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July 18, 1975



Mr. Peter Zschunke
Grace GmbH
6520 Worms
Rh. Postfach 449
In der Hollerhecke
Germany

Dear Peter:

Bob Byrne has asked me to respond to your letter of June 24, 1975 on the subject of the use of asbestos in filter equipment and packaging material for pharmaceuticals and food. This has been an emotional and controversial subject in the United States ever since Nicholson, Maggiore, and Selikoff published their data and publicly expressed their concern.

Basically two different problems have been examined by the FDA:

1. The use of asbestos filters for the processing of injection drugs, foods, and beverages.

2. The use of asbestos contaminated talc in foods.

After much debate and testimony, the FDA decided to put severe restrictions on filters and packaging for injection drugs only. No restrictions have been placed at this time on talc contaminated with asbestos in foods or on the use of asbestos filters for processing foods and beverages. Extensive research on the effects of injected asbestos are planned to determine if such restrictions are necessary.

The essentials of these decisions are summarized in the attachment, "Consumer Health." A copy of the complete regulations from the Federal Register is also provided if you want more details. You may also be interested in an excellent summary of the facts on the problem that was submitted to the FDA by the Asbestos Information Association. The AIA concluded that there was no evidence of any danger in the use of asbestos filters for injection drugs but did not object to the requirement of an after-filter as an extra precaution.

I hope this gives you the information you need for the customer. If you have any further questions, please let us know.

Very truly yours,

Harry

H. B. Rhodes
Technology Manager

HBR:pcr
Enclosures

Grace GmbH
July 18, 1975

Added Notes:

1. A copy of the J. L. Myers paper which you requested is also enclosed.

2. Mine Safety Appliances tells us that they have offices in most of the principal cities in Europe. We are enclosing a list of addresses.

Harry

H. B. Rhodes

HBR:pcr
Enclosures

cc: R. E. Byrne, Jr.
J. L. Myers
A. Dambach, W. R. Grace, Lausanne, Switzerland

FDA/Asbestos Filter Regulations (David L. Mallino)

On March 14, 1975, the Food and Drug Administration promulgated regulations governing the use of "asbestos-containing or other fiber-releasing filters" in the manufacture of parenteral drugs. (Federal Register, March 14, 1975, pp. 11865-11869)

According to the regulations:

- No asbestos-containing or other fiber-releasing filter may be used in the manufacturing, processing or packaging of parenteral drugs unless it is not possible to manufacture the drug product or component without the use of such a filter. Filtration shall be through a non-fiber releasing filter.

- For the purposes of this regulation a "non-fiber releasing filter" is defined as "a nonasbestos, nonglass fiber filter," which after any appropriate pretreatment will not continue to release fibers into the drug product.

- If use of a fiber-releasing filter is required, an additional non-fiber releasing filter of maximum pore size of 0.22 microns (0.45 microns if the manufacturing conditions so dictate) shall be subsequently used to reduce the content of any asbestos-form particles.

- If the use of a fiber-releasing filter is necessary, proof of its necessity must be submitted to FDA.

- Substititution for a fiber-releasing filter shall be achieved on or before September 14, 1976, with more time allowed if necessary.

- Drug packages, containers and components shall be cleansed and made suitable for their intended purpose.

FDA/Asbestos-Containing Talc in Food (David L. Mallino)

On March 14, 1975, the FDA acknowledged that available scientific and medical information does not warrant banning talc-containing asbestos in foods. (Federal Register, March 14, 1975)

The Agency also rejected its original proposal to tie the "generally recognized as safe" use of talc in food packaging to the absence of asbestos particles. At the same time, the FDA reaffirmed its original decision not to propose any restrictions on asbestos-containing filters used in the processing of food or beverages.

FDA stated that, in conjunction with other agencies, it plans to conduct extensive research into the potential health hazards of ingested asbestos. Until such time that positive data is available, FDA concluded that "a prohibition on the use of asbestos-containing filters in the processing of food and beverages, and of asbestos-containing talc as a food or food additive... is unwarranted due to a lack of sufficient data."

ASBESTOS INFORMATION ASSOCIATION
NORTH AMERICA
1650 L Street, N.W., Washington, D.C. 20036 (202) 223-4835

20 December 1973

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

Dear Sir:

The following comments are respectfully submitted by the Asbestos Information Association/North America in reference to Department of Health, Education and Welfare: Food and Drug Administration (21 CFR Parts 121, 128, 133), proposed rulemaking on Asbestos Particles in Food and Drugs, as printed in the Federal Register, Vol. 38, No. 188, Friday, September 28, 1973.

The Asbestos Information Association/North America consists of 22 member companies and associations which represent approximately three-quarters of the asbestos mining, milling, manufacturing and importing industries in the United States. The members of the Association are listed on a sheet which has been attached.

