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Johnson & Johnson

BABY PRODUCTS COMPANY

February 13, 1975

SUBJECT: CTFA Talc Subcommittee Meeting
with Food and Drug Administration
Washington, D.C. February 7, 1975

TO: Distribution

Detail official CTFA minutes will be issued by Dr. Norman Estrin but the following is a summary of the major discussions.

This meeting was held in Dr. R.N. Schaffner's office on February 7, 1975 at 1:00 PM. Representing FDA were: Dr. R. Schaffner, Mr. H. Eiermann, Mr. H. Davis, Dr. W. Horowitz and Dr. Yates. The CTFA was represented by: Dr. N. Estrin, Mr. G. Sandland, Dr. M. Berdick, Dr. R. Rolle and G. Lee.

Dr. Estrin introduced Mr. Sandland as chairman of the CTFA Talc Subcommittee and indicated that the purpose of our meeting was to present the analytical methodology which had been developed by the CTFA Task Force as applicable to cosmetic talcs.

FDA indicated that there had been no eminent plans to publish new proposed methodology in this regard and did not give us the impression that this matter was being assigned any urgency. They reported no further work with the optical microscopy method. Dr. Horowitz was asked by Dr. Schaffner to elaborate on the only apparent area of analytical activity which is being directed towards Food Regulatory. This is being carried out under contract by the Franklin Institute, who are investigating an SEM method. They're attempting to develop methodology for detecting low levels of asbestos contamination and have experienced difficulty in presenting a uniform sample to the SEM. It's expected that this study may take one to two years. Any further steps to be taken with regards to Food Regulation will therefore have to wait on developments from the Franklin Institute.

When questioned as to FDA efforts and progress in the approach of "concentrating asbestos" to increase the level

of sensitivity, Dr. Yates replied in a tone of frustration that all attempts have met with failure; they had investigated heavy density liquid separation. Dr. Yates did not state that efforts would be continued in this direction, but we volunteered help in evaluating methodology should they develop something.

Dr. Rolle outlined the proposed CTFA methods and the expected limits of detection. It was emphasized to the FDA that these were methods evaluated and recommended for cosmetic talc and would be practical to apply for industrial monitoring purposes. Dr. Rolle highlighted the fact that despite numerous inquiries, it had been impossible to find any natural-occurring chrysotile in talc for his methods development program. Dr. Berdick supported this by stating that Chesebrough-Ponds has examined numerous talcs from around the world for cosmetics application and have not found chrysotile. The writer reiterated similar J&J experience with domestic and overseas talcs. Dr. Schaffner agreed that no one has purported to have seen chrysotile in cosmetic talc except Professor Lewin. At this point, Dr. Schaffner asked us what Professor Lewin was doing (if anything) in talc analysis. Dr. Rolle outlined a conversation he had had with Professor Lewin the day before and Dr. Schaffner directed Dr. Horowitz to interview Professor Lewin for his most current views regarding chrysotile in talc. Dr. Berdick made the point that if chrysotile is not expected to be found in talc, then the FDA should not propose regulations to cover chrysotile. After an exchange of philosophy, where Mr. Eiermann took a strong stand for chrysotile in talc regulation, Dr. Schaffner suggested that if the CTFA would submit supporting data attesting to the absence of chrysotile in talc the FDA would take the matter under consideration. Mr. Sandland indicated that the CTFA will be proposing self-regulatory action by amending its present CTFA Talc Standard to include the asbestiform tremolite proposal.

Mr. G. Sandland stated that a regulation of 1% asbestos in talc was not only achievable by throughly tested methods, but also gave a safety factor of 48,300 (Sivertson calculation). Mr. Eiermann bluntly said that the calculation was wrong since the standard of 2 fibers/cc. is not a time weighted average. Before we had a chance for rebuttal Dr. Schaffner said that the Sivertson calculation was foolish since no mother was going to powder her baby with 1% of a known carcinogen irregardless of the large safety factor. Because of Dr. Schaffner's strong stand we did not correct Mr. Eiermann's misunderstanding of the calculation.

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Dr. Schaffner emphasized that there is an ultimate and more important need for talc clinical safety data in order to satisfy the consumerist advocates. The writer assured him that this would be forthcoming from J&J.

Copies of the DTA and X-Ray Diffraction Detection Procedures together with the Sivertson Report "An Estimate of a Safe Level of Asbestos in Baby Powder Talc" were distributed to the FDA representatives and the meeting was closed with Dr. Estrin thanking the FDA for the opportunity of exchange and discussion.

The general impression received by the writer was that the FDA was not anxious to publish further proposals relative to "asbestos-in-talc" pending outcome of the Franklin Institute Study, as long as the consumerist advocates remain quiescent. It is also evident that the FDA would depend on clinical data to defend the safety of talc.

In a post-meeting caucus of the CTFA attendees, it was agreed that the CTFA would proceed to compile information from consultants and manufacturers which attest to the fact that chrysotile has never been found in cosmetic talcs and submit this to the FDA.

G. Lee

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