

FILE NAME: Talc (TALC)

DATE: 1971-1975

DOC#: TALC301

DOCUMENT DESCRIPTION: Barry Castleman Letters & Communications

Johnson & Johnson

DOMESTIC OPERATING COMPANY

NEW BRUNSWICK, N. J.

August 2, 1971

Mr. Barry Castleman
Department of Environmental Engineering
Johns-Hopkins University
Baltimore, Maryland 21201

Dear Mr. Castleman:

This is in answer to your letter of July 25:

1. The use of talc as a cosmetic extends far back in historical time. More specifically, Johnson & Johnson has marketed baby powder since 1895.
2. We have no asbestos in our baby powder. To prove this, we have had extensive analytical work carried out by mineralogists at the Colorado School of Mines, by McCrone Laboratories in Chicago and by Professor Fred Pooley at the University of Wales in Cardiff. Professor Pooley is associated with one of the teaching scientific groups studying the relationship of asbestos and other inorganic particles to cancer.
3. We have no meaningful information regarding baby powder manufactured by other companies. We suspect, however, that the "5 to 25" percent quoted by the newspapers is not based on carefully documented scientific evidence.

I hope the above answers your questions.

Sincerely,



Thomas H. Shelley, Ph.D
Director
Central Research Laboratories

mc

1662
August 2, 1971

Mr. Barry Castleman

Mr. L. G. Foster

The attached is, I believe, self-explanatory. I obtained the 1895 data from Bill Ashton.

If you agree, please send it out.

T. H. Shelley

mc

cc: Dr. G. Hildick-Smith

Dr. W. Nashed

Talc File - 503

August 2, 1971

Mr. Barry Castleman
Department of Environmental Engineering
Johns-Hopkins University
Baltimore, Maryland 21201

Dear Mr. Castleman:

This is in answer to your letter of July 25:

1. The use of talc as a cosmetic extends far back in historical time. More specifically, Johnson & Johnson has marketed baby powder since 1895.
2. We have no asbestos in our baby powder. To prove this, we have had extensive analytical work carried out by mineralogists at the Colorado School of Mines, by McCrone Laboratories in Chicago and by Professor Fred Pooley at the University of Wales in Cardiff. Professor Pooley is associated with one of the teaching scientific groups studying the relationship of asbestos and other inorganic particles to cancer.
3. We have no meaningful information regarding baby powder manufactured by other companies. We suspect, however, that the "5 to 25" percent quoted by the newspapers is not based on carefully documented scientific evidence.

I hope the above answers your questions.

Sincerely,

Thomas H. Shelley, Ph.D
Director
Central Research Laboratories

mc

bcc: Mr. L. G. Foster
Dr. G. Hildick-Smith
Dr. W. Nashed

Talc File - 503

FILE NAME: Johnson & Johnson (JAJ)

DATE: 1971 Aug 3

DOC#: JAJ105

DOCUMENT DESCRIPTION: FDA Meeting Summary - Asbestos and Talc

MEMORANDUM OF A SYMPOSIUM
August 3, 1971

PLAINTIFF'S
EXHIBIT
JNJ-95

ASBESTOS AND TALC

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

Moderator: Dr. Alfred Weissler, 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. Weissler 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, $\text{Mg}_3 \text{Si}_4 \text{O}_{10} (\text{OH})_4$

Serpentine Class

Chrysotile, $\text{Mg}_3 \text{Si}_2 \text{O}_5 (\text{OH})_4$

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

Amphibole Class

Anthophyllite $(\text{Mg, Fe})_7 \text{Si}_8 \text{O}_{22}(\text{OH})_2$

Tremolite $\text{Ca}_2 \text{Mg}_5 \text{Si}_8 \text{O}_{22}(\text{OH})_2$

Actinolite $\text{Ca}_2 (\text{Mg Fe})_5 \text{Si}_8 \text{O}_{22}(\text{OH})_2$

- 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

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 Nashed, Ph.D.	Johnson & Johnson
Gavin Hildick-Smith, M.D.	"
R. F. Rolle, Ph.D.	"
T. H. Shelley, Ph.D.	"
A. Goudie, Ph.D.	"
Prof. F. D. Pooley (Consultant)	"
W. T. Caneer (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. Lewin (Consultant)	"
Paul Gross, M.D.	Medical University of South Carolina
Sidney Speil, 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 M. Schaffner, Ph.D.	"
Alfred Weissler, Ph.D.	"
John M. 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.	"
Jule K. Lamar, M.D.	"
Mrs. Manjeet Singh	"
Armand R. Casola, 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

RECEIVED

JUL 27 1971

CONS & PROF SERVICE

Dept. of Environmental
Engineering

Johns Hopkins University

Baltimore, Maryland 21201.

July 25, 1971

Johnson and Johnson
New Brunswick, New Jersey

Dear Sir:

I am presently finishing a literature review on health effects of asbestos. In assessing the justification of current calls for removal of asbestos from talcum powders, there are several things I wish to know:

- (1) How long have cosmetic talcs, in particular Johnson's powder, been in widespread public use?
- (2) What would be involved (cost, plant process changes) in removing the asbestos fiber from talc, in which (I believe) it naturally occurs?
- (3) Do all talcum powders contain asbestos, and, among those which do, what is the range of asbestos content?

Any information you can provide will be greatly appreciated, in making a fair appraisal of this "problem".

Sincerely,

Frank C. Clement

FILE NAME: Johnson & Johnson (JAJ)

DATE: 1971 July 28

DOC#: JAJ089

DOCUMENT DESCRIPTION: Memo RE Barry Castleman Letter Requesting
Asbestos Health Information

Johnson & Johnson

New Brunswick, N.J.

July 28, 1971

Subject: Asbestos Inquiry--
Mr. Barry Castleman

RECEIVED

JUL 29 1971

Dr. T. H. Shelley:

T. H. SHELLEY

Jack Walcott has asked me to direct the attached letter from Barry Castleman to you. Mr. Castleman is in the Department of Environmental Engineering at Johns Hopkins University.