The adverse health effects of inhaling large quantities of asbestos fiber over a substantial period of time are documented in technical literature. Some researchers have reported an increased rate of gastrointestinal cancer among some long-term asbestos industry employees. Other researchers have been unable to support an increase in cancer of the GI tract among populations with above normal exposure to asbestos particles. In 1971, the seven-man Panel on Asbestos of the National Academy of Sciences' Committee on Biologic Effects of Atmospheric Pollutants examined all of the relevant data and concluded: "Associations between asbestos exposures and malignancies of the gastrointestinal tract and of other sites have been reported, but the data are still inconclusive". Reviewing the situation two years later, the Advisory Committee on Asbestos Cancers of the International Agency for Research on Cancer

of the World Health Organization concluded that for some exposed populations, such an increase does exist, but that the excess is relatively small, that further research is needed, and that there is no cancer hazard resulting from the ingestion of "asbestos fibres present in water, beverages, food or in the fluids used for the administration of drugs."

If the human evidence as to a possible relationship between asbestos exposure and an increased risk of gastrointestinal cancer is scanty and contradictory, animal experimentation performed to date is even more so. As is pointed out in the proposed rulemaking, the major feeding (as exposed to injection) experiments of L. M. Swinburn (your reference number 40) and W. E. Smith (your reference number 41) produced no tumors in the gastrointestinal tracts of the animals, even though the amounts of fiber fed to the animals were massive when compared with human occupational exposures known to result in respiratory disease.

These findings have been further confirmed by the work of J. M. G. Davis of the Institute of Occupational Medicine, Edinburgh, Scotland, whose feeding experiments with rats have thus far produced no GI tumors. A 1967 paper by G. M. Bonser and D. B. Clayton ("Feeding of Blue Asbestos to Rats," 1967 Annual Report, British Empire Cancer Campaign for Research, p. 242) likewise reported no tumors in 40 rats fed crocidolite asbestos throughout their lifetime.

Since it has been suggested that mesothelioma might be caused in some instances by a migration of asbestos fibers from other parts of the body, including the gastrointestinal system, it should be pointed out that no mesothelial tumors were found in any of the animals involved in the various feeding experiments.

While some injection experiments have produced site and mesothelial tumors in test animals, the amount of fiber used in each case was so large as to render any attempted translation to human experience completely inappropriate. In addition, the work of M. F. Stanton of the National Cancer Institute ("Some Aetiologic Considerations of Fiber Carcinogenesis," as presented at the World Health Organization Conference on the Biological Effects of Asbestos, Lyon, France, October 2-5, 1972, Paper 43A) and of P. Gross ("The Locus of Pathogenicity of Asbestos Dust," Archives of Environmental Health, Vol. 27, October 1973, p. 240) strongly suggest that injection or implantation cancers in test animals are directly related not only to dose but, even more

importantly, to the size of the fiber used in the experiment. Electron microscope sized fibers did not produce tumors in the test animals. This is extremely relevant to the proposed rulemaking in that the vast majority, if not all, of the asbestos fibers found in air, water, beverages, drugs and food in the United States are in this apparently non-carcinogenic size range.

On the basis of the human and animal studies contained in the literature, one would have to conclude that the relationship between asbestos exposure and an increased risk of gastrointestinal cancer remains tentative. Because of the known respiratory health hazards of asbestos, there has been a tendency among some researchers to ascribe to asbestos sole blame for an excess mortality from any cause experienced by an exposed cohort, even if that cohort was exposed to recognized toxic substances. It is theoretically possible that some other substance or agent is responsible for the excess GI cancer rate found among some asbestos-exposed populations. This would explain why other exposed cohorts have shown no such increase and also why animal feeding experiments have failed to demonstrate an increased risk. Until further research is completed, this possibility cannot be excluded from consideration.

Even if it is eventually proven that a relationship between asbestos exposure and an increased risk of gastrointestinal cancer does exist, the animal feeding experiments performed to date would have to cast serious doubt on the proposition that the ingestion of asbestos fibers is the cause of this increase.

It should also be pointed out that despite the long-term use of asbestos filters in this country, there is no evidence that anyone in the United States -- or in the world, for that matter -- has ever contracted either GI cancer or mesothelioma from drinking a beverage filtered through an asbestos filter or by being injected with a drug filtered in the same fashion. In fact, the GI cancer rate in the United States is on the decline, and if we were going to see an epidemic of these diseases because of asbestos filter contamination, certainly we would have had some evidence of it before now.

With regard to the question of asbestos-related disease, it must be borne in mind that all of the human groups studied to date have had occupational, para-occupational, neighborhood or household exposures of a magnitude far greater than that which could reasonably be expected to

exist to affect the general public. While precise comparisons are impossible because of different measurement techniques used to quantify asbestos concentrations in the workplace and in ambient air and water (occupational exposures are measured in fibers per cc while ambient exposures are measured in nanograms per cubic meter of air or micrograms per liter of water), rough approximations indicate that even safe occupational exposures are many thousands of times higher than those to which the general public is or has been exposed.

