DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

October 6, 1971

To: Participants in "Asbestos and Talc" Discussion Session at FDA on August 3, 1971

Attached is a summary of our recent Discussion Session on "Asbestos and Talc." As many of you know, I have requested submissions of detailed analytical procedures from all of the laboratories represented which perform such work. At this writing, I have received most, but not yet all, of the material requested. When the submissions are complete, I shall proceed with the synthesis of these into a package which will be circulated for comment.

Thank you once again for your assistance and participation.

Sincerely yours,

Alfred Weinzierl

Alfred Weinzierl, Ph.D., Acting Director
Division of Colors and Cosmetics Technology
Office of Product Technology

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MEMORANDUM OF A SYMPOSIUM
August 3, 1971

ASBESTOS AND TALC

Held at the Food and Drug Administration
200 "C" Street, S.W.
Washington, D.C. 20204

Moderator: Dr. Alfred Weisler, Director
Division of Colors & Cosmetics Technology

SUMMARY

The amount of asbestos fibers in talcum powder products, and the inhalation health hazards associated with their presence, are subjects of current interest but differing reports.

At a symposium held on August 3 at the Food and Drug Administration attended by over 40 scientists, physicians and consumers, it was generally agreed that most talcum powders of major manufacturers are relatively free of asbestos.

Nevertheless, on behalf of consumers, FDA is working on the details of a laboratory procedure for the analysis of asbestos in talcum powders which will give consistent meaningful results.

Accurate analyses for the amount of asbestos in talcum powder will be obtainable, according to many of the participants, only through the use of a battery of specialized instruments and techniques, including x-ray diffraction, polarizing optical microscopy, electron microscopy, and electron diffraction of selected particles.

In addition to extensive discussions of the analytical methods for asbestos used by various laboratories, the group also considered such topics as the medical significance of asbestos and other fibers, and the mineralogy of asbestos and talc ore deposits.

INTRODUCTION

Dr. Weisler opened the meeting by outlining some of the events which had brought the question of asbestos particles in talc to the attention of FDA. He indicated that in response to a letter from Jerome Kretchmer (Administrator, Environmental Protection Agency, New York City) to HEW Secretary Richardson, on June 28, 1971 the FDA was taking steps to investigate the problem of asbestos particles in talc.

As a first step the FDA would like to establish a laboratory procedure for the determination of asbestos in talcum powder products that will give meaningful and consistent results. Once the methodology is agreed upon FDA would be in a position to determine if such products on the market contain asbestos fibers.

The format of the meeting consisted of short presentations by each participant followed by informal discussions which served to pool the knowledge of the experts present. A list of the discussion topics is attached.

GENERAL DISCUSSION

1. Dr. Ross of the U.S. Geological Survey made the first presentation. Dr. Ross, a mineralogist, outlined the various associations of asbestos mineral species with talc. During this presentation and the discussion which ensued the following salient points emerged:

a. Definition: Asbestos is a generic term for a variety of hydrated silicate minerals which have one common attribute, the ability to be separated into relatively soft, silky fibers. Although the name is ordinarily associated with those varieties which have technologic importance, it is applicable to all minerals which fit the above descriptions. The term "asbestoform minerals" is perhaps most descriptive (1).

b. The known varieties of asbestoform minerals can be divided into two main classes on the basis of their crystal structures: serpentine and amphiboles. The sole member of the serpentine class is chrysotile asbestos, which is by far the most common of the asbestoform minerals. It accounts for more than 95% of the asbestos fiber produced today.