From the tone of this letter, it seems clear that Mr. Castleman has scientific knowledge far beyond the normal type of inquiry we have received from the public. The inquiry appears to require a more scientific response than we have been using in handling consumer correspondence.

Therefore, we believe that this letter should be handled by someone in R&D.

Before the response is sent to Mr. Castleman, it should be checked with Larry Foster.

Thanks very much for your help.



G. F. Tyrrell

GFT/lm
Attachment

cc: Mr. J. T. Dettre
Mr. L. G. Foster
Dr. R. A. Fuller
Mr. R. J. Howland
Mrs. D. Matsu
Mr. J. C. Walcott



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

April 6, 1972

Mr. Barry I. Castleman
Division of Air Pollution and
Industrial Hygiene
Bureau of Environmental Services
Baltimore County Department of Health
Maryland Avenue and Hillen Road
Towson, Maryland 21204

Dear Mr. Castleman:

Your inquiry of March 22, 1972 to Dr. John Palmer concerning asbestos has been referred to me for reply.

The Food and Drug Administration is aware of the asbestos problem and we have been studying it intensively for the past year. There is some difficulty in identifying asbestos in talc since they are chemically the same and much of our effort has been directed to the development of methods for the analysis of talcum powders for the presence of this contaminant. We now have several methods which we are preparing to apply to commercially available talcs. We do not anticipate that the air levels of asbestos fibers incident to the use of talc will be anywhere near the tolerance level established for industrial exposure (see attached FR statement of January 12th) but are planning research to determine this point.

A proposal has been published to ban asbestos coats and other garments except in those circumstances where asbestos clothing is necessary for fireproofing. A copy of this proposal is also enclosed (February 18th).

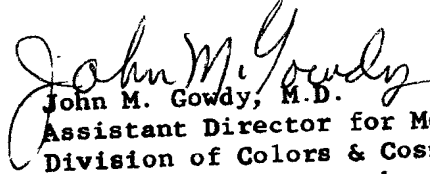
Building materials as such do not come directly within the purview of the Food, Drug and Cosmetic Act. If no other agency is prepared to deal with this problem it is possible that the Hazardous Substances Act could be stretched to cover it, however we would require advice from our General Counsel before attempting any action in this area.

- 2 -

In addition to the above problems we are also investigating the incidence and significance of asbestos fibers in liquid drugs and beverages.

I hope this is the information you desire.

Sincerely yours,


John M. Gowdy, M.D.

Assistant Director for Medical Review
Division of Colors & Cosmetics Technology
Office of Product Technology

Enclosures

April 13, 1972

Division of Colors and Cosmetics Technology
Office of Product Technology
Food and Drug Administration
Washington, D.C. 20204

Attention: Dr. John M. Gowdy
Assistant Director for Medical Review

Dear Dr. Gowdy:

I am writing in reply to your letter of April 6, about the FDA's studies on talc and asbestos containing products.

It is apparent that no epidemiological or toxicological studies are being performed by FDA on talcs without asbestos. It also appears that, although the FDA could probably require labeling of asbestos-containing products (such as building materials sold to homeowners in hardware stores) under the Hazardous Substances Act, this course is not being actively pursued. I don't know of another U.S. government agency which has responsibility for requiring labeling of hazardous substances on the consumer market or banning the use of hazardous products.

I am concerned about the availability of unlabeled asbestos products to the public. I am also disturbed about the use of talc, a suspected carcinogen, as a major constituent in cosmetic powders and perfumed vaginal sprays (its use in dusting surgical gloves has been discontinued).

The National Institute for Occupational Safety and Health has recommended that asbestos containing materials used industrially bear a hazard label (in "Criteria for a Recommended Standard . . . Occupational Exposure to Asbestos", February, 1972). It is possible that in adopting a new standard for occupational exposure to asbestos, the Labor Department will require the labeling of asbestos-containing products used by the labor force.

Nonetheless, even if the Labor Department requires labeling of some asbestos products, the problem of labeling other asbestos products on the consumer market will remain. The problem of evaluating the hazards of specific products in the light or darkness of present knowledge, and then deciding if these products should be withdrawn from the market (do-it-yourself home boiler insulation of asbestos, talc vaginal sprays, asbestos filters in processing foods and drugs, asbestos "binder" in cigars, etc.) - will remain. Correct

Food and Drug Administration
April 13, 1972
Page two

me if I am wrong, but isn't this the responsibility of the Food and Drug Administration?

Very truly yours,

BDC

Barry T. Castleman
Technical Services Section
Division of Air Pollution and
Industrial Hygiene
Bureau of Environmental Services

BIC/cms

CC: Senator Charles M. Mathias
Representative Paul S. Sarbanes

305 West Biddle Street
Baltimore, Maryland 212
August 3, 1972

Dr. Thomas H. Shelley
Director
Central Research Laboratories
Johnson and Johnson
New Brunswick, New Jersey

Dear Dr. Shelley:

When I was doing research on asbestos at Johns Hopkins I asked you some questions about Johnson's tale, and you sent a very informative reply. It is apparent that Johnson's tale is free of asbestos.

What I am interested in knowing is whether tale per se can enhance likelihood of cancer development, in individuals who are occupationally exposed. Kleinfeld's study of tale miners revealed a fourfold excess of lung cancer; however, the tremolite and anthophyllite (asbestos) content of the dust these men breathed was about 30%, so there is considerable doubt as to whether

it was the talc or the asbestos (these varieties of asbestos are of little commercial value, consequently there is hardly anything in the literature about the cancer experience of workers so exposed) which was the cause. Kleinfield knows of no other studies of talc workers, to date.

Dr. Shelly, what is needed are records of at least 100 men who have had occupational exposure to talc which commenced at least 20 years ago. The study would consist of following up to see which of them have died, and of what causes. Can you help me to locate a study group, either from your company's records or from union records?