Asbestos is ubiquitous in our environment. It exists naturally in small, though detectable, amounts in serpentine rock formations throughout the world and is constantly being released into the atmosphere through erosion by wind and water. Asbestos is natural to our environment and -- as analysis of dated ice from the polar caps has revealed -- has been for thousands or even millions of years. Man, therefore, evolved into his present form in an atmosphere containing a natural background of asbestos -- both in the air he breathed and in the water he drank. While precise comparisons are impossible, today's atmospheric levels of asbestos, even in urban settings, are still only marginally higher than in the distant past. Most speculation as to the health hazards of the minute amounts of asbestos that have been demonstrated to exist in air, water and in beverages or drugs completely ignores these two most important factors -- the differences in magnitude between occupational and ambient concentrations, and the ubiquitous nature of asbestos in the environment.

To conclude, therefore, as some have done, that because exposure to heavy concentrations of asbestos fiber in the workplace is a recognized health hazard, general public exposure to infinitesimally smaller quantities of the same material must also be a hazard, flies in the face of logic, especially since man has survived such exposures for millions of years. It is reasonable to conclude that the general public is not at risk from infinitesimal quantities of asbestos. Such is the conclusion in the "Report of the Advisory Committee on Asbestos Cancers to the Director of the International Agency for Research on Cancer" (your reference number 52).

On the question of fiber release from asbestos-containing filters into the finished product, it is important once again to comment upon the ubiquitous nature of asbestos in our environment. A number of studies have been undertaken in the United States, Canada, and in the United Kingdom to

determine the so-called "natural background" level of asbestos in ambient air and water. Because of the different analytical techniques employed, the results of the various studies are not 100 percent comparable. However, it would appear that the average background level in water in the U.K. is in the vicinity of 4×10^{-8} grams per gallon; and in the United States and Canada, somewhere between 2 and 5 micrograms (1×10^{-6} grams) per gallon. Because of the complexity of the analytical techniques used to measure the asbestos content in water, an error factor of from 400 to 500 percent must be assumed in evaluating the results. The higher background found in North America is probably due to the greater quantity of asbestos-bearing serpentine rock found on the continent -- especially on the Eastern seaboard, where the samples were collected. To place the results in perspective, one microgram per gallon equals one ounce in 2.84 billion gallons.

If these background levels can be considered "normal" for human ingestion, the question must then be raised: how do these levels compare with beverages, drugs, etc. filtered through asbestos-containing filter pads? Research into this aspect of the problem has been conducted by Cunningham and Pontefract (your reference number 43); Nicholson, Maggiore and Selikoff (your reference number 45); Badami and Rickards (unpublished data submitted to FDA on May 1, 1973 by S. Holmes of the Asbestosis Research Council); J. P. Leineweber (unpublished summary of asbestos fiber content in United States commercial beers -- copy attached); Dr. Philip McGrath (FDA memorandum to Dr. Armand Casola); and Dr. J. R. Crout (FDA Preliminary Results of Special Survey).

The results of the Cunningham et al, Badami et al, and Leineweber studies all showed the asbestos fiber content of the various soft drinks, beers, wines and parenteral drugs tested to be no more than, or in many cases, less than the natural background level of asbestos that one would expect to find. Badami and Leineweber could find no correlation between the use of asbestos-containing filter pads and an increase of asbestos fiber in the finished product. Only Nicholson et al found levels of asbestos in parenteral drugs higher than would be considered normal. This is not particularly surprising, because the Mount Sinai laboratory has consistently reported higher asbestos levels in ambient air and water than have been found by other laboratories in the United States and abroad. Professional speculation is either that the Mount Sinai electron microscopy technique is faulty to some extent, or that improper attention is being

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paid to achieving true clean room conditions so that the samples are not contaminated prior to measuring. When seeking to obtain accurate measurements of such infinitesimally small quantities, even the slightest contamination could throw the results off considerably.

Of special interest with regard to the proposed rulemaking are the reports of McGrath and Crout. While only preliminary in nature, the Crout survey shows that the use of asbestos-containing filters bears no relationship to the presence of asbestos fibers in the finished product. In this respect, it confirms the studies of Badami and Leineweber, and throws considerable doubt on the proposition that the elimination of asbestos filters for parenteral drugs would result in any reduction in asbestos content of the finished product. In fact, the McGrath survey could lead to the conclusion that asbestos filters should be required for all filtration systems, since, to quote the McGrath memorandum, "Filtration through an asbestos filter demonstrated the remarkable capacity of this device to reduce the amount of asbestos in a given sample". It would be highly ironic, in light of the controversy that this subject has generated, if it turned out that the best method for the reduction of natural background levels of asbestos in base liquids would be the use of an asbestos filter!

To summarize briefly:

1. The evidence for a relationship between asbestos exposure and an increased risk of gastrointestinal cancer is inconclusive.

2. If such a relationship could be established, the evidence to date casts serious doubt on the proposition that the ingestion of asbestos fibers causes either gastrointestinal cancer or mesothelioma.

3. The size range of fiber most commonly found in beverages, drugs, etc. does not appear to be carcinogenic.

4. Asbestos is ubiquitous in our environment and has been for millions of years.

5. With the exception of the Nicholson et al study, which has been the object of serious criticism, none of the studies done to date shows an unnatural

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5. (Continued)
level of asbestos fibers in the finished product.

6. No correlation has been demonstrated between the use of asbestos filters and the presence of excess asbestos fibers in the finished products.