There are five recognized asbestoform varieties of amphibole: crocidolite, amosite, anthophyllite, tremolite, and actinolite. Although the amphiboles are common rock-forming minerals, the asbestoform varieties are much less abundant than chrysotile (1).

c. The empirical formula of talc and some asbestoform minerals can be represented as follows:

Talc, $Mg_3 Si_4 O_{10} (OH)_4$

Serpentine Class

Chrysotile, $Mg_3 Si_2 O_5 (OH)_4$

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(1) Speil, S. and Leineweber, J.P., Environmental Research 2 166-208 (1969)

Amphibole Class

Anthophyllite $(Mg, Fe)_7 Si_8 O_{22}(OH)_2$

Tremolite $Ca_2 Mg_5 Si_8 O_{22} (OH)_2$

Actinolite $Ca_2 (Mg Fe)_5 Si_8 O_{22} (OH)_2$

d. It is not unusual to find large variations in the composition of a mineral within a relatively small area of a given deposit. The differences depend to a great extent on the mineralogy involved.

2. Dr. Cralley of the National Institute for Occupational Safety and Health spoke on the fibrous content of cosmetic talcum products. His presentation, centered in part on a paper he co-authored entitled "Fibrous and Mineral Content of Cosmetic Talcum Products," Amer. Industrial Hygiene Association Journal, 29, 350-4 (1968). The following conclusions were made in this paper:

> "With the exception of 4 of the 22 cosmetic talcum products analyzed, the levels of free silica, cobalt, nickel, chromium, and manganese were generally of a low magnitude and within a narrow range. It is not known whether the four products represent a significant proportion of sales in the industry or to what extent the sources of the talc in these four formulations are the same as sources of talc specified for use in other talcum products in the competitive market. The levels of silica, chromium, and nickel in these four products are sufficiently high, however, to be of concern in their potential to cause disease.
>
> All of the 22 talcum products analyzed have an appreciable fiber content, ranging from 8 to 30% by count of the total talcum particulates, and averaging 19%. The fibrous material was predominantly talc but probably contained minor amounts of tremolite, anthophyllite, and chrysotile as these are often present in fibrous talc mineral deposits. Cosmetic talcum products should be included as a source of the fibers, from which may be derived ferruginous bodies observed in the lungs of humans. The meaning of the presence of these ferruginous bodies, however, is uncertain."

3. The third discussion topic on the program dealt with the biological and medical significance of asbestos and other fibers. Three speakers addressed themselves to this topic.

a. Dr. Selikoff of Mount Sinai School of Medicine outlined briefly the history of fibrosis in asbestos workers which has been known to the medical profession for over 30 years. He reported that a few years ago when he met with FDA officials there was no apparent

problem presented to the general population with regard to asbestos. It was considered at that time to be mainly an occupational problem. He reported that recently acquired knowledge has greatly increased his concern over the whole question of asbestos fibers in the environment. He felt that the new dimension added to the problem was the possibility that lung cancer may result even from exposures at less than occupation levels.

b. Dr. Hildick-Smith, Director of Clinical Research for Johnson and Johnson (J&J), outlined briefly the medical aspects of talc production and uses. He reported that J&J has been in the talc business for over 70 years. Talc, along with a whole host of other materials can give rise to a biological response. J&J has not noted any adverse effects from the use of talc in either their employees or reported in the literature.

Talc manufactured by J&J is highly refined to produce a "platy talc." Available data indicates that there is no health hazard associated with the use of cosmetic grade talc. It was also pointed out that talc introduced surgically does not apparently cause mesotheliomas.

c. Dr. Gross of the Medical University of South Carolina reported that there is very little if any data on the effects of talc in man or animal. Intratracheal injection of talc in hamsters caused no ill effects. In these animals no lung scarring was seen. Asbestos particles less than 5 microns in length reportedly do not cause lung damage. This point, however, has not been definitely confirmed.

4. Dr. Kraybill of FDA's Bureau of Foods reported that the subject of asbestos in food and the environment had been evaluated within the past few years and that no need for regulatory action was indicated. Recent events, however, may require that the problem be restudied.

Dr. Barzilai of the Bureau of Drugs reported that particulate matter in drug products are under study and that he would be very interested in learning about the analytical methodology which can be used for the identification of small particles.

