



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Eli Granek
McGivney & Kluger
80 Broad Street
23rd Floor
New York, NY 10004

DEC -2 2009

Food and Drug Administration
Rockville MD 20857

F09-8987

Dear Mr. Granek:

In response to your request of October 30, 2009 for information pertaining to the presence of asbestos in talc.

xx Enclosed are the records you requested.

 We have searched our files and find no responsive information.

 Your request is also being referred to one of our component offices.

 Certain material has been deleted from the records furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed and that disclosure is not appropriate. FDA has taken this approach to facilitate the process of responding to you. If you dispute FDA's preliminary determination and would like FDA to reconsider any particular deletion, please let us know in writing at the following address: Food and Drug Administration, Division of Freedom of Information, HFI-35, 5600 Fishers Lane, Rockville, MD 20857 within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed. If you do request further consideration and if the agency then formally denies your request for any or all of the previously-withheld information, you will have the right to appeal that decision. Any letter of denial will explain how to make this appeal.

The following charges for this request to date may be included in a monthly invoice:

Reproduction\$ 23.50 Search\$ 90.00 Review\$ 90.00 Other\$ 0 Total:\$ 203.50

THE ABOVE TOTAL MAY NOT REFLECT THE FINAL CHARGES FOR THIS REQUEST.
PLEASE DO NOT SEND PAYMENT UNLESS YOU RECEIVE AN INVOICE.

Sincerely yours,

FOI OFFICER
Executive Operations Staff
Center for Food Safety
and Applied Nutrition

Enclosure



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RLY

MEMORANDUM OF MEETING

March 22, 1976

at

Environmental Sciences Laboratory
Mount Sinai School of Medicine
City University of New York

BETWEEN: Members of the Staff of Environmental Sciences Laboratories

Arthur M. Langer
Arthur N. Rohl

Division of Cosmetics Technology, FDA

Clifton H. Wilson
Ronald L. Yates

SUBJECT: Analytical Methodology for the Detection and Determination of
Asbestos Minerals in Talc

Upon arriving at the laboratory, Dr. Wilson and Mr. Yates were greeted by Dr. Rohl. He stated that Dr. Langer would be present as soon as possible. Mr. Yates gave Dr. Rohl the cosmetic talc samples that Dr. Langer had agreed to analyze. In turn we requested and received subsamples of the 10 cosmetic talcs in which Dr. Langer reported the presence of tremolite and/or anthophyllite. These are:

1. Body powder, Cashmere-Bouquet
2. Rosemary talc
3. Brut for Men, Faberge
4. Air Spun Face Powder, Coty
5. Baby talc, Bauer and Black
6. Black Label, Yardley
7. After Shave talc, English Leather
8. ZBT Baby Powder
9. Invisible talc, Yardley
10. Shave talc, Mennen

Dr. Langer arrived approximately 30 minutes after our arrival. Mr. Yates presented him with the covering letter concerning the cosmetic talc samples DCST had provided for his analysis.

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Dr. Langer, Dr. Rohl, Dr. Wilson and Mr. Yates then discussed the following topics:

Sample Preparation and Instrumental Conditions for Analysis of Talc by x-ray Diffraction. - Dr. Langer stated that he did not believe it possible to prepare a sample for x-ray analysis that had a completely random orientation of the crystal lattice. He did not think that random distribution was important if sample preparation techniques were consistent. Mr. Yates informed Dr. Langer that in the proposed CTFA method, preferred orientation was inevitable because the sample was pressed hydraulically. Dr. Langer thought the technique acceptable if consistent results were obtained. Dr. Langer demonstrated the sample preparation technique used by his group. After preparation was completed, sample was step-scanned in increments of 0.02° through the area of interest until a count of 2000 was obtained at each step. Divergence slits of 4° are frequently, although not always, used. When Dr. Wilson asked Dr. Langer about the possibility of scatter and high background from the use of a 4° slit, Dr. Langer stated that the use of a smaller slit would probably increase resolution and sensitivity. He was somewhat noncommittal about the effect of a 4° slit on quantitative results. Dr. Langer summed up by stating that if good standards are used and sample preparation is reproducible and consistent, reliable analytical results should be obtained. He said that all of the 10 samples found to contain tremolite and anthophyllite by x-ray diffractometry were examined by transmission electron microscopy using selected area diffraction to verify x-ray results. Dr. Langer was somewhat disgusted by the talc industry's attitude. He said the results of his work has been known to the industry for several years but nothing was done until the analytical results became public.

