TALC FILE

MEMORANDUM OF MEETING
Wednesday, March 10, 1976

BETWEEN: Andrew Maguire, M.C., 7th District, NJ
Christopher Burdick, Legislative Aid
John Walcott, Staff
Steve d'Arazine, Staff
Katherine Meyers, Staff
Lowell Dodge, Special Counsel

and

Heinz J. Eiermann, Director (HFF-440)
Division of Cosmetics Technology
Food and Drug Administration

SUBJECT: Asbestos in Talc and Other Cosmetic Regulatory Matters

Congressman Maguire and his staff came to my office unannounced in the early afternoon and remained until 5 p.m. The primary purpose of the visit was to discuss the issue of asbestos in talc. Congressman Maguire had read the Marian Burros article in the Washington Post of March 8 and had been in contact with Dr. Selikoff of Mt. Sinai Hospital.

Congressman Maguire was elected to Congress in 1974 as the representative of the 7th District of New Jersey (Bergen County, Northern NJ). He holds a Ph.D. from Harvard University (1966), either in political science or international affairs. Among his many committee responsibilities, Representative Maguire serves on the Committee on Interstate and Foreign Commerce, the Subcommittee on Health and Environment chaired by Representative Rogers, and the Subcommittee on Oversight and Investigations chaired by Representative Moss.

I described to the visitors (1) the mining, processing and commercial usages of talc, (2) the chemical and physical characteristics (and similarities) of talc and asbestos, (3) the instrumental methods (differential thermal analysis; x-ray diffraction; optical, step scanning and transmission electron miscroscopy) with their levels of sensitivity and interferences, (4) the agency's and DCST's activities since 1971 in regard to sampling and testing of talc products, analytical methods development, and regulatory actions, and (5) the current status of our efforts in regards to asbestos in talc. When questions were raised concerning asbestos in food, I suggested that they contact Mr. R. Ronk, Division of Food and Color Additives.

In regard to the aspect of mining and refining of talc, I pointed out that a highly sophisticated and time consuming method (electron microscopy) for the analytical determination of asbestos in talc would not be feasible because of the continuous processing procedure (instead of batch processing) and the usage of large quantities

of this raw material. To obtain statistically significant quality control data, many samples would have to be analyzed within a relatively short time period. For this reason, electron microscopy (EM) was not considered practicable, and our analytical methods development efforts concentrated therefore on differential thermal analysis (DTA) and x-ray diffraction (X-RD). Optical microscopy (OM), once thought by the FDA as the most suitable method for the determination of fibrous asbestos, fell into disfavor when it became apparent that chrysotile could not be resolved successfully for its small particle size, and tremolite could not be readily quantitated unless the analyst was an expert microscopist. Furthermore, our analytical methods development efforts during the past three years taught us also that DTA and X-RD (determining the presence of asbestos as a mineral and not its physical; i.e., fibrous, form) had a minimum level of detection of 0.5 - 1.0% and that enrichment methods by floatation cannot be employed successfully.

In 1971 the FDA convened a symposium on asbestos in talc which was attend by over 40 scientists, physicians and consumers. The purpose of the meeting was to discuss the mineralogy, analytical chemistry and epidemiology of asbestos and talc, and to assess their potential health hazard as cosmetic ingredients. Following this symposium, the FDA commissioned Dr. Z. Lewin, New York University, to analyze for asbestos 200 commercial talc samples. The results, made public in 1973, implicated 40 samples (of 195 tested), of which 17 were reported to contain chrysotile and 23 tremolite (or both). Other investigators, including the FDA, analyzed later some of the Lewin-implicated samples. C was never confirmed; tremolite was confirmed semi-quantitatively by OM and in some cases by X-RD, the method used by Dr. Lewin. While these investigations were under way, the FDA worked also on analytical methodolo suitable for routine quality control.

In 1975, as part of the cosmetic sampling survey, the FDA investigated 76 commercial talc samples for chrysotile (by DTA) and tremolite ~~(by X-RD~~ None were found to contain asbestos. Also tested in 1974 and 1975 were a few consumer complaint samples that had been brought to our attention. The results were negative. Current efforts, it was explained, centered on the adaption of X-RD and DTA for analytical control of talc by new personnel in DCST. (The minerologist left the agency in mid-1975).

Representative Maguire was informed that contact had been established with Dr. Selikoff and his group as far back as 1971. Recent contact with his Dr. Langer dated back to March 1. Both, the FDA and Marian Burr were aware of the fact that the samples implicated by her in the Washington Post article were sampled in 1973. Some of the same brands were sampled by us in 1975 and were found to be free of asbestos.