It would be of great value to provide a scientific basis for saying whether talc exposure carries any excess risk of developing cancer. Reports of talc particles in ovarian tumor tissue (J. Obstet. Gynecol. 78, 266, 1971) and excess lung cancer among workers with mixed talc/asbestos exposure are cause for concern, but they provide no proof of talc hazard.

Sincerely,

Barry J Castleman

Johnson & Johnson

DOMESTIC OPERATING COMPANY

NEW BRUNSWICK, N. J.

August 10, 1972

Mr. Barry I. Castleman
305 West Biddle Street
Baltimore, Maryland 21201

Dear Mr. Castleman:

This is in reply to your letter of August 3. Since the information you request is largely medical in nature, I have forwarded it to Dr. Hildick-Smith, Director of Clinical Research.

Dr. Hildick-Smith is presently on vacation, but I am certain he will write to you shortly after his return.

Sincerely,



T. H. Shelley, Ph.D.
Director

Central Research Laboratories

mf

cc: Dr. G. Hildick-Smith

Johnson & Johnson

TF

New Brunswick, N.J.

August 10, 1972

Subject: Mr. Barry Castleman's letter
re Talc-Asbestos

Dr. G. Hildick-Smith

The attached re info on talc toxicity is self explanatory. I really think this demands a medical answer and would appreciate your handling.

THS

T. H. S.

mf
att.

cc: Mr. J. T. Dettre
Mr. L. G. Foster
Dr. R. A. Fuller
Mr. R. F. Kniffin
Mrs. D. Matsu
Dr. W. Nashed ✓
Mr. R. C. Stites

RECEIVED

AUG 11 1972

W. NASHED
JOHNSON & JOHNSON

CHARLES MCC. MATHIAS, JR.
MARYLAND

REPLY TO:
1616 FEDERAL BUILDING
31 HOPKINS PLAZA
BALTIMORE, MARYLAND 21201
(301)-962-4850

United States Senate

WASHINGTON, D.C. 20510

June 15, 1972

Mr. Barry I. Castleman
Technical Services Section
Division of Air Pollution and
Industrial Hygiene
Bureau of Environmental Services
Baltimore County Department of Health
Maryland Avenue and Hillen Road
Towson, Maryland 21204

Dear Mr. Castleman:

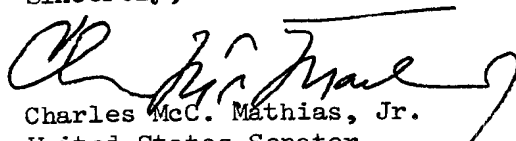
Please find enclosed a copy of a letter I have received from the Department of Health, Education, and Welfare relative to asbestos-containing products.

I hope the information provided in Mr. Meyer's letter will help to clarify some of the points you raised in your correspondence to the Food and Drug Administration in regard to this matter.

I was happy to have had an opportunity to be of assistance to you.

With best wishes.

Sincerely,


Charles McC. Mathias, Jr.
United States Senator

CM/esg

Enclosure



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

JUN 7 1972

Honorable Charles McC. Mathias, Jr.
United States Senator
Suite 1616, Federal Building
31 Hopkins Plaza
Baltimore, Maryland 21201

Dear Senator Mathias:

This is in further reply to your letter of April 20 concerning asbestos-containing products.

The Food and Drug Administration is aware of the recent concern over the presence of asbestos-form particles in talc which may be used in food products.

Since there is some difficulty in identifying asbestos in talc because of their chemical similarity, we are now in the process of evaluating the available analytic procedures for determination of asbestos in talc. However, in the meantime we are moving ahead with analysis of products containing talc, with existing methodology, for the presence of asbestos-form particles. We are attempting to determine the degree of exposure by the average consumer to products containing these substances. We are also preparing a draft for a proposed provisional regulation for the use in foods of talc which is free of asbestos-form particles.

Funds for animal studies on the toxicological effects of talc have not been available. A memorandum of need is being developed to justify the needed funds for contract feeding studies on silicates, including talc.

The Bureau of Product Safety of the Food and Drug Administration has reviewed the NIOSH document "Criteria for a Recommended Standard ... Occupational Exposure to Asbestos" and the quotation Mr. Castleman gave from page V-3. We are unaware of any type of asbestos product, intended for use in the household, which could be expected to give rise to such concentrations of airborne fibers that its use would overwhelm the clearing mechanism. Since long-term exposure to levels contemplated by the standard would not be expected to overwhelm the clearing mechanism, the level contemplated by the quoted passage must be much higher.

Page 2 - Honorable Charles McC. Mathias, Jr.

FDA has at the present time no specific regulatory actions underway except the prohibition of use of asbestos as a component of general use garments. We are continuing to explore the possibility of hazard from other uses of asbestos-containing products in the home and methods for control of such hazards as are discovered, including in our consideration labeling, construction criteria such as resin-bonding, and if it should become necessary, banning specific as yet unidentified products, to control likelihood of release of airborne fibers of asbestos.

Thank you for your interest. Please let us know if we can be of further assistance.

Sincerely yours,

Gerald F. Meyer, Director
Office of Legislative Services

Enclosure
Constituent's letter

cc: Your Washington Office



Johnson & Johnson

NEW BRUNSWICK, N. J.

March 7, 1972

Mr. Barry Castleman
305 W. Biddle Street
Baltimore, Maryland 21201

Dear Mr. Castleman:

First, I must apologize for the delay in replying to your inquiry about JOHNSON'S Brand Baby Powder. Your card was sent in inter-office mail with some correspondence in re-usable envelope. The other mail was taken from the envelope which was then placed in a stack to be used again. Unfortunately, it was not used again until this week, and your card was re-discovered at that time.

To answer your question, Johnson & Johnson takes great care in the formulation and production of all its products. In the case of JOHNSON'S Baby Powder, the talc comes from our own mines, specifically selected for the quality of their talc. This high-grade talc is processed through repeated "washings" in order to free it of impurities. Under careful analysis by independent experts, the finished product has been shown to be free of asbestos.

