MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Acting Director
Bureau of Foods

DATE: March 19, 1976

FROM : Associate Director for Technology

SUBJECT: Asbestos in Talc - Proposed Regulation

As you may recall, since the recent Washington Post article, our people have been having numerous meetings with members of the cosmetic industry regarding talc. At our last meeting on March 15, 1976, various companies submitted to Mr. Eiermann summaries of their analyses.

Mr. Eiermann has in the attached memorandum evaluated their summaries and comes to the conclusion that although the companies have done some work, the work has not been terribly extensive, and based on the work to date we probably could not say with certainty that the industry is adequately handling the problem. Therefore, Mr. Eiermann recommends and I concur that a proposed regulation be drawn up stating essentially that talc would be asbestos free when examined by using x-ray diffraction and differential thermal analysis.

If you agree, we will prepare such a proposed regulation, discuss with our counterparts within the Agency, and try to have it to you within a month. If you agree to the proposal, I think it should appear on our priority list and I would suggest that we plan to have it ready to leave the Bureau during the second quarter of the 1976 calendar year.

Robert M. Schaffner, Ph.D.

Attachment

cc HFF-440

PLAINTIFF'S EXHIBIT
CAM-45

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Robert M. Schaffner, Ph.D.
Associate Director for Technology (HFF-400)

DATE: March 18, 1976

FROM : Director, Division of Cosmetics Technology (HFF-440)

SUBJECT: Asbestos in Talc

I reviewed the correspondence submitted by CTFA's Dr. Estrin at the meeting of the CTFA Talc Subcommittee with the FDA on March 15 and would like to submit the following comments:

AVON had McCrone Associates, a consulting laboratory, evaluate in 1973, 170 talc samples by x-ray diffraction (X-RD). Since 1974, 250 samples have been evaluated in-house by differential thermal analysis (DTA) and by infrared spectroscopy (IR) for tremolite. This amount of analytical work appears to confirm Avon's statement that essentially every shipment of talc is tested. I do not know whether IR is adequate to determine tremolite.

CHESEBROUGH-PONDS conducted 84 analyses in the last three years for chrysotile and amphiboles by X-RD. Where X-RD showed positive results the samples were subjected to analysis by optical microscopy (OM) to verify the fibrous structure. Chesebrough-Ponds appears to be conducting only random analyses considering their talc business, number of tests conducted and the fact that talcs from three different sources are concurrently being used.

COLGATE-PALMOLIVE claims to have conducted 42 talc analyses since 1971, however, these analyses reflect only 20 raw materials and 17 finished products, and the same material may have been tested twice, first as a raw material and then as a finished product. Tests have been conducted by McCrone Associates and in-house using X-RD and OM or TEM where necessary to determine the fibrous structure. Three samples, two in 1971 and one in 1972, were found to contain chrysotile up to 100 ppm which Colgate-Palmolive claims to be possible background contamination. Considering the size of Colgate-Palmolive's talc business, the analytical effort is very small.

COTY claims to have analyzed selected lots of talc by X-RD and TEM at Pfizer's Laboratory. No numbers of analyses are provided. The talc supplier is Whittaker, Clark & Daniels.

CYPRESS INDUSTRIAL MINERALS, CO., a supplier of Montana Talc to the cosmetic industry claims to have conducted 2,839 evaluations by CTFA's

X-RD method up to August 1975 and 50 additional evaluations thereafter. This appears to be a responsible test program.

FABERGE had McCrone Associates investigate 12 talc products in 1972 when the asbestos issue was first raised and an additional six samples in November 1975. Obviously, no meaningful quality control program has been instituted.

JOHNSON & JOHNSON reports to have tested in 1972 - 1973, 93 lots of talc by X-RD and since October 1973 an additional 100 lots by X-RD and DTA, and occasionally, where appropriate, by TEM. Allegedly every talc shipment is routinely examined for asbestos. The number of analyses appears to be low, however.

Johnson & Johnson also reported the analyses of American and British talc products based on a cooperative study between Dr. Langer and Dr. Pooley. This study involved the 19 samples analyzed by Dr. Langer of which 10 samples were implicated to contain asbestos. Wherever Dr. Langer reported tremolite and anthophyllite, Dr. Pooley only found anthophyllite. Dr. Pooley did not find asbestos in those samples where Dr. Langer determined asbestos at concentrations of less than 5% i.e., Dr. Pooley implicated only five samples. In the British talc samples Dr. Pooley found anthophyllite in one and Dr. Langer found anthophyllite and tremolite in four samples. These were also samples collected in 1973.

McCRONE ASSOCIATES reported to have done analytical work under contract for Avon, Bristol-Myers, Chesebrough-Ponds, Colgate-Palmolive, Faberge, Johnson & Johnson, Windsor Minerals, and Whittaker, Clark & Daniels, using principally X-RD and OM where appropriate. TEM examinations were also conducted. Since 1973 no chrysotile or asbestiform amphibole was detected, however, no figures were provided on the analyses conducted.

STERLING DRUGS, the manufacturer of ZBT Baby Powder, reports one-third of all talc lots purchased have been tested by X-RD. No mention is made as to how many samples of each lot were collected to obtain statistically meaningful data. Furthermore, it is difficult to determine whether sampling of one-third of the lots is adequate, particularly if one does not know whether different sources of supply were used simultaneously.

WHITTAKER, CLARK & DANIELS (WC&D), perhaps the most important supplier of talcs of various origins and quality grades to the cosmetic industry, claims to have analyzed, under contract, 74 samples during the past four years. Considering the nature of WC&D's business volume, the variety of sources of supply, the various quality grades of talc involved, and the fact that this firm also supplies other industries with industrial talcs which do contain asbestos, I am greatly concerned about their limited effort to control the quality of their cosmetic talc. Their sales catalogue lists at least 20 grades or types of cosmetic talc. Accordingly, any type of talc underwent one analysis for asbestos per year. On the basis of this effort WC&D have provided their consumers with written assurance that they routinely monitor shipments of talc for asbestiform minerals and have found no detectable amounts. This assurance might be misleading and give the cosmetic industry the false impression that WC&D talcs are adequately tested for asbestos. I am also very much concerned about the fact that a firm of this standing in the cosmetic industry does not have facilities to do its own analytical work.

In summary, though the submission by the CTFA Talc Subcommittee looks impressive at first hand, it does not offer much assurance that cosmetic talcs are adequately tested for asbestos. If this is all that can be expected from the cosmetic industry in the form of analytical effort in the light of the asbestos in talc publicity since 1971, we have not much choice but to move ahead as speedily as possible with a proposal of a regulation on asbestos in talc using X-RD and DTA procedures and basing the levels of adulteration of talc with asbestos fibers on the levels of sensitivity provided by these methods.

Heinz J. Eiermann