Tremolite. - Dr. Langer stated that tremolite and talc fibers can be easily differentiated using light microscopy. The cleavage of tremolite and anthophyllite is 90° to the crystal axis while talc has an angular cleavage. There is also a difference in refractive index. Tremolite and anthophyllite can be differentiated by the difference in aspect ratio. Dr. Langer demonstrated by preparing a slide of Cashmere Bouquet talc. Under the microscope tremolite was observed as short particles with 90° cleavage. Anthophyllite had the same cleavage but was definitely fibrous, having aspect ratios typically 30 or 40 to 1. Talc fibers appeared to have a cleavage of approximately 60° . Dr. Wilson asked Dr. Langer to examine a sample of tremolite he had brought along. Dr. Wilson said that he had been using the sample as a standard but that x-ray analysis indicated impurities. Dr. Langer examined the sample using

optical microscopy. He stated it contained anthophyllite, tremolite, quartz and talc. X-ray analysis of the sample indicated talc, anthophyllite and tremolite. He had a microscopist on his staff examine the sample using optical microscopy. His analysis confirmed Dr. Langer's results. Dr. Langer stated that our tremolite standard was very impure and probably originated from New York. He gave Dr. Wilson the address of the Cape Asbestos Co. in London, a firm that could provide samples of Korean tremolite, considered to be the purest available.

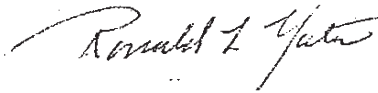
Dr. Langer said detectability levels for tremolite was approximately 0.1% by x-ray diffractometry. If tremolite particles had aspect ratios of 3 to 1 or greater they were considered fibrous.

Chrysotile. - According to Dr. Rohl, detectability by x-ray fluorescence was 0.25% depending on size and crystallinity. Dr. Rohl had some photographs taken of chrysotile fibers (fibrils) using transmission electron microscopy (TEM). Photograph showed fibers containing several fibrils and individual fibrils. Aspect ratios were extremely high. When examining talcs by TEM a count of 3-5/grid square is considered background. In two of the 19 commercial cosmetic talcs examined, fiber counts of approximately 24 fibrils/grid square were obtained. Dr. Langer considered this to be quite low and probably not hazardous. In general he did not think that chrysotile was a real problem as far as cosmetic talcs were concerned. He refuted claims made by some that asbestos fibers were not present in the environment due to use of asbestos brake shoes in automobiles. He stated that they have analyzed dust obtained from auto brake drums and have identified asbestos fibers.

Nickel. - In reference to the high amounts of nickel present in some talcs, Dr. Langer said that nickel replaces magnesium in the talc lattice and becomes a nickel hydroxy silicate complex. He is not convinced that nickel is harmless in this form because of its similarity to nickel hydroxide, which has been found to cause rhabdomyosarcomas in rats when injected.

Transmission Electron Microscopy (TEM). - Dr. Rohl demonstrated the use of TEM for the analysis of talcs using previously prepared samples. Using a prepared sample of unknown identity, he pointed out structures typical of talc and tremolite. He also demonstrated that use of selected area diffraction. The crystal to be examined is centered on the screen and the beam is then passed through the area of the crystal desired. The diffraction pattern is displayed on the screen as a series of dots quite similar to a Laue photograph. The pattern can then be compared with those of standards for characterization.

In general, the Environmental Sciences Laboratory is well equipped for mineralogical analysis having two transmission electron microscopes, two scanning electron microscopes, an x-ray diffractometer, an optical microscope and a differential thermal analyzer.

A handwritten signature in cursive script, reading "Ronald L. Yates". The signature is written in dark ink and is positioned above the printed name.

Ronald L. Yates