Thank you for your interest in Johnson & Johnson products and please forgive the delay in replying to your card.

Sincerely,

Steven Sawchuk, M.D.

Steven Sawchuk, M.D.
Associate Director of Clinical Research

SS:ev

March 22, 1972

Food and Drug Administration
Department of Health, Education and Welfare
5600 Fishers Lane
Rockville, Maryland 20852

Attention: Mr. John W. Palmer, M.D., Deputy Director
Bureau of Drugs

Dear Dr. Palmer:

I am writing to find out what the FDA is doing to research the suspected carcinogenicity of talcs (with and without tremolite asbestos); and what measures are being taken to safeguard the public against exposure to asbestos-containing consumer products (building materials, fabrics, etc.).

As you probably know, the National Institute for Occupational Safety and Health has just published the document, "Criteria for a Recommended Standard Occupational Exposure to Asbestos." The closing remark in section V, Development of Standard, reads, "Thus, the effect after several decades of a one-time acute dose of limited duration which overwhelms the clearing mechanism, and is retained in the lungs, may be as harmful [carcinogenic] as the cumulative effect of lower daily doses of exposure over many years of work." Asbestos is known to have been used in over 3000 applications including filter media for production of drugs, cheap cigars, home boiler insulation, heat-resistant clothing, paper products, sprayed fireproofing insulation, and numerous building products.

Talc is mineralogically similar to asbestos, and in a survey of 51 commercial talcs in 1942, 17 were found to have greater than trace amounts of tremolite asbestos, which frequently occurs combined with talc deposits. Recent publications have pointed out the possibility of talc causing ovarian cancer and stomach cancer (in Japan). However, as far as I know, no one has been able to firmly establish talc as being either carcinogenic or harmless. The most disturbing use of talc I know of is in recently-marketed feminine hygiene sprays. Also, some cosmetic powders have strikingly high fibrous content.

Any information you can send about the FDA's activities on asbestos and talc will be deeply appreciated.

Sincerely yours,

Barry L. Castleman
Barry L. Castleman
Division of Air Pollution and
Industrial Hygiene
Bureau of Environmental Services

BIC/cms
cc: Dr. Earl Meyers
Dr. Jerome Goldstein



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

May 2, 1972

Mr. Barry Castleman
Technical Services Section
Division of Air Pollution and
Industrial Hygiene
Bureau of Environmental Services
Baltimore County Department of Health
Maryland Avenue and Hillen Road
Towson, Maryland 21204

Dear Mr. Castleman:

Thank you for your letter of April 25, 1972, and the enclosed material.

During the past six months various members of the Food and Drug Administration have had a number of conferences with Dr. Selikoff and his staff here and in New York. We have collected and reviewed about one hundred papers on asbestos toxicity.

Largely because of the long time lag and also because of a reluctance to allow human exposure to a potentially toxic substance the dose response relationships of asbestos toxicity are undetermined. The industrial tolerance rests on rather shaky ground, however it will be 20 to 40 years before it can be determined whether it is too high or too low.

In the meantime, tremolite, because it is not widely used, does not have the background of proven injury as does chrysotile. I have talked with some experts who feel that tremolite is less hazardous than other forms of asbestos. This point can not be settled by argument.

With regard to cosmetics, the Food, Drug and Cosmetic Act, which governs our activities states precisely that products must be shown to contain a harmful or deleterious substance before they are subject to action, i.e. The FDA must be prepared to prove a cosmetic is hazardous before it can act against it.

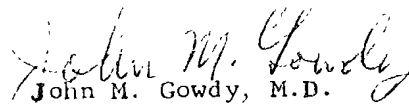
Condoms and diaphragms are dusted with talc. Henderson et al (Henderson, W. J., C. A. F. Joslin, A. C. Turnbull and K. Griffiths,

Page 2 - Mr. Barry Castleman

Talc and carcinoma of the ovary and cervix, J. Obstet Gynecol Br. Commonw, 78:266 - 272, (March), 1971) were able to demonstrate talc, but not asbestos within malignant tissue. Unfortunately, they also noted talc particles in normal tissue.

I would very much like to see the results of a survey such as you discuss. There may be a problem in that women who do not use talc dusted contraceptives may have been examined with talc dusted gloves so that there may be some problem in developing a control group.

Sincerely yours,



John M. Gowdy, M.D.

Assistant Director for Medical Affairs
Division of Colors & Cosmetics Technology
Office of Product Technology

Phone Number
301-494-3775

May 10, 1972

Dr. Albert Fritsch
Center for Science in the Public Interest
1346 Connecticut Avenue, N.W.
Washington, D.C.

Dear Mr. Fritsch:

I was referred to you by Ken Lassen. I am interested in research on the adverse effects on health of asbestos and talc, in particular carcinogenesis. Ken said that your center performs action-oriented investigations and you might be working on these topics now.

As far as I know, no one has yet demonstrated, that non-occupational, environmental exposures to talc carry an excess risk of developing cancer. (This has been done for asbestos, and the government has begun to effect restrictions on its use.) However, the striking chemical similarity between talc and asbestos, the occurrence of greater than trace amounts of tremolite asbestos in talcum powders, and the knowledge that occupational exposure to talc carries an excess risk of lung cancer - are very disturbing, in view of the widespread use of talc in infant and cosmetic powders, perfumed vaginal sprays, etc. My correspondence with FDA indicates that they are doing a minimal job (analyzing talcs for asbestos) about regulating both asbestos and talc in consumer goods. I would like to know of ways to get them "interested."

In my spare hours here, I have reviewed some of the literature on cervical cancer epidemiology. I also understand that some, but not all, prophylactics are dusted with talc in processing and packaging. Dr. Abraham Lilienfeld at the Johns Hopkins School of Hygiene has an interest in talc also, and I hope to work out some kind of study with him soon.