7. It is unlikely that the elimination of asbestos filters for parenteral drugs will result in a reduction in the asbestos content of the drugs.

8. The levels of asbestos found in beverages, drugs, etc. have not been shown to be hazardous to human health.

On the basis of the above, the following comments and recommendations are offered:

1. The FDA acted properly in not placing restrictions of any type on the use of asbestos filters in the food and beverage processing industries. This decision should not be altered.

2. In light of (a) the available medical evidence (b) the proven value of asbestos filters in removing pyrogens from parenteral drugs, and (c) the unlikelihood that asbestos filters contribute significantly, if at all, to the asbestos content of the final product, it is our recommendation that the FDA delete from Section 133.8 (j) of the proposed regulations that portion prohibiting the use of asbestos filters "unless it is not possible to manufacture that drug or drug ingredient without the use of such a filter".

3. Applying the "prudent person" approach, we support the precautionary measure of requiring a non-asbestos-containing after-filter whenever an asbestos filter is used for filtering parenteral drugs, even though it is highly unlikely that this is necessary either from the public health or drug purity standpoint.

4. Because of the extreme complexity of the technology involved and the possibility of substantial error, we further recommend that the requirement for proof of reduction be eliminated from the proposed regulation. Since the sampling method as described in the NIOSH document is useful only for detecting light-sized fibers, and not those in the EM range,

4. (Continued)
which constitute the vast majority of all asbestos fibers likely to be found in a parenteral drug, the method is in-appropriate and misleading for evaluating the asbestos burden of a particular drug. In addition, it would appear from the studies described above that the asbestos content of the pre-filtered solution is more important in determining the content of the final product than whether or not an asbestos filter with or without an after-filter is used.

5. We support that portion of Section 133.8 (j) with regard to the use of an asbestos-containing filter without an after-filter.

We believe these recommendations will provide the public with the health protection as required in the proposed regulations. In addition, the elimination of the sampling requirement and of that portion of the regulations prohibiting the use of an asbestos filter unless it is not possible to manufacture the drug in any other fashion, will considerably ease FDA's administrative enforcement of the standards. It would be much simpler for an FDA inspector to merely check to see that an after-filter was being used to assure compliance with the regulations than it would be to set up some type of permit system that could create confusion and serve neither the FDA nor the companies involved in the joint interest of best public service.

The Association appreciates the opportunity to submit this letter and requests that the recommendations and comments herein be given fullest consideration in the development of final standards on the use of asbestos-containing filters by the Food and Drug Administration.

Sincerely yours,

R. H. Mereness
Executive Director

Attachments: Summary of Asbestos Fiber Content in Commercial Beers, J. P. Leineweber

Member list Asbestos Information Association/ North America

SUMMARY OF ASBESTOS FIBER CONTENT IN COMMERCIAL BEERS

Brand	Filtration	Fiber Content (μg/gal.)*
SCHLITZ (regular) Sample 1	(Primary - diatomite only	0.23
SCHLITZ (regular) Sample 2	(Polish - asbestos-cellulose precoat + diatomite body feel	2.50
SCHLITZ draft	Same as regular + Millipore	2.50
RHEINGOLD extra dry	(Primary - diatomite only (Polish - asbestos-diatomite precoat + diatomite body feel	0.61
SCHMITZ	Same as Schlitz regular	1.39
NARRAGANSET	(Primary - diatomite only (Polish - diatomite only	1.14
OLD BOHEMIAN	(Primary - two stage diatomite (No polish	3.07
KAIERS	(Primary - diatomite only (Polish - diatomite only	0.24
PIELS regular	?	3.96
PIELS draft	?	0.74

*1 μg/gal. = 1 gram in 1,000,000 gallons = 1 ounce in 2,840,000,000 gal.

All values determined by electron microscope observation. No fibers were visible in any of the samples under optical microscopic observation at 450X magnification.

J. P. LEINEWEBER, P.H.D., Assistant Director Central Research Dept.,
10-15-68 Johns-Manville Corp.

FRIDAY, MARCH 14, 1975

WASHINGTON, D.C.

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PART I

HIGHLIGHTS OF THIS ISSUE

This listing does not affect the legal status of any document published in this issue. Detailed table of contents appears inside.

NONHUMAN PRIMATES—HEW proposes restricting importation; comments by 4–14–75 11897

EXHAUST EMISSION STANDARDS—EPA grants auto manufactures suspension request for 1977 model year 11900

HIGHWAY SAFETY—DOT criteria for incentive grants to States for annual fatality rate reductions; effective 3–14–75 11870

CAREER EDUCATION PROGRAM—
HEW/OE announces closing date of 4–21–75 for receipt of funding applications 11930
HEW/OE proposes fund criteria for FY 1976; comments by 4–14–75 11928

FOREIGN LANGUAGE AND AREA STUDIES—
HEW/OE sets closing date of 4–15–75 for receipt of applications 11931
HEW/OE proposes funding criteria for FY 1976; comments by 4–14–75 11930

