PLAINTIFF'S EXHIBIT WCD-6

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
5001 Campus Drive
Harvey Wiley Building
College Park, Maryland 20740

CERTIFICATE

Pursuant to the provisions of Rule 44 of the Federal Rules of Civil Procedure, I hereby certify that Sheila Wright, Freedom of Information Officer, Center for Food Safety and Applied Nutrition, Office of Regulations Policy and Social Sciences, United States Food and Drug Administration, whose affidavit is attached, has custody of official records of the United States Food and Drug Administration.

In witness whereof, I have, pursuant to the provisions of Title 42, United States Code, section 3505, and the authority delegated to me by the Commissioner of Food and Drugs, hereto set my hand and caused the seal of the Department of Health and Human Services to be affixed this 1st day of December 2016.

Chalmer Rennie

Chalmer Rennie
Supervisory Information Disclosure Specialist
Center for Food Safety and Nutrition

By Direction of the Secretary of
Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
5001 Campus Drive
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College Park, Maryland 20740

AFFIDAVIT

Sheila Wright, being first duly sworn, deposes and says:

1. I am the Freedom of Information Officer in the Center for Food Safety and Applied Nutrition, Office of Regulations Policy and Social Sciences, United States Food and Drug Administration (FDA).

2. In this capacity, I have custody of official records of the United States Food and Drug Administration.

3. Attached is a certified and authentic copy of records of the Food and Drug Administration as follows:

FDA Memorandum of Meeting between FDA Representatives, Division of Cosmetics Technology dated March 15, 1976 consisting of 3 pages, total.

Sheila Wright

County of Prince Georges
State of Maryland

Subscribed and sworn to before me this 1st day of December 2016.

Notary Public in and for the
State of Maryland

Sharon A. Brooks
Notary Public, Price George's County, MD
My Commission Expires 09/29/2018

(Seal)

MEMORANDUM OF MEETING
March 15, 1976

BETWEEN: FDA Representatives, Division of Cosmetics Technology;

Robert M. Schaffner, Ph.D. (HFF-400)
Heinz J. Eiermann (HFF-440)
John A. Wenninger (HFF-441)
Martin Greif (HFF-442)
Henry M. Davis (HFF-446)
Ronald L. Yates (HFF-446)

and

Industry Representatives;

Murray Berdick, Ph.D., Chesebrough-Ponds
Christopher H. Costello, Ph.D., Colgate-Palmolive Company
Norman Estrin, Ph.D., Cosmetic Toiletry and Fragrance Association, Inc. (CTFA)
George Lee, Johnson and Johnson
Roderick A. Mundy, Streling Drugs
Frederick F. Roesch, Whittaker, Clark & Daniels, Inc.
Joseph P. Simko, Jr., Colgate-Palmolive Comapny
Terry Smith, Faberge
Ian M. Steward, Walter C. McCrone Associates, Inc.
John J. Travers, Avon Products, Inc.

SUBJECT: Asbestos in Talc

The meeting was requested by Dr. Estrin on behalf of the cosmetic industry representatives to present to the Food and Drug Administration information on the activities of some cosmetic firms in regard to the analytical testing of talc for asbestos. The meeting was held on the afternoon of March 15 at the FDA.

Dr. Estrin presented copies of letters addressed to his attention from the following firms:

Avon Products, Colgate-Palmolive, Chesebrough-Ponds, Cypress Industrial Mineral Co., Faberge, Johnson and Johnson, Walter C. McCrone Associates, Sterling Drugs, and Whittaker, Clark & Daniels.

In addition, a copy of a memorandum of a telephone conversation of March 12 between Dr. Jenkins, of Leeming-Pacquin, and Ms. Curry of the CTFA was submitted. The distribution of this correspondence was followed by verbal presentations of the contents of the individual letters by those industry representatives attending the meeting. The substance of

these presentations and letters was that, with three exceptions, none of the samples of talc and cosmetic talc products tested in recent years contained asbestos, taking into consideration the levels of detectability of the procedures employed. The exceptions were three samples, two representing talc sampled in 1971 and one a cosmetic talc product samples in 1972, registering chrysotile at concentrations up to possibly 100 ppm. These findings were interpeted to possibly represent background contamination.

The ensuing discussion dealth with the issues of analytical methodology for determination of asbestos, sampling of talc and talc products to adequately represent the quality of current production and the production dates of the commercial talc products implicated by Dr. Langer of Mt. Sinai Hospital to contain asbestos.

In regard to the subject of analytical methodology, the industry representatives expressed the viewpoint that x-ray diffractometry (X-RD) was the most suitable procedure in that it permitted to determine both amphiboles (5% level of detection) and serpentine (at a 2% level of detection at second order of reflection). Should asbestos be determined by this method, it would be followed by optical microscopy (OM) to determine whether or not it was present in fibrous form (anthophyllite, tremolite or chrysolite). The FDA representatives felt that differential thermal analysis (DTA) would be a better method for the determination of serpentine because of its greater sensitivity (at least at the 1% level of detection) and the lack of interference by chlorite, a mineral often found in talc. The industry representatives indicated that electron microscopy (SEM or TEM) would not be suitable for routine analysis because of its complexity and high cost.

Questions were raised by the FDA representatives whether or not the sampling of talc and talc products as documented in the submitted correspondence would be representative of current production. It was apparent during the conversation that the frequency of sampling varied greatly from firm to firm in that no pattern existed which would be representative of the entire industry. It was recommended that the industry establish sampling guidelines which would assure meaningful sampling of talc and talc products. Dr. Schaffner suggested that the industry voluntarily report the results of any sampling program to the FDA on a regular basis. He mentioned that food manufacturers undertook a similar voluntary testing program of lead in canned evaporated milk and reported the data to the FDA.

With regard to the cosmetic talc samples reported by the press to contain asbestos, the industry representatives pointed out that these products were manufactured as far back as 1968, and one product was discontinued many years ago. Mr. Eiermann reported that, as part of the FY 75 product

sampling program, the FDA sampled 76 cosmetic talc products and tested them for asbestiform minerals by DTA and OM. None were found to contain asbestos. Some of the samples represented the same brands as implicated by Dr. Langer to contain asbestos. Dr. Estrin asked to be made available the code numbers of the samples of these brands so that the industry could provide the FDA with the respective dates of manufacture. Mr. Eiermann read the code numbers and also offered to provide the CTFA with subsamples of the implicated brands collected in FY 75 by the FDA.

Heinz J. Eiermann

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