Please let me know your interest and activities in the subjects of asbestos and talc. I would be glad to come down and see you if you think it worthwhile.

My best wishes in your work.

Sincerely,

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

BC:dh

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

1346 Connecticut Avenue, N.W., Room 812

Washington, D.C. 20036

(202) 833-3721

May 15, 1972

Barry Castleman
Technical Services Section
Division of Air Pollution &
Industrial Hygiene
Bureau of Environmental Services
Baltimore Co Dept. of Health
Towson, MD 21204

Dear Barry:

Thanks for writing and showing your interest in the talc and asbestos question. There is no reason why we can't cooperate on a project in the full since our type of public interest work is so entirely different from what you anticipate doing. We hope to have a program started in the fall on checking consumer items containing asbestos and talc and finding which ones are most dangerous. We have a partial list of the 3000 or more items and I am hoping that Consumer's Union (which is funding us on other chemicals) will be willing to give us \$10,000 for the coming year.

I would like to get together with you people and plot a cooperative program where we deliver items which are highly dangerous and you would test them to see how friable they really are. We could then carry on the work we are doing now of alerting the FDA, EPA, etc through letters, petitions and lawsuits if necessary; we would eventually write a map of consumer items made from asbestos and talc and give this to Consumer's Union and other consumer groups to generate citizen pressure for regulations.

We asked the NIH to endorse our proposal. They simply couldn't believe that scientists would work at sustenance wages and said the project was good but the funding (about all the CU can afford) was unrealistic. If you folks would show an interest in a cooperative venture and be willing to do analysis, it would fortify our project. If you are so moved, please send a note to the following:

Mr. David Swankin Consumers Union, National Press Bldg, Wash. DC 20004.

You are right in suspecting that the talcs are bad. Art Langer who works with Sellikoff's group at Mt. Sinai is very concerned about their many uses. I think the FDA will have to be shaken from their complacency and made to start some systematic action on these commodities.

Let's get together and talk about these problems (talc and asbestos). My schedule is very tight for the next 5 or 6 weeks (three talks and the Environmental Forum in Europe plus seeing some public interest centers in Europe. I have a few free days next week and will be back after June 22.

Sincerely yours,

Albert J. Fritsch
Albert J. Fritsch

May 15, 1972

Mr. Paul S. Sarbanes
Congress of the United States
House of Representatives
Washington, D.C. 20515

Dear Mr. Sarbanes:

Enclosed is my continued correspondence with Dr. John Gowdy of the Food and Drug Administration, on the subject of regulation of asbestos- and talc-containing consumer goods.

One thing is clear to me at this point: the FDA is either unable or unwilling to take regulatory action; and, I don't think we should have to await another 40 years of mortality studies to know the degree of hazard to which the public is now being exposed.

Mr. Sarbanes, I urge you to use your influence to see that something is done about this situation. Of course, I will be glad to discuss it at length with you or members of your staff at your convenience.

Sincerely,

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

BC:43
Encl.

Johnson & Johnson

NEW BRUNSWICK, N. J. 08903

September 19, 1972

Mr. Barry I. Castleman
305 West Biddle Street
Baltimore, Maryland 21201

Dear Mr. Castleman:

I am taking the liberty of replying to your letter dated August 3, addressed to Dr. T. H. Shelley, Director of our Central Research Laboratories. First, let me express our appreciation of your bringing to our attention your concern about the possibility that talc by itself may be a carcinogen. As we market talc we have real concern about any potential harmful effects it may have and have been monitoring on a continuing basis the world literature on the biological activity of talc. We are primarily interested in determining whether the cosmetic use of talc can cause any harmful effects and at this time have no reason to believe that talc alone will induce neoplastic changes.

The publication by Kleinfeld (Arch. Exper. Health, 14: 663-7, 1967) that you mentioned in your letter is familiar to us and, as you know, reports on the incidence of pulmonary cancer in miners working in talc mines which contained tremolite and serpentine.

I am submitting some points which support our position that pure talc is not a carcinogen which may be of interest to you.

1. The monitoring of adverse effects relating to the commercial use of a product that has been marketed for over 70 years by us and used cosmetically for centuries.
2. The continuing review of the world literature on talc shows that it has been used therapeutically when introduced into the pleural cavity, has been

introduced into the peritoneal cavity from ruptured surgical gloves and has been respired by industrial workers. In both the pleural cavity and the peritoneal cavity talc produces local fibrosis in the tissues and to date we have not been able to find any reports of cancer in the extensive medical literature on this subject.

Excessive exposure to talc causes talcosis in miners, and I know of no data to indicate that cancer of the lung occurs in such miners exposed to talc free of asbestos.*

3. Controlled studies have been conducted in hamsters in which talc was introduced into lungs and pleura and the results showed no cancer development when the animals were followed for their life. These data were in contrast to results obtained when asbestos was used in place of talc. A paper on these studies will shortly be reported in the medical literature.
4. In order to confirm the findings reported in '3', two separate, extensive animal studies are being conducted independently in which the animals will inhale talc for different time periods and will be followed for their lifetime and then examined histologically.

Your comment concerning the follow up of talc miners to determine the cause of their death is pertinent but is time consuming, and the numbers involved are relatively small. However, in order to obtain epidemiological data more rapidly, we are currently following an extensive epidemiological survey of the cause of death in a large group of industrial workers exposed to talc with a view to determining whether they differ from other appropriate populations. In addition we are attempting to obtain data on the cause of death of

*Van Orstrand, H.D.: Talc pneumoconiosis, Chest, 58(1):2, July, 1970

Mr. Barry I. Castleman

-3-

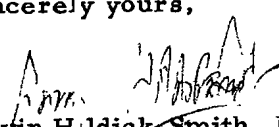
September 19, 1972

talc miners and determine if the cause of death differs from other populations.

I am hopeful that the comments I have submitted will be of assistance to you.