5. Morris Kaplan of Consumers Union indicated that we always seem to be looking at problems after they occur rather than anticipating them. He hoped that existing knowledge on the subject of asbestos and talc would be resolved in the interest of the consumer rather than in the interest of the producer.

6. Dr. Estrin of the Cosmetics, Toiletry and Fragrance Association reported that the Association was ready to join with FDA and the academic community to determine if there is a consumer safety problem with talc.

ANALYTICAL METHODOLOGY

The afternoon session was devoted to a discussion of analytical methods that could be used for the identification and determination of asbestos in talc. Six presentations were given outlining methods used in various laboratories.

1. Mr. Eisenberg of the Division of Microbiology reported on optical methods, such as the use of the polarizing microscope, for the detection of asbestoform minerals in talc.

2. Dr. Speil of Johns Manville Research Center reported that tremolite and chrysotile could be determined in talc at a level of about 0.5% by x-ray diffraction. Dr. Speil felt, however, that the important question to be answered is: How much gets into the lung of the person who is exposed? He suggested that a model be set up to determine the real exposure values.

3. Dr. Lewin, a consultant for Whittaker, Clark and Daniels reported that x-ray powder diffraction would be an ideal screening technique for rapidly determining which samples of talc contain asbestos minerals. He indicated that there are talcs on the market which appear to be objectionable.

4. Dr. Langer and Dr. Maggiore of Mount Sinai reported that they use the following techniques to detect and determine asbestoform minerals; light microscopy, x-ray powder diffraction, electron microscopy, electron microprobe and electron diffraction. During the discussion that followed Dr. Langer's presentation he was asked if he had analyzed a sample, referred to as 344-L, from Johnson and Johnson. He said that he had and that it was a high quality talc. He added that all the talc producers represented at the meeting produced a high quality talc product.

5. Dr. Norwood of Charles Pfizer and Company agreed that x-ray diffraction would be the method of choice for the analysis of asbestos in talc. He indicated that by using step scanning and other sophisticated techniques you could probably detect down to 0.1% of chrysotile in talc.

6. Dr. Nashed of Johnson and Johnson introduced Dr. Rolle who made available a table which outlined "Methods of Analysis of Fibers in Talc." (Copy attached). Dr. Rolle recommended that optical microscopy be used as a first step in detecting fibers in talc. If very few or no fibers are seen, electron microscopy with electron diffraction should be used. If many fibers are seen x-ray diffraction should be used.

7. In closing the meeting Dr. Weissler thanked the participants and summarized the most promising approaches which might be used to determine the presence of asbestos in talc. Detailed procedures on analytical methodology will be sent to FDA by some of the participants at the meeting, and these will be synthesized by FDA and circulated for comments.

John A. Wenninger
Assistant Chief, Cosmetics Branch
Division of Colors & Cosmetics Technology

The following people attended the symposium:

Lewis J. Cralley, Ph.D.	National Institute of Occupational Safety and Health, Cincinnati, Ohio
Irving J. Selikoff, M.D.	Mt. Sinai School of Medicine
Arthur M. Langer, Ph.D.	"
William J. Nicholson, Ph.D.	"
C. J. Maggiore, Ph.D.	"
Malcolm Ross, Ph.D.	U. S. Geological Survey
Wilson Meshed, Ph.D.	Johnson & Johnson
Gavin Wildick-Smith, M.D.	"
R. F. Kolle, Ph.D.	"
T. H. Shelley, Ph.D.	"
A. Goudie, Ph.D.	"
Prof. F. D. Pooley (Consultant)	"
W. T. Concer (Consultant	"
Ian M. Stewart, Ph.D. (Consultant)	"
G. R. Grieger, Ph.D. (Consultant)	"
Dr. Norwood	Charles Pfizer & Company
Harold D. Stanley, Jr., Ph.D.	"
Commr. Harold Romer	N.Y.C. Dept. of Air Resources
S. R. Mountsier, Jr.	Whittaker, Clark & Daniels
Prof. S.Z. Levin (Consultant)	"
Paul Gross, M.D.	Medical University of South Carolina
Sidney Spell, Ph.D.	Johns-Manville
Morris Kaplan	Consumers Union
Norman Estrin, Ph.D.	Cosmetic, Toiletry & Fragrance Assn.
Murray Berdick, Ph.D.	"