SUPPLEMENTARY EDUCATIONAL CENTERS—
HEW/OE sets closing date of 4–25–75 for receipt of applications 11931
HEW/OE proposes funding criteria for FY 1976; comments by 4–14–75 11885

ANTIBIOTIC DRUGS—HEW/FDA provides test method for Tetracycline; effective 3–14–75 11869

ASBESTOS PARTICLES—HEW/FDA restricts use in manufacture of parenteral injection preparations; effective 4–14–75 11865

BIOLOGICS—HEW/FDA proposal changing testing requirements for Smallpox Vaccine, Live; comments by 4–14–75 11884

(Continued Inside)

PART II:

DRINKING WATER—EPA proposes interim primary standards; comments by 5–16–75 11989

PART III:

MINIMUM WAGES—Labor/ESA determinations for Federal and federally assisted construction 11999

Union Carbide trial exhibit UC-1354: H. B. Rhodes to Peter Zschunke (Grace GmbH) on FDA Asbestos Filter Rule…
Published by AsbestosClaims.Law
ACL Doc 16493 · Page 13 of 28
asbestosclaims.law/library/16493/13

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER C—DRUGS

PART 133—DRUGS; CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURE, PROCESSING, PACKING, OR HOLDING

Asbestos-Form Particles in Drugs for Parenteral Injection

The Commissioner of Food and Drugs published in the FEDERAL REGISTER of September 28, 1973 (38 FR 27076), a notice proposing to restrict the utilization of asbestos filters in the manufacture of parenteral drugs and parenteral drug ingredients, and to prohibit the use of asbestos-containing talc as a food, or food or drug ingredient, or in food and drug packaging materials, within certain analytical restrictions. The notice provided for the filing of comments within 90 days.

Asbestos fibers are known to cause cancer when inhaled in large amounts. Also, asbestos and other fibers are considered likely to have a similar adverse effect if present in parenteral drugs, although this has not been proven. Because of this likelihood, this order provides that, whenever possible, asbestos-containing or other fiber-releasing filters not be used in the manufacture, processing or packaging of drugs intended for parenteral injection in humans. Also, it provides for measures to reduce the amount of fibers present in such products, where it is not possible to eliminate these filters in the production of a drug.

The comments made in response to the September 28, 1973 proposal fall into two main categories. One concerns provisions to decrease the potential for ingestion of asbestos fibers. The other concerns provisions to decrease the potential for injection of asbestos fibers. A discussion of each category of comments, and the Commission's conclusions, are set forth below.

A. Comments on provisions dealing with ingestion potential of asbestos fibers:

1. The Commissioner proposed that any food, food packaging material, drug, drug ingredient or drug packaging material containing talc that is not free from asbestos fibers as determined by a particular analytical method should be deemed adulterated in violation of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act.

Nineteen comments related to the proposed analytical method for talc under § 121.2006 (21 CFR 121.2006). The comments were primarily from representatives of food, drug, and talc mining firms, but also included four consultant laboratories and two other federal agencies. Although it is apparent that most of these respondents did not actually use the designated method, and were, therefore, reflecting their general experience with optical crystallography or a personal preference for other analytical methods, none of the respondents supported the proposed method for compliance purposes. The predominant objections to the proposed method were that it is difficult to use, laborious, and not practical for its intended purpose. Several comments offered the opinion that only the most highly trained microscopists would be capable of using the method with any reasonable accuracy or precision. Members of one trade association collaboratively studied the method with 10 microscopists, each examining seven samples of talc. Four participants admittedly could not use the method to count the samples, and there was obvious inconsistency in the results reported by other microscopists.

A number of alternative methods for determining asbestos particles in talc were suggested by the respondents. Although optical microscopy using dispersion staining was the most frequently suggested method, others suggested x-ray diffraction, spectrophotometry, and several electron microscopy and microprobe techniques as preferred or supportive analytical methods. Many of the respondents additionally expressed their willingness to join a Food and Drug Administration analytical task force to evaluate applicable methodology.

Although the Commissioner cannot agree that the designated optical crystallographic method is unreliable when used by those experienced in the art, he recognizes that an effective compliance method must have greater utility and acceptance than indicated by the comments on the proposed method.

The Commissioner has, therefore, decided to delay any final regulation for talc until an acceptable method for determining the presence of asbestos particles can be developed for this substance. This

Union Carbide trial exhibit UC-1354: H. B. Rhodes to Peter Zschunke (Grace GmbH) on FDA Asbestos Filter Rule... Published by AsbestosClaims.Law
ACL Doc 16493 · Page 14 of 28 asbestosclaims.law/library/16493/14

area of research currently is being actively pursued by the Food and Drug Administration.

2. Several comments objected to the purity limitations for talc which were established by the proposed method. Many thought that requirements that talc be 99.9 percent amphibole-free and 99.99 percent chrysotile-free unreasonable, while others insisted that any limitation was unreasonable unless it could be demonstrated to reflect known hazard levels by ingestion. While one respondent calculated that 20,000 amphibole and 3,500 chrysotile fibers (of 5 micrometers x 1.7 micrometers size) should be permitted before any talc sample exceeded the established limits, another respondent observed that individual asbestos particles often vary in size a million-fold, thus making it difficult to relate particle counts to the percentage of asbestos contamination in talc.

