffner said that he was not aware that we had made a point of this with Dr. Weissler when this meeting was set up. He said it would be embarrassing to him to withdraw the invitation. We agreed on the basis of no participation by CTFA and other industry representatives in the discussion.

We also requested that, in view of the fact that our data are now conclusive and contain new information on the composition of Italian talc which may explain the errors of Dr. Lewin, we be allowed to present the data first, to give Dr. Lewin a chance to gracefully withdraw from his position. Dr. Schaffner agreed.

The meeting was started on time and we were asked to present our data. The data were presented by our consultants in the order set up by Drs. Shelley and Goudie in a meeting on September 20 as follows:

1. Dr. Pooley reviewed in detail his comprehensive examination of the Italian mine, showing that it contains no deposits of chrysotile asbestos and very minor amounts of tremolite. He stated that mining is done by hand selection of rocks, which reduces further the likelihood of significant tremolite in the powder. He pointed out that the mine contained two species of chlorite ore which show X-ray peaks which could be confused for chrysotile asbestos. He also mentioned that the Italian Mining Institute at Turin has also determined no chrysotile asbestos in the mine. He presented data on SHOWER-TO-SHOWER and Italian talc samples provided by Johnson & Johnson England dating back to 1949, establishing absence of chrysotile asbestos by various techniques (EM, diffraction, X-ray, and microscopy).

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2. I reported on a communication from our supplier citing an analysis indicating absence of chrysotile asbestos in the talc supplied to us (actually this report was signed by Dr. Lewin but I did not mention this fact). I also reported that analysis of Italian talc at Harwell A. E. C. supported Dr. Pooley's findings.
3. Dr. Brown (Princeton) and Dr. Buerger (M.I.T.):

X-ray camera technique - no chrysotile asbestos.

X-ray special techniques - no chrysotile asbestos
4. Mr. Caneer presented his findings on SHOWER-TO-SHOWER:

X-ray - step scan - no chrysotile asbestos.

Petrographic - no chrysotile asbestos.
5. Dr. McCrone, of McCrone Associates, presented a petrographic technique which is specific to chrysotile asbestos detection. He also had a demonstration with his own microscope for Dr. Schaffner to look at. He stated that SHOWER-TO-SHOWER contains no chrysotile asbestos.
6. Dr. Ian Stewart, of McCrone, presented his data by electron microscope and diffraction, as well as petrographic and X-ray, showing absence of chrysotile asbestos.
7. Dr. Schelz of Johnson & Johnson presented his technique of determining chrysotile by DTA. He showed that adding one percent chrysotile to our SHOWER-TO-SHOWER clearly showed in the DTA graph, where no peaks were apparent before, and concluded that SHOWER-TO-SHOWER contains no chrysotile.

Dr. Lewin provided two handouts of his analysis of two lots of SHOWER-TO-SHOWER, C512Z and 0709X1. In both cases he reported the presence of two percent chrysotile. His findings showed an X-ray diffraction pattern for both lots where a peak was labeled "chrysotile?". However, with the microscopy work, he could see it. He proposed a theory that chrysotile was in the process of being formed inside the talc platelets in a new form. Drs. Pooley and Hildick-Smith pointed out that only fibrous chrysotile is implicated in lung problems. Dr. Lewin had no comment.

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Dr. McCrone reviewed the data by Dr. Lewin and pointed out a logical explanation for what Dr. Lewin was seeing, namely, the talc had not one but three refractive indices, and Dr. Lewin's observations only indicated this fact and not the presence of chrysotile. Dr. Stewart pointed out that Dr. Lewin's photographs indicated only talc shards.

Several more questions and comments were made by Dr. Buerger, Dr. Brown, and Mr. Caneer, criticizing Dr. Lewin's conclusions. Dr. Brown was very positive in his statement that the X-ray pattern presented by Dr. Lewin clearly showed the absence of chrysotile.

The meeting was beginning to deteriorate into a nonfruitful pathway. I interrupted to suggest a compromise, namely, that Dr. Lewin has carried out the procedure we had agreed on in the last meeting. It was obvious that the X-ray scan did not show definitive chrysotile, that microscopy was indicated, and since Dr. McCrone is very familiar with this technique, I suggested that the decision be made that Dr. Lewin work with Dr. McCrone to establish the best microscopy technique to be followed. Dr. Schaffner obtained agreement from Drs. Lewin and McCrone to implement this suggestion.

The meeting with our consultants was reconvened later at the hotel and they were asked to review their impressions of the meeting. They were unanimous in their criticism of Dr. Lewin and his findings, and they all individually agreed to present their views in writing. Dr. Fuller suggested that we convey these views to Dr. Schaffner and indicate that Johnson & Johnson will not accept any publication of Dr. Lewin's findings, which we consider to be an outright lie.

I called Dr. Schaffner the next day and conveyed that message. After thinking about it, Dr. Schaffner asked "Could we have these views in writing?" I said, "Yes" and he said "Could you put together all the reports and the views of the experts in one submission?" I said "yes."

I believe that Dr. Schaffner is now fairly convinced that Dr. Lewin's findings are not reliable. I don't expect that he will allow the release of Dr. Lewin's report.

Also, the assay scheme which will result will be acceptable to both FDA and industry.

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