We appreciate your interest in writing to us and look forward to supplying you with pertinent published data as they become available.

Sincerely yours,


Gavin Hildick-Smith, M.D., F.A.A.P.
Director of Clinical Research

GHS:MMS

ENVIRONMENTAL
DEFENSE
FUND



1525 18th
~~XXXX~~ STREET, N.W., WASHINGTON, D.C. 20036/202 833-1485

1276

December 19, 1973

Hearing Clerk
Food and Drug Administration
Room 6-86
5600 Fishers Lane
Rockville, Maryland 20852

Re: Comments on the Food and Drug
Administration proposed regula-
tion Asbestos Particles in Food
and Drugs, 38 Fed. Reg. 27076-81,
Sept. 28, 1973.

Dear Sir:

We attach the comments of the Environmental Defense Fund
and the Center for Science in the Public Interest concerning the
proposed regulation cited above.

CSPI is a Washington-based non-profit corporation composed
of scientists dedicated to public interest research and advocacy
on public health and environmental issues. EDF is a non-profit
public benefit corporation organized under the New York State
law with a nationwide membership of approximately 45,000 indi-
viduals.

CSPI and EDF had earlier petitioned FDA to promulgate
a regulation prohibiting the use of materials or procedures in
the manufacture of food and drugs which would result in the
addition of asbestos to food or drugs. In the following comment,
we discuss the adequacy of the resultant proposal by FDA.

Respectfully submitted,

Lucile F. Adamson, Ph.D.
Environmental Defense Fund

Barry Castleman
Center for Science in the Public
Interest

Enclosure

OFFICES IN: EAST SETAUKET, NY (MAIN OFFICE); NEW YORK CITY (PROGRAM SUPPORT OFFICE); WASHINGTON, DC; BERKELEY, CALIF.

This paper is recycled to protect the environment.

JNJNI61_000022535

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

1779 Church Street, N.W.
Washington, D.C. 20036

June 4, 1973

(202) 332-6000

Food and Drug Administration
Bureau of Drugs
OTC Drugs Products Evaluation Staff (BD-109)
5600 Fishers Lane
Rockville, MD 20852

OTC Drug Review Information--Contraceptives and Other
Vaginal Drug Products:

IV. Human Safety Data on Talc

A. Individual Active Components

5. Pertinent Medical and Scientific Literature.

- a. Henderson, W.J. et al, "Talc and Carcinoma of the Ovary and Cervix," J. Obstet. Gyn. Brit. Comm., 78: 266, 1971
- b. Blejer, H.P. and Arlon, R., "Talc: a Possible Occupational and Environmental Carcinogen," J. Occup. Med., 15: 92, 1973.

VI. Summary Statement--Talc is commonly used in the manufacture and packaging of condoms and diaphragms. Henderson's study revealed the presence of talc deeply imbedded in the majority of primary malignant ovarian and cervical tumors examined. The fact that these researchers could not find talc in thorough studies of a secondary tumor, and the fact that no asbestos was found in any of the tissue studied support the hypothesis that talc per se had a role in causing malignancies to develop.

Blejer and Arlon develop the hypothesis of talc carcinogenicity in their recent literature review, citing the strong chemical similarity between talc and certain asbestiform minerals (which have been proven to be carcinogenic agents). One problem in trying to isolate the effects of pure talc is the fact that most talc deposits and talc products contain traces to large fractions of tremolite asbestos. On August 12, 1972 the FDA proposed to ban the use of asbestos-containing talcs in the preparation and packaging of foods (Federal Register v. 37, no. 157). It would

certainly be appropriate to ban the use of asbestos-contaminated talcs in contraceptives, other vaginal drug products, and cosmetics immediately.

In view of Henderson's report and some points made by Blejer and Arlon there is clearly reason to consider that talc per se is a "possible carcinogen." In view of this it would be prudent to minimize the introduction of talc-bearing contraceptives into the vagina, where the talc may easily find its way to prime cancer sites.

As talcum cosmetic powders (when used by females and males) and vaginal sprays are additional sources of talc insult to the female genital tract, it is obvious that FDA's findings and actions on talc (both pure talc and asbestos-contaminated talc) in contraceptives will have direct implications for talc in cosmetics.

Sincerely yours,

Barry Castleman /MJ

Barry Castleman

Michael Jacobson

Michael Jacobson

November 13, 1973

Mr. Barry Castleman
Center for Science in the Public Interest
1779 Church Street, N. W.
Washington, D.C. 20036

Dear Mr. Castleman:

Thank you for your letter of October 30, 1973.

As requested, we are attaching a copy of our Talc Safety -
Literature Review which has been recently updated.

I hope you will find it useful.

Very truly yours,
JOHNSON & JOHNSON

W. Nashed, Ph.D.
Director of Science Information

wn/cw

Attach: 1 vol.

bcc: Mr. D. Clare
Dr. R. Fuller
Dr. G. Hildick-Smith
Mr. D. D. Johnston
Mr. J. Melton
Dr. T. Shelley
Mr. H. Stolzer
Dr. D. Petterson

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

1779 Church Street, N.W.
Washington, D.C. 20036

(202) 332-6000

October 30, 1973

W. Nashed, Ph.D.
Director of Science Information
Johnson and Johnson Company
New Brunswick, New Jersey

Dear Dr. Nashed:

I read with interest a copy of your informative booklet, "Talc Safety - A Literature Review", which was submitted to the Food and Drug Administration this March. I would be grateful if you would send me a copy.

Sincerely yours,

Barry Castleman
Barry Castleman

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W. NASHED
JOHNSON & JOHNSON

ENVIRONMENTAL
DEFENSE
FUND



1525 18th STREET, NW, WASHINGTON, D.C. 20036/202 833-1485

1294

January 28, 1974

Hearing Clerk
Food and Drug Administration
Room 6-86
5600 Fishers Lane
Rockville, Md. 20852

RE: FDA Proposed Rulemaking
relating to Asbestos
Particles in Food and Drugs
(F.R. Sept. 28, 1973)

Dear Sir:

The above-noted proposal invited comments from interested parties on or before December 27, 1973. The Environmental Defense Fund and the Center for Science in the Public Interest did file such comments before that date. Since that time, we have had the opportunity to consider the Comment of 12/21 filed by Johns-Manville (J-M) on the same proposal. As a result, we are now submitting a supplemental comment with the hope that it, although late, can be considered as well.

