

MEMORANDUM OF TELEPHONE CONVERSATION

April 25, 1978

Between: Ms. Linda Donaldson (245-6733)
Office of the Secretary, DHEW

and R. M. Schaffner, Ph.D.
Associate Director for Technology

Subject: Asbestos in foods and cosmetics

At Mr. Tom Brown's suggestion, I called Ms. Donaldson to furnish her information on what action Food and Drug has taken on asbestos in foods and cosmetics. This information was needed to brief the Secretary before he has a meeting on asbestos.

I told her that in 1971 it was brought to our attention that asbestos was present in talc that was used in cosmetics. As a result of our investigations, discussions in scientific meetings with the cosmetic industry we have been successful in greatly reducing the amount of asbestos that is present in talc. Food and cosmetic grade talcs now contain such insignificant quantities that they do not appear to present a health hazard. However, the Agency is interested in having a method developed so that fractions of 1% of asbestos can be tested in foods or cosmetics.

On September 28, 1973, we issued a proposal which indicated an analytical method that should have shown that talc was free of asbestos fibers. This method has been tested by industry and others and is not a practical one. On March 14, 1975, we informed the public that the problem had not been solved.

Asbestos in foods can also result from the use of asbestos filters for clarifying beverages. Many of the asbestos filters have been replaced by filters using glass fibers and other materials. The Bureau is of the opinion that the presence of asbestos in foods from filters is minimal and does not present a health hazard.

We are spending about \$80,000 a year for contract research on developing new analytical methods, and our contractor informs us that progress is being made.


Robert M. Schaffner, Ph.D.

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FDA PROJECTS AND METHODS
PART II FOOD AND COSMETICS - AN FDA UPDATE ON
THE ASBESTOS QUESTION

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My discussion will focus on FDA's activities to prevent the contamination of cosmetics and foods by asbestos particles. I have been involved only with the problem of asbestos in cosmetics, but I will extend my discussion to cover foods. Cosmetics and foods share similar regulatory and physical-science characteristics, but there the similarity ends; to a large degree, the problem with food centers on ingested fibers whereas with cosmetics it centers more on inhalation of such fibers.

No regulations for either food or cosmetics have yet been established which either prohibit the use of asbestos-containing filters in food processing or limit the amount of asbestos fibers in talc used as a component of food or cosmetics. A proposal for certain restrictions on food only was published in the Federal Register (38 FR 27076-81),

For proceedings of National Bureau of Standards Workshop on Asbestos: Definitions and Measurement Methods, Gaithersburg, MD, July 20, 1977.

September 28, 1973. However, this regulation has not been published as a final order and is still pending. The comments received in response to this proposal clearly indicated that no regulation for food and food processing was warranted until more reliable data could be obtained on methodology for the determination of asbestos and on a more complete evaluation of the health hazard associated with ingested asbestos fibers. FDA's reply to these comments were published in the Federal Register (40 FR 11865-70), March 14, 1975. It should be emphasized that on the basis of information received the agency did conclude that the asbestos content of talc used in the manufacture of food - or drug - contact paper packaging does not represent a potential contaminant of packaged food or drugs as assessed by current methodology.

With regard to cosmetics it is unlikely that we will be in a position in the near future to propose a limitation on the asbestos fiber content of talc used for cosmetic talcum powders. However, we do have a modest surveillance program under which we monitor the asbestos fiber content of retail units of cosmetic talcum powder products. To date we have not found any grossly contaminated cosmetic talcum powder products on the market. Although this is somewhat reassuring, our sampling of products was small;

for example we looked at only 28 samples by x-ray powder diffraction during 1975 and 1976. Of these, one sample was found to contain 0.7% tremolite and three samples contained traces of tremolite (approximately 0.1%) and anthophyllite.

In our laboratories we are now using three basic methods for the evaluation of asbestos contamination of cosmetic talcs. We estimate our limits of detection as follows:

	<u>X-Ray Diffraction</u>	<u>Optical Microscopy</u>	<u>Differential Thermal Analysis</u>
CHRYSTILE	2%*	-	0.5%*
TREMOLITE	0.1%	0.1%	
ANTHOPHYLLITE	1%	-	

* In the absence of interference from chlorite.

The Cosmetic, Toiletry and Fragrance Association, Inc. (CTFA) has continued to cooperate with FDA's Division of Cosmetics Technology in developing reliable methodology for the determination of asbestos in cosmetic talc. Results from a testing program set up by the CTFA to establish the reliability of analytical methodology are expected to be available in the near future. The CTFA has been active in

establishing appropriate specifications for cosmetic talc and developing analytical methodology for industry.

An article on cosmetic talc powder which appeared in Lancet (Volume 1, pp 1348-9, June 25, 1977) concluded: ... "there is no reason to believe that normal consumer exposure to cosmetic talc in the past led to either cancer at any site or to measurable loss of lung function. It seems unlikely that future exposure to cosmetic talc of the specifications now agreed to by major manufacturers will present a health hazard."

We do not know if this assessment is correct. However, it is the responsibility of all of us to assure that appropriate steps are taken to prevent the use of talc unsuitable for use in food and cosmetics. It now appears that several years may be required to fully clarify some of the scientific questions on this subject. In the meantime it may be prudent to establish by regulation a standard for all to follow. No doubt this approach will be questioned in the absence of widespread gross contamination. However, we know that efficient enforcement of any specification is very difficult without the assistance of regulation.

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