MEMORANDUM

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

TO : Robert M. Schaffner, Ph.D., Director
Office of Product Technology (BF-400)

DATE: July 20, 1972

FROM : Acting Director
Division of Colors & Cosmetics Technology (BF-430)

SUBJECT: Background Memorandum on Asbestos in Talc

Asbestos is widely distributed in the environment, primarily as a component of man made artifacts, but also, in certain areas, as a component of surface mineral deposits, especially talc. Because of its heat resistant properties asbestos finds vide application in construction as a component of floor tiles, shingles, wall and ceiling board, and paints. It is sprayed or painted on water lines and air conditioning ducts to prevent heat loss or exchange. Around 600,000 tons per year are used in the building and allied trades in the United States. About 90% is bound so that it does not enter the environment readily.

200,000 tons a year are used for miscellaneous purposes in texiles, brake linings, clutch facings, paper, insulating tape, plastics and other products where heat or friction resistance are important.

The toxicity of asbestos was recognized as early as 1900 when asbestosis of the lungs was recognized both in miners and other workers exposed to dust. Later, asbestos was found to produce malignant tumors of the pleura (membrane surrounding the lungs) or peritoneum (membrane surrounding the intestines), mesothelioma. This tumor occurs so rarely in persons not exposed to asbestos that its discovery in a patient is considered diagnostic of asbestos exposure. Recently, asbestos exposure has been correlated with an increased incidence of carcinoma of the lung, stomach, and, possibly, other sites.

Asbestos exists in six major forms: chrysotile, anthophyllite, amosite, crocidolite, tremolite and actinolite. Evidences of differential toxicity among these various forms is difficult to evaluate because of differences in distribution in nature, differences in levels of use and the very long latent period before evidence of toxicity can be detected after exposure.

Crocidolite was formerly thought to be the sole cause of mesothelioma and thus the most toxic form of asbestos. However, evidence gathered

by Selikoff indicates that amosite and chrysotile are equally toxic with crocidolite. Chrysotile is the form commonly used in industrial applications. Anthophyllite has caused trouble in Finland. Actinolite and tremolite have not been as widely used for a long a period as the others and their lack of reported toxicity can not be taken as proof of their safety at present, although some experts feel that they are not as bad as the other forms. Everyone agrees that more study is needed.

Particle size is of some concern. In theory particles above 50 μ are trapped in the upper air passages. Particles smaller than this may enter trachea, bronchi or bronchioles and particles smaller than 5 μ can penetrate the alveolae and be retained in the lung. However, particles smaller than 0.5 μ are generally expelled from the alveolae and not retained. Several factors modify or eliminate the behavior of particles in the lung. Small particles may coalesce or adhere due to surface charge or moisture absorbtion. In the case of asbestos, fibers readily breakdown into fibrils. Even large particles may be swallowed and penetrate the intestinal wall. It has not been determined if peritoneal mesothelioma is due to ingestion or inhalation of asbestos fibers. It is readily demonstrable that asbestos fibers penetrate the tissue of the lung forming a characteristic scar like lesion, the ferruginous body. These ferruginous bodies are found in 50% of the adult male population regardless of whether or not they have a history of asbestos exposure. Ferruginous bodies are so named because they attract and concentrate tissue iron.

Animals working in (mules, donkeys) or living near (dogs, monkeys) asbestos mines also show ferruginous bodies and changes in the lungs characteristic of asbestosis. Because of differences in pulmonary dynamics and species susceptability, no suitable laboratory model for asbestosis or carcinogenesis by asbestos has been developed. However, by various methods of administration, pulmonary fibrosis, mesothelioma and carcinogenesis have been demonstrated.

The carcinogenic effect of asbestos has been attributed to trace amounts of metals such as nickel, iron or chromium or to absorbtion of hydrocarbons such as benzpyrene. It has been shown that cigarette smoking greatly accelerates the appearance of carcinoma of the lung in asbestos workers. Whether or not asbestos can eventually be rehabilitated by the removal of impurities is of little importance in solving the present problems. Methods and practices are currently available for limiting human exposure to these fibers.