This comment can be summarized by two statements: a) We do not object to the described use of asbestos-containing talc for pitch control in food and drug papers if it is shown that such talc does not migrate into food or drugs with which the paper is in contact; and b) the use of additional asbestos-containing talc for brightness filling or any other purpose should not be acceptable in food and drug wrappings.

There are a number of statements in Section 3 of the J-M Comment (Health Hazard of Ingestion) to which we would take strong exception. We do not wish any of the statements which we make here to indicate agreement that asbestos ingestion can be assumed to be harmless. We do not believe that such an assumption is justified. However, this question is not relevant to any use of talc which does not give rise to asbestos ingestion.

OFFICES IN: EAST SETAUKET, NY (MAIN OFFICE); NEW YORK CITY (PROGRAM SUPPORT OFFICE); WASHINGTON, DC; BERKELEY, CALIF.; DENVER, CO. **SI**

J&J-0134952

Protected Document--Subject to Protective Order

JNJ 000288719

We have considered the matter of talc use in the manufacture of paper used for food packaging. J-M states that talc which contains up to 5% tremolite by volume and is used for pitch control becomes "locked into place in the paper" and will not migrate into food with which it is in contact. J-M further maintains that due to talc's unique surface properties, no equivalent substitutes are known and that surface active agents, if used as an alternative to talc, are a cause of pollution at pulpmills.

We are now making our own appraisal of the environmental impact of talc and non-talc systems for pitch control. However, it is our preliminary opinion that the advantages of the use of talc for pitch control need not be sacrificed if, as J-M's tests indicate, the incorporated talc does not migrate from papers to food.

It is our understanding that talc for pitch-control is added during pulping in amounts up to 1.5%, with further addition of as much as 2% during paper making. These figures were given by Johns-Manville in their December 21, 1973 Comment to you.

If testing by procedures approved by the FDA does establish that no tremolite will migrate from paper to any food or drug during foreseeable conditions of use, we would not object to this use of talc containing up to 5% tremolite by volume, in the amounts noted above, for the purpose of pitch control.

Use of talc for other purposes in food and drug wrappings should not be allowed. For example, Johns-Manville also sells a 20 to 30% tremolite talc for use as a "functional filler" in paper making, and says that such filler is used little in making food papers. Normal rates of talc addition for this purpose exceed the combined amounts used in pitch control, and serve only an admittedly cosmetic purpose. Where manufactures require such brighteners for food or drug wrappings, substitutes for talc such as titanium dioxide can be used.

As the use of 5 to 15 percent talc containing 20 to 30% tremolite constitutes a relatively massive amount of tremolite added, we believe that the use of talc for brightness filling in food and drug papers should be prohibited immediately.

It is unlikely that papers with such high talc loading would completely retain their talc during the tearing, abrasion, and repeated foldings to which some food papers are subjected. J-M states that the use of such high-talc papers for food and drug packaging would be unusual due to high cost. Nevertheless, we believe that such use should be explicitly prohibited in the regulation to be promulgated by FDA.

J&J-0134953

1296

We are unable to comment on the acceptability of talc-treated recycled paper since we have no information as to how much talc is retained after the waste pulp stock is reclaimed, whether it is more or less securely "locked in" than talc added for pitch control, and to what extent recycled paper is used for direct wrapping of food and drugs. We are aware that recycled paper is apt to contain other contaminants (i.e. PCB's) which can make it unsuitable for food and drug wrapping. We urge FDA to clarify these points before approving the use of recycled paper for direct contact with food and drugs.

Sincerely yours,

Lucile F. Adamson

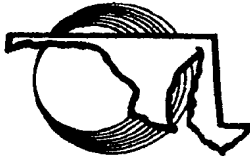
Lucile F. Adamson, Ph.D.
Environmental Defense Fund

Barry Castleman

Barry Castleman
Center for Science in the
Public Interest

LFA/BC:mew

J&J-0134954



MARYPIRG

MARYLAND PUBLIC INTEREST RESEARCH GROUP, INC.

3110 Main Dining Hall
College Park, Maryland 20742
University of Maryland
(301) 454-5601

Consumerism

April 17, 1975

Dr. Gavin Hildick-Smith, M.D., F.A.A.P.
Director of Clinical Research
Johnson & Johnson
New Brunswick, New Jersey 08903

Dear Dr. Hildick-Smith:

Several years ago I received a letter from you (September 19, 1972) in response to my concern that talc per se may be a carcinogen. You referred to several ongoing studies, and I would like to receive prints or reports of any that have been completed. I would also like to know of any new literature (1972-) in which cohorts of talc-exposed individuals were followed up for mortality, any case reports regarding the possible carcinogenicity of talc, and pertinent animal studies.

Specifically, your letter mentioned:

- (1) controlled studies on hamsters in which talc was introduced into the lungs and pleura.
- (2) separate, extensive animal inhalation studies with talc
- (3) an extensive epidemiological survey of the cause of death in a group of talc-exposed workers
- (4) other studies on the mortality of talc miners.

I hope this request is not overly burdensome. As one who is sometimes asked about the health effects of talc, I try to keep as up-to-date on the literature as possible.

Sincerely,

Barry Castleman
Barry Castleman
Environmental Engineer

BC:ljh

202/387-7595

March 17, 1975

FDA DELAYS ACTION ON ASBESTOS-CONTAINING TALC IN FOOD

The Food and Drug Administration on March 14 said that currently-available information does not warrant a ban on asbestos-containing talc in foods, acknowledging that it will delay any action on its long-pending proposal to institute such a ban (See FOOD CHEMICAL NEWS, Oct. 1, 1973, Page 37).