Although the decision of the Commissioner to delay any final regulation on talc has rendered these comments moot, the Commissioner wishes to respond to these comments to clarify his position on possible future talc regulations.

As indicated in the proposal, the Commissioner recognizes that the evidence concerning the possible hazard from ingestion of asbestos particles is contradictory and inconclusive. The method was therefore not proposed in order to indicate any known hazard from asbestos, but was intended to establish a good manufacturing practice limitation for the use of talc in food and drugs until an assessment of the hazard, if any, of ingested asbestos can be determined.

The particle limitation accompanying the proposed method represents the best assessment by the Food and Drug Administration of the probability of occurrence of such particles in natural talc deposits, the ability of the method to detect such particles, and the need to assign a limit to define the absence of asbestos. The Food and Drug Administration has also examined numerous talc samples of undefined grade in the past 2 years, using the proposed methodology, and finds that approximately two-thirds of such samples are within these limitations. The Commissioner therefore concludes that the proposed particle limitations would not impose an unreasonable burden on manufacturers of talc if these limitations are ultimately adopted.

The Food and Drug Administration has been aware of the possible extreme variation in asbestos particle size that may occur in natural deposits of talc. Eliminating particles less than 5 micrometers long or with less than a 3-to-1 length-to-width ratio considerably narrows the range of permissible particles counted by the proposed method. Considering the variation in particle size that may yet be possible, however, a typical particle of 500 cubic micrometers, weighing approximately 1 nanogram (Ref. 1) was used to assure a purity of talc at least 99.9 percent free of amphibole types of asbestos fibers and at least 99.99 percent free of chrysotile asbestos fibers.

3. Three comments from industrial firms objected to the proposed analytical requirements for talc used in the manufacture of paper and paperboard in § 121.101(h) (21 CFR 121.101(h)). All of these comments contended that asbestos, in asbestos-containing talc, does not migrate to packaged food when talc is used for this purpose. One of these comments contained results of recently conducted studies which were intended to prove this contention.

After a thorough review of submitted comments, and examination and evaluation of additional requested studies, the Commissioner concludes that this comment has demonstrated the validity of this contention in a manner consistent with available methodology. In the conducted studies, the comment has demonstrated that dry packaged and shipped salt contains less than 0.01 part per billion asbestos when in direct and continuous contact with uncoated paper containing up to 6 percent tremolitic asbestos. 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 has also demonstrated that these products contain less than 10 parts per billion asbestos under test and market conditions. The analytical details of these studies are on file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20352.

The Commissioner concludes that the above reported salt study represents a practical upper limit of migration of asbestos from food-contact paper and paperboard. This 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 percent) as compared to reported levels of use (0.02–0.4 percent) in food-contact paper and paperboard.

The Commissioner therefore concludes that the comment has demonstrated that the asbestos content of talc used in the manufacture of food- or drug-contact paper and paperboard does not represent a potential contaminant of packaged food or drugs, as assessed by currently available methodology. Accordingly, the Commissioner is withdrawing the analytical limitations proposed for talc in § 121.101(h), unless new methodology or toxicological assessment requires further evaluation of this question.

4. The Commissioner stated in the proposal that it had been decided not to promulgate a proposed regulation governing the utilization of asbestos filters in the processing of food and beverages. One comment stated that this was inconsistent with the Commissioner's proposed regulation on the asbestos content of food-grade talc, and that attempts to limit asbestos ingestion should apply uniformly to all sources. Another comment stated that the Commissioner's decision not to regulate the use of asbestos filters in food, beverage and nonparenteral drug preparations was based on the unproven notion that the amounts of asbestos which are contributed to man's overall exposure by these substances are small. The comment contended that evidence is lacking to show that the ingestion of small amounts of asbestos is safe and that the responsibilities of the Food and Drug Administration for promulgation of regulations to lessen the total human exposure to asbestos were not mitigated by the fact that all human exposure to asbestos cannot be regulated by the agency.

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.

The Commissioner also concludes 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. Evidence indicates a wide variation of asbestos fiber contamination in the water supply of the cities of the United States, with some reports that the waters of the San Francisco, CA, and the Duluth, MN, areas are among the highest in asbestos content. However, the lack of consistency of test methods and their applications leads to questions concerning these data. A recent epidemiological study of cancer mortality in Duluth over the last 14 years (Ref. 2) has concluded that, up to this time, no carcinogenic effect could be demonstrated from ingestion of the municipal waters. Some reports have been received, claiming little or no asbestos addition to the aforementioned products by the use of filters (Ref. 3). Other reports from Canada, which indicate some increases in the asbestos content of beverages (Ref. 4 and 5) over background water, show that the final levels are comparable to the background levels in areas of the United States. Therefore, the Commissioner has decided to delay 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 concentrations of asbestos in drinking water and the role of asbestos filters in regard to the addition of fibers to ingestible products.