Herman F. Kraybill, Ph.D.	Food and Drug Administration
Robert H. Schaffner, Ph.D.	"
Alfred Weissler, Ph.D.	"
John H. Gowdy, M.D.	"
Sylvan H. Newburger, Ph.D.	"
John A. Wenninger	"
Charles J. Kokoski, Ph.D.	"
George Thompson, Ph.D.	"
Dennis J. McGrath, M.D.	"
J. W. Cook	"
Hyman R. Gittes	"
William V. Barzilai, M.D.	"
Julo K. Lamar, M.D.	"
Mrs. Manjeet Singh	"
Armand R. Canola, Ph.D.	"
M. A. Weinberger, M.D.	"
Paul E. Corneliussen	"
K. S. Heine	"
Albert C. Kolbye, M.D.	"

cc: To all Attendees

JAWenninger:vbl:9-10-71

METHODS FOR ANALYSIS OF FIBERS IN TALC

METHOD	FIBER ANALYSIS QUAL.	FIBER ANALYSIS QUANT.	MINIMUM PARTICLE SIZE DETECTABLE	LOWER LIMIT OF DETECTABILITY	TIME FOR QUANTITATIVE ANALYSIS
Optical Microscopy	Yes Presence and Kind of Fiber	Yes Point and Area Count	~ 0.5μ	Not Applicable	1/2 Day
Scanning Electron Microscopy	Presence of Fiber	Yes Point and Area Count	~ 0.1μ	Not Applicable	One Day
Electron Microscopy	Yes Presence and Kind of Fiber	Yes Point and Area Count	~ 0.01μ	Not Applicable	One Day
X-Ray Diffraction	Kind of Fiber	Yes (wt/wt)	Minimum Particle Size for Diffraction is ca. 0.1μ	~ 0.5% w More Favorable Cases	Two Hours to a Day Depending on Method

From: R. F. Rolle, Ph.D.

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DIVISION OF COLORS AND COSMETICS TECHNOLOGY
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C.

ASBESTOS AND TALC

Discussion Session, August 3, 1971, Room 1409, 200 C Street, S.W.
Moderator: Dr. Alfred Weissler

Discussion Topics

1. Asbestos and Talc Mineral Deposits - Dr. Malcolm Ross
   U.S. Geological Survey

2. Fibrous Content of Cosmetic Talcum Products - Dr. L. J. Cralley
   NIOSH

3. Biological-Medical Significance of Asbestos and Other Fibers -
   Dr. I. J. Selikoff, Mt. Sinai School of Medicine
   Dr. G. Hildick-Smith, Johnson & Johnson
   Dr. Paul Gross, Medical University of S.C.

4. Current FDA Interests in Asbestos - Dr. R. E. Barzilai, Bureau of Drugs
   Dr. J. K. Lamar, Bureau of Drugs
   Dr. H. F. Kraybill, Bureau of Foods

5. Consumer Interest in Asbestos - Morris Kaplan
   Consumers Union

6. Cosmetics Industry Interest in Asbestos - Dr. Norman Estrin
   CTFA

7. Analytical Methods for Asbestos - William Eisenberg, FDA
   Dr. S. Speil, Johns Manville
   S. R. Mountsier, Jr., Whittaker, Clark & Daniels
   Dr. A. M. Langer, Mt. Sinai
   Dr. Norwood, Chas. Pfizer & Company
   Dr. W. Nashed et al., Johnson & Johnson