At the same time, FDA withdrew its proposal to tie the "generally recognized as safe" use of talc in food-packaging paper and paperboard to the absence of asbestos-form particles. The agency also reaffirmed its decision not to propose limitations on use of asbestos-containing filters in food and beverage processing.

The agency did issue a regulation dealing with asbestos-form particles in drugs for parenteral injection, and at the same time discussed at length the comments filed on its proposals dealing with talc in food, drugs, and in packaging (See FOOD CHEMICAL NEWS, Oct. 22, 1973, Page 18; Dec. 3, 1973, Page 2; Dec. 10, 1973, Page 3; Dec. 24, 1973, Page 20; Jan. 7, 1974, Page 30; Jan. 14, 1974, Page 30; and Feb. 18, 1974, Page 16).

FDA noted that it plans, in conjunction with other agencies, "extensive experiments to determine if long term exposure to ingested asbestos fibers represents a definitive hazard to human health." Until the study is completed or other data are available, the agency concluded "that a prohibition of the use of asbestos-containing filters in the processing of food and beverages, and of asbestos-containing talc as a food or food additive or in drugs or drug ingredients is unwarranted due to lack of sufficient data."

Industry Investigations Urged by FDA

However, FDA urged manufacturers "to investigate all means of eliminating the use of such filters and talc, and to keep the FDA informed about changes in formulation and processing of this type."

As expected, FDA decided to delay any final regulations for talc until "an acceptable method for determining the presence of asbestos particles can be developed for this substance" (See FOOD CHEMICAL NEWS, Feb. 17, Page 32). The agency said it is actively pursuing research on methodology.

FDA did not agree with comments "that the designated optical crystallographic method is unreliable when used by those experienced in the art," but did recognize "that an effective compliance method must have greater utility and acceptance than indicated by the comments on the proposed method."

Most of those who commented did not actually use the proposed method, FDA said, but reflected their general experience with optical crystallography, or "a personal preference for other analytical methods." The proposed method was supported in none of the comments. Most commonly-expressed objection was the difficulty in using the method. A collaborative study by members of one trade association resulted in inconsistent results, and four of the ten participants could not use the method, the agency said.

March 17, 1975

"Although detection was limited by the bulk of ash recovered from other products, such as fresh wrapped and frozen meat, dry packaged macaroni, dried milk, rice, and corn flakes, the comment also demonstrated that these products contain less than 10 p.p.b. asbestos under test and market conditions," FDA said.

Concluding that the salt study "represents a practical upper limit of migration of asbestos from food-contact paper and paperboard," FDA explained that the conclusion "is based upon consideration of the extreme abrasive nature of salt as compared to other dry foods, and the unusually high tremolitic asbestos content of the test paper (6%), as compared to reported levels of use (0.02-0.4%) in food-contact paper and paperboard."

FDA delayed "the promulgation of any regulation on the prohibition of use of asbestos filters for the preparation of foods and nonparenteral drugs until more reliable data can be obtained on the background concentration of asbestos in drinking water and the role of asbestos filters in regard to the addition of fibers to ingestible products."

The agency had stated in its proposal that it had decided not to issue a regulation governing the use of asbestos filters in food and beverage processing. Some comments urged that use of filters be regulated on the basis of a lack of evidence to show that the ingestion of small amounts of asbestos is safe. FDA said:

"The Commissioner agrees that uniform and consistent regulations should be adopted on an industry-wide basis. In this instance, the lack of available reproducible methodology for determining asbestos-form fibers in beverages and other foods led the Commissioner to propose the regulation of talc before handling other related matters. In any event, the comment has now become moot since the Commissioner has decided to delay a final ruling on talc as a direct food or drug ingredient."

FDA also said that "neither the available data on the addition of fibers to foods and nonparenteral drugs by use of asbestos filters nor the data on the asbestos content of municipal water are sufficiently reliable to permit promulgation of regulatory controls at this time." Noting asbestos content in some municipal water supplies, FDA said a Canadian study indicated that asbestos content of beverages is comparable to the background levels in areas of the U. S.

Noting its analysis of the comments, a re-review of the methodology, and the "controversial nature of evidence to demonstrate the hazard to health presented by ingestion of the amounts of asbestos fibers normally to be expected in talc used in food or drugs, or in food or drug packaging containing talc, or in beverages, other foods and nonparenteral drugs prepared with the use of asbestos filters," FDA concluded that --

"... The promulgation of regulations on the limitations or prohibition of the use of asbestos filters for the preparation of foods and nonparenteral drugs and of the amount of asbestos fibers in talc for use in food and drugs or which

Call from Dr. Bruce Semple, Johnson & Johnson

May 7, 1975 201-524-5025

Semple responded to my letter to Dr. Hildick-Smith, to tell me of current studies on the effects of talc. There are several reports that will be issued between now and September.

Talc miners and millers in Italy. Choser for its pure talc and stable population. Paper preprint will be sent in one month. No difference in mortality between miners and millers and controls. More pneumoconiosis in controls, more in miners than millers (the latter indicating that other dusts than talc produce the disease talcosis). Semple thought there may be no pneumoconiosis caused by pure talc, so I told him about the Mount Sinai case report on the man who cleaned ventilation equipment in the condom factory.

A prospective study is underway on millers, dust levels are known, and good ventilation has been there since 1971.

Battelle hamster study... to be presented in September at a world congress, exposures up to 750 times that with normal cosmetic talc use.

I asked about Henderson's work and its implications. He replied that Tenovus lab has been "scientifically discredited" over that work, and Henderson is gone. Problem was background sources of contamination that were not controlled. The work has been repeated with better control. Will be presented in September (Baden).

Semple thinks the relative innocuousness of talc is because of its platy morphology, that it easily picked up by the mucous stream and little is retained in the lungs.