5. Many comments endorsed or condemned the proposals, or parts of them, with respect to water, food, and beverage contamination. Although most of these comments did not supply any additional data or information, a current asbestos feeding study by J. M. G. Davis (Ref. 6) and a 1967 study by G. M. Hoiser and D. B. Clayton (Ref. 7) were cited as further evidence of no harm from ingested asbestos. Other comments cited the 1972 conclusion of the Advisory Committee on Asbestos Cancers (Ref. 8) that there

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ACL Doc 16493 · Page 15 of 28 asbestosclaims.law/library/16493/15

is no evidence of an increased risk of cancer from asbestos fibers in water, beverages, and food, or in fluids used for the administration of drugs, and one comment cited a recent study by Elemfeld, Messite, and Zaki (Ref. 9) which reports no increase of gastrointestinal and peritoneal cancer among talc workers exposed to talc dusts for a minimum of 15 years.

From analysis of the foregoing comments received concerning the limitation of asbestos in talc, from thorough re-review of the scientific evidence available concerning the adequacy of the available methodology to determine the amount of asbestos in talc, and from consideration of 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 materials containing talc, or in beverages, other foods and nonparenteral drugs prepared with the use of asbestos filters, the Commissioner concludes 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 might migrate into food or drugs from talc-containing packaging materials is unwarranted until more reliable data can be obtained concerning these matters.

The Food and Drug Administration, in conjunction with other agencies, is planning extensive experiments to determine if long term exposure to ingested asbestos fibers represents a definitive hazard to human health. As noted, until this study is completed or other data become available, the Commissioner has determined 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. In the interim, manufacturers of food and drugs are urged to investigate all means of eliminating the use of such filters and talc, and to keep the Food and Drug Administration informed about changes in formulation and processing of this type.

B. In order to deal with the injection potential of asbestos fibers, the Commissioner proposed that the good manufacturing practice regulations for drugs be amended to require that filtration procedures for parenteral drugs shall utilize either a non-fiber-releasing filter such as a membrane filter or, if an asbestos-containing filter is used because it is necessary, the procedures shall also utilize an additional non-asbestos-containing or non-fiber-releasing filter such as a membrane filter to reduce asbestos fiber content to the minimum level feasible unless such a subsequent filter will compromise the safety, identity, strength, quality, or purity of the product.

Comments received in response to this part of the notice, dealing with the issues as follows:

1. A number of comments stated that there is no conclusive evidence that asbestos filters add fibers to the filtrate, or that asbestos has caused deleterious effects as a result of parenterally administered drugs.

Asbestos fibers were found in a number of samples of parenteral drugs by Nicholson et al. (Ref. 10) and also by a subsequent Food and Drug Administration investigation of parenterals. Although the Food and Drug Administration has demonstrated that filtration through asbestos of a water sample highly contaminated with asbestos fibers can significantly reduce the number of fibers present, the Food and Drug Administration also has direct evidence that the utilization of asbestos filters can cause asbestos contamination. The preliminary report of the latter study is on public display in the office of the Hearing Clerk. The evidence of the deleterious effects of parenteral asbestos administration (Ref. 1, 11, 12, and 13) requires that the amount of contamination in these products be minimized. Consequently, the Commissioner has determined that it is important that asbestos-containing filters be replaced with non-fiber-releasing filters unless it is demonstrated that it is not possible to manufacture a safe and effective parenteral drug or parenteral drug ingredient without the use of such an asbestos-containing filter. In the latter instance, a final non-fiber-releasing filter shall be used to reduce the content of any asbestos-form particles in the drug or drug ingredient. Use of an asbestos-containing filter with subsequent use of an additional non-asbestos-containing, non-fiber-releasing filter shall be permissible only upon submission of evidence to the appropriate bureau of the Food and Drug Administration that substitution for the asbestos filter of a non-fiber-releasing filter will or is likely to compromise the safety or effectiveness of the drug. Use of an asbestos-containing filter without subsequent use of an additional non-asbestos-containing, non-fiber-releasing filter shall be permissible only upon submission of evidence that neither the substitution for the asbestos-containing filter nor the use of a subsequent non-fiber-releasing filter can be accomplished without compromising the safety or effectiveness of the drug.

2. One comment noted that, although there have been several demonstrations of the addition of nonasbestos filters as final filters in the production of injectable biologics, there remains concern that the replacement of asbestos filters with non-asbestos-containing filters would upset delicate filtration parameters of the product preparation process. An 18-month period was suggested as the allowable period of time for technical development of the new processes.

The Commissioner agrees that a specific period for process development and modification should be provided in the regulations. Therefore, 18 months will be allowed for compliance. Firms not conforming to these regulations within 12 regulation will be required to submit monthly progress reports thereafter concerning attempts to implement the required procedures and any difficulties in maintenance of product quality.

3. A large number of comments stated that many parenteral products would suffer in safety and quality because of a requirement to replace asbestos-containing filters in the manufacturing process.