In regard to regulatory activity concerning asbestos, Representative Maguire was made aware of the proposed regulation on asbestos in food and drugs of September 29, 1973 (38 FR 27076) and the final order concerning parenterals of March 14, 1975 (40 FR 11865). The reasons for not going forward with the food regulation because of the problems with the OM method were explained. (Other analysts could not reproduce the results in round-robin testing of talc samples).

Representative Maguire wanted to know why we did not cooperate with Dr. Langer, why we did not find the asbestos he determined, and why we did not use electron microscopy. I assured him that we were in contact with him, that Dr. Langer's samples dated back to 1973 whereas ours were collected in 1975 (and he used his own, modified X-RD method which had not been fully confirmed to provide reproducible results), and that the electron microscope was not suitable for routine control for the aforementioned reasons. He insisted that all talc should be tested by EM and none should be permitted that contained any asbestos. In fact, he suggested that the FDA test all commercial talc by this method to make sure it is free of asbestos. I pointed out that budgetary constraints would not permit that, nor did we consider this necessary in the light of the 1975 sampling results.

In regard to the question of the health hazard associated with asbestos, I explained to Representative Maguire that the determination of carcinogenicity was based on epidemiological findings among asbestos workers and that a no-effect level was not known. From this he concluded that any concentration of asbestos in talc must therefore be unsafe. I could not concur with this conclusion. I explained that no data were available demonstrating that asbestos was hazardous at any concentration, and one could therefore state only that it <u>may</u> be hazardous.

At various times the discussion turned to budgetary and statutory issues. He wanted to know our current cosmetic budget, manpower and contract funding and what resources the Eagleton bill would require. I gave him the information presented in the morning by the Commissioner to Senator Eagleton at the Senate budget hearing. In regard to statutory issues, I explained to Representative Maguire the differences in authorit between the drug, food and cosmetic provisions of the FD&C Act. For example, he felt we should perhaps ban hair dyes in the light of the Ames mutagenicity test results in Salmonella. I pointed out to him that this would not be enough evidence to conclude that they are deleterious substances which "may render [hair dyes] injurious to users under the conditions of use prescribed . . ." etc. Furthermore, coal tar hair dyes bearing the caution statement of section 601(a) of the Act would not be subject to the provisions of the FD&C Act. When asked whether or not I favored the Eagleton bill, I indicated that the agency had endorsed the bill and that it would greatly improve the regulatory effectiveness

of the FDA provided the required resources were made available at the same time. He indicated that Representative Rogers had a similar bill in the House and asked me whether I favored it. I replied that the Rogers bill had not been re-introduced in this Congress but that I was very impressed with it. In essence, it contained all the provisions of the Eagleton bill. Representative Maguire said he would see to it that the bill were re-introduced.

Other items of discussion were vinyl chloride monomer(VCM) in cosmetic packaging, chloroform in toothpaste, microbial contamination of eye products and consumer complaint handling. I gave him a status report on the regulatory activity regarding VCM (awaiting review of comments on food proposal and final notice on the food regulation) and chloroform (a regulatory proposal is being drafted). In regard to eye product contamination, I reviewed our contract study at Emory University and its effectiveness with respect to better preservation of commercial products. When asked how much longer the study would have to be carried on before a regulation could be written and answering that this may take another 1 1/2 years, he indicated impatiently that we should be finished with it in 6 months. I explained to him why this was impossibl The handling of consumer complaints was explained in detail.

Representative Maguire requested that he or one of his staff be permitte to review the files on asbestos in talc and perhaps on other projects. When I replied that I had to check this request with the Office of Legislative Services, he pointed out that he could subpoena the files. I answered that this check was a routine procedure and that we had nothing to hide. On recommedation of Mr. H. Dausch (OLS), the files were made available. Mr. Burdick reviewed the asbestos-in-talc files and the data on the Ahearn-Wilson contract (Microbial Contamination of Eye Cosmetics). Mr. d'Arazine inspected the consumer complaint files paying particular attention to complaints involving lead acetate hair dyes. Copies of the attached documents were requested and were provided.

Representative Maguire was also interested in the voluntary cosmetic registration program and any other statistical data on consumer adverse reactions to cosmetics. I provided him with copies of our tabulations o industry-reported adverse reactions for 1974 and the first half of 1975, and with a copy of the Westat report on the 10,000 household consumer survey. Furthermore, I gave him background information on the purpose, methodology, results, conclusions and limitations of these studies. I cautioned him that the household survey data could not be extrapolated statistically to draw conclusions about the rate of adverse reactions to cosmetics within the entire population of the United States. (He had multiplied the average rate of 193 adverse reactions per 10,000 people by 210 million to arrive at a figure of 4 million adverse reactions). He expressed concern about the much higher rate of adverse reactions determined in the Westat study as compared to the industry-reported statistics.

Heinz J. Eiermann

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