FILE NAME: Talc (TALC)

DATE: 1972 Apr 25

DOC#: TALC065

DOCUMENT DESCRIPTION: Letter to FDA from Barry Castleman

April 25, 1972

John M. Gowdy, M.D.
Assistant Director for Medical Affairs
Division of Colors & Cosmetics Technology
Office of Product Technology
Department of Health, Education, and Welfare
Food and Drug Administration
Washington, D.C. 20204

Dear Dr. Gowdy:

Pursuant to your letter of April 19, I will offer an explanation for my concern about the present widespread availability to an unwary public of asbestos-and talc-containing products.

Asbestos is a generic term applied to a group of hydrated silicate minerals that separate readily into fibers. They fall into two groups: serpentine-chrysotile; amphibole-crocidolite, amosite, anthrophylite, tremolite, and actinolite. About 95% of the world output is chrysotile.

Mortality studies of asbestos workers in mining, processing, and application of insulation materials have established that occupational exposure to each of the major types of asbestos is associated with very high incidence of certain forms of cancer and asbestosis.

It has been shown that asbestosis is usually associated with long-term, moderately heavy occupational exposure. Lung cancer is probably a hazard only to those who are occupationally exposed; although (1) the safe threshold level of exposure is lower than that for asbestosis, and (2) a strong cocarcinogenic (risk factor=90) effect was found among cigarette smoking workers. Malignant mesothelioma of the pleura and peritoneum, a tumor which occurs in the general population in 0.01 to 0.1% of all deaths, is a relatively frequent occurrence among asbestos workers and their families, and neighbors of asbestos plants and mines. Lastly, gastrointestinal cancer has been found to occur in three to fourfold excess among some groups of asbestos workers studied. Among the insulation workers studied by Selikoff, 40% of those dead by 1971 died of the above causes, in excess of the mortality experience which would be expected in this group based on age-specific U.S. death rates.

A very important factor, from the point of view of a governmental control agency, is the long latency period from onset of exposure until development of disease or even symptoms of disease. It is clear from the literature that this latency period is rarely less than 20 years and often closer to 40, for all asbestos diseases. This of course means that today's mortality experience is a measure of conditions in the 1940's - and the effects of today's preventive measures will not be visible until the end of this century.

The existing literature is unable to provide us with a dose-response curve for exposure of human populations to asbestos. The "safe" level is so low that it hasn't been identified, or even seriously guessed at. And most alarming are the numerous reports of mesothelioma among non-asbestos workers in shipyards(where a large quantity of asbestos is handled), families of asbestos workers, and neighbors of asbestos mines, processing plants, and shipyards.

By 1965, it was well established that asbestos, especially asbestos insulating materials, were very hazardous. Yet, sprayed asbestos fireproofing insulation was used from 1938 until 1971 in the construction industry before Chicago and Boston became the first cities to ban its use. This material is probably used no where in the country today, but 3,000,000 building trades workers (carpenters, Electricians, etc.) worked in these structures every year and there is every reason to expect a resulting epidemic of asbestos cancer among these workers, starting in the 1990's.

Similarly, hazards exist in some consumer products where asbestos could be deleted or replaced with substitute materials. Example: dry-mix powders for making puppets and masks in elementary schools, cheap cigars (as a binder to augment "cohesiveness of the ash"), imported women's coats (1971, from Italy, 5% chrysotile), filters used to prepare foods and drugs, do-it-yourself home boiler insulation, numerous building products in hardware stores, filler in highway construction, and sprayed automobile undercoating (For a more complete list, I refer you to Professor I.J. Selikoff, Mount Sinai School of Medicine, 100th St. and 5th Avenue, New York, New York). Asbestos is used in thousands of products, and I'd give a day's salary to see a list, if one exists. Obviously, it should not be necessary to prove that each of these applications is hazardous before taking any action.

Tremolite, one of the least common and least commercially useful forms of asbestos, occurs frequently in combination with talc deposits. Talc crystals are plates rather than fibers, but chemically talc is very similar to the asbestiform minerals. At any rate, one result of the natural occurrence of tremolite in combination with talc is that some talcs used in cosmetic and infant powders (as well as some perfumed "feminine hygiene" sprays, I suspect) contain tremolite. I understand that the practice of dusting surgical gloves with talc has been quietly discontinued. It is known that long-term occupational exposure to talc causes a fibrosis of the lungs (talcosis) which can be fatal. It has been suggested that talc-dusting of rice is a major cause of the high rate of stomach cancer in Japan (Harlico, SCIENCE, 9/17/71). Talc miners in New York have been found to experience excessive rates of lung cancer (Kleinfeld et al, ARCH. ENV. HEALTH, 14, 663, 1967).

A recent case report (Miller et al; AM. J. MED. 50, 395, 1971) of a man with talcosis gave his background as follows: "From 1941 to 1950 he cleaned the factory ventilators which collected excess talc dust used in moulding and packaging rubber condoms." Is it standard practice to market condoms which are dusted with talc?

If so, is this necessary, or could a less suspect material, corn starch for example, be used instead? I understand that contraceptive diaphragms are also talc dusted by manufacturers. Several papers have appeared suggesting talc as a cause of ovarian cancer. I am in the process of reviewing the literature on cervical cancer epidemiology. I would like to perform a retrospective study of women who have used talc-rich contraceptives and matched controls who have no known genital exposures to talc. If you know you may find others in the process of performing or even publishing such a study now.

The problem with talc is, there is good reason to suspect it is a carcinogen but the subject has received very little attention in the past.

In the dim light of our present knowledge, unnecessary applications of this suspected carcinogen on tissues which are prime cancer sites should come under federal scrutiny and regulation.

Enclosed are "Criteria for a Recommended Standard .. Occupational Exposure to Asbestos" by the U.S. Public Health Service, a recent paper on disease hazards associated with community asbestos air pollution by Selikoff et al., and a table from another paper by Selikoff et al. (Mortality Experience of Asbestos Insulation Workers, 1918-1971). I hope that these references provide a more complete picture of the asbestos problem and answer some questions which my letter may have raised.

In addition, I hope you will write or call (301-494-3775) if you or your co-workers have questions which I might be able to help find the answers to. There is a great deal more in the literature than I have been able to cover here. I would be glad to spend an afternoon with you either here or in Washington discussing the problems of asbestos and talc.

Very truly yours,

Harry Castleman
Technical Services Section
Division of Air Pollution and
Industrial Hygiene
Bureau of Environmental Services

BC:dh
Encl.