There is a long latent period between asbestos exposure and the appearance of the various adverse effects. This has created great difficulties in

defining dose response relationships in both the level and duration of exposure. Mesothelioma appears after 20 to 30 years. Asbestosis usually requires 10 to 20 years to develop, while carcinogenesis is rare before 20 years but approaches 100 per cent after 40 or 50 years.

Asbestosis is said to have appeared after a single day's exposure. Mesothelioma has resulted from as little as six months exposure. The lower limit of exposure time required for carcinogenesis has not been defined.

Current opinion is that a dose of less than 100 fiber years will not produce asbestosis in more than 1% of the exposed population. The fiber year is exposure to 1 fiber/ml during a 40 hour week for a period of one year. This level is not adequate to prevent maligrancy. Tolerances for industrial workers are being revised downward and are now 2 fibers/ml average for an eight hour day with peak levels not to exceed 10 fibers/ml> 5 μ.

A number of sources have reported the presence of asbestos fibers in talc. This asbestos is generally present as a natural contaminant in talc deposits. The amount varies within deposits and among different geographical areas. There are talc deposits which are essentially free of asbestos fibers. Tremolite is the form of asbestos associated with talc and, since it has no commercial applications, its toxic properties have not been well defined.

The chemical characteristics of talc and asbestos are identical so that special techniques are required to determine the amount of asbestos present in talc. Two methods are generally use, optical microscopy and x-ray diffraction. X-ray diffraction determines the percentage, but does not give any idea of the number of size of fibers present. This information is readily obtained by light microscopy, but positive identification of the fibers can not be made.

Amounts varying from less than 1% to 30% asbestos have been detected in commercial talcs. Preliminary studies for FDA by a contractor show that 27 out of 36 brands of commercial talc contain asbestos fibers.

Experiments conducted for FDA at the NIOSH laboratories in Cincinnati indicate that dispersal of 100 mg of asbestos (10% in talc) results in a peak level of 45 fibers per ml in the air. If this level can be extrapolated downward, dispersal of talc containing 2% asbestos should be within the allowable peak level of 10 fibers per ml.

On a fiber year basis it would require 200 years of exposure at this level to produce asbestosis in 1% of the population. However, if this level

is high enough to produce malignancy in 50 to 70 years most of the mothers would have 50 years of life expectancy and the babies would have a life expectancy of more than 70 years. Since this is an unnecessary risk it should be eliminated.

Asbestos has also been detected in foods and drugs either due to the use of asbestos filters in the processing system or by contamination from insulating or other materials in the environment. In certain areas it is customary to coat rice with talc to improve its flavor. This practice of the rice may lead to asbestos contamination if the talc used has an appreciable asbestos content. While ingestion has not been studied to the extent that inhalation has, available evidence indicates that introduction of asbestos fibers into the body by any route is or may be detrimental.

Asbestos has been formally declared a hazardous air pollutant by the EPA (FR Doc 71-4529). Limits for industrial exposure have been proposed by the Department of Labor (29CFR Part 1910; FR Doc 72-402) and the EPA has proposed a ban on asbestos fabrics other than for firefighting purposes (21 CFR 191; FR Doc 72-2457).

In summary, inhalation of asbestos fibers has been shown to be associated with serious pulmonary disease and cancer of the lung and other organs of the body. The amounts of asbestos fibers dispersed by the use of talc containing more than trace amounts of this contaminant exceed the standards promulgated for occupational exposure. Although the total daily exposure may be small, this exposure begins in infancy and may continue throughout life. Therefore talc containing more than 1% asbestos by weight should be declared a hazardous cosmetic and banned from interstate commerce.

The presence of asbestos fibers in foods and drugs is equally objectionable on the foregoing grounds and should be limited correspondingly.

In addition to asbestos, talc is occasionally contaminated with quartz. Amounts up to 50% have been reported. Such adulteration at best represents an economic fraud. At worst daily exposure to high levels of silicon dioxide could contribute to the development of silicosis. Therefore talc containing more than 5% free silicon dioxide should be considered adulterated and a paragraph to that effect should be inserted in the statement on asbestos.

Alfred Weissler, Ph.D.

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