The Commissioner agrees that it is essential that there be no increase in risk to the public as a result of this action. The regulation provides for continued use of asbestos filters where no alternative is feasible. The responsibility for demonstrating that the replacement of asbestos filters or the utilization of a final non-fiber-releasing, non-asbestos-containing filter decreases product quality and effectiveness of safety remains that of the manufacturer. Evidence for such product alteration must be submitted to the appropriate bureau of the Food and Drug Administration for approval of the continued use of the unmodified asbestos filtration processes.

4. One comment objected to the utilization of the terms "membrane filter" and "non-fiber-releasing filter," stating that the former term was too limiting as a recommendation for a replacement of filters which may release asbestos fibers and that the latter phrase should be changed to "asbestos-containing or media-migration-exhibiting filter." This comment claimed that the term "non-fiber-releasing" should be replaced since small quantities of the fibrous support used in many cellulose-ester membrane filters, as well as fibers and particles from the manufacturing process for cartridge and other type filters, are released by cleaning and flushing prior to marketing of the product. Another comment stated that the proposed regulations did not contain a definition of a non-fiber-releasing filter. Comments also stated that § 133.8 should not use the terms "fiber-releasing" and "asbestos-containing" interchangeably, and one comment objected to the synonomous use of the terms "fiber" and "asbestos fiber."

The Commissioner agrees that the regulation should not specify only one type of filter which would satisfy the new requirements, and thus has deleted the term "membrane filter." The Commissioner also concludes that, for the purposes of these regulations, a non-fiber-releasing filter shall be defined as a nonasbestos, nonglass fiber filter which, after any appropriate pretreatment such as washing or flushing, will not continue to release fibers into the drug or drug ingredient which is to be filtered. The distinction is, therefore, made between filters which release fibers by media migration, i.e., continuous release due to the nature of the filter, and filters which contain fibers from structural supports and contamination. The utilization of nonasbestos, nonglass fiber filters in the latter category will be permitted provided that appropriate pretreatment,

Union Carbide trial exhibit UC-1354: H. B. Rhodes to Peter Zschunke (Grace GmbH) on FDA Asbestos Filter Rule…
Published by AsbestosClaims.Law
ACL Doc 16493 · Page 16 of 28
asbestosclaims.law/library/16493/16

which eliminates fiber contaminant release, has been accomplished. As the similarity between the carcinogenicities of asbestos and fibrous glass has been noted, fibrous glass filters have been added to this definition to prevent the widespread conversion from asbestos to this type of filter (Ref. 14 and 15). A fiber is defined as "any particle with length at least three times greater than its width" (Ref. 15 and 16).

The Commissioner realizes that the definition of a fiber-releasing filter excludes the possibility of the use of an asbestos or fibrous glass filter locked into a matrix which precludes the release of fibers. However, no such technology was presented as feasible by any of the comments. Therefore, the Commissioner concludes that the definition of a fiber-releasing filter is appropriate for this regulation and that, should a method for production of such a non-fiber-releasing asbestos or glass containing filter become available, the definition will be subject to review.

5. One comment suggested that the proposed requirement that "no asbestos-containing filter may be used unless it is not possible to manufacture a drug without the use of such a filter" be replaced by "when an asbestos-containing filter is utilized, a suitable after-filter must also be utilized to retain fibers."

The Commissioner concludes that such a change would be unacceptable since the purpose of these regulations is to minimize the amount of asbestos or asbestos-form fibers in parenteral drugs thereby minimizing the possibility of deleterious effects, and although an after-filter will substantially reduce the number of these fibers in the product, it cannot be assumed that it will remove all of this material. Hence, the Commissioner has determined that the best means to eliminate asbestos contamination from parenteral drugs is by removal of the asbestos filters from the process whenever possible. As stated in paragraph B.3. of this preamble, the Commissioner agrees that there must be no increase in risk to the public from any product the manufacturing process of which is required to be changed. However, he reiterates that the use of an asbestos filter will be permissible only upon a demonstration by the manufacturer that the replacement of an asbestos filter by a non-fiber-releasing filter or the utilization of a final or after-filter is non-fiber-releasing adversely affects the quality, safety, and effectiveness of the product.

6. One comment objected to the statement in the proposal that the use of asbestos filters in parenteral drug manufacturing is prohibited "unless it is not possible to manufacture that drug or drug ingredient without the use of such a filter," claiming that the lack of a more specific statement will lead to capricious regulatory decisions.

The Commissioner concludes that there is no more reasonable method by which to make a determination of the impossibility of achieving the desired product quality and effectiveness without the use of asbestos-containing filters than by individual evaluation by knowledgeable scientists. No automatic decision scheme was suggested in the comment. Therefore, the responsibility for submission of the evidence required for this determination will rest with the manufacturer and the responsibility for accepting or rejecting the request for use of asbestos-containing filters will rest with the appropriate bureau in the Food and Drug Administration.

7. Two comments objected to the fact that the regulations were limited to the release of asbestos and asbestos-form fibers and suggested that all extraneous material such as diatomaceous earth, carbon, silica, micro-fiberglass, etc., also be regulated.

The Commissioner agrees that there is reason to be concerned about all particulate contamination in parenteral drugs, but concludes that this problem should be considered separately from the subject regulations. Therefore, except for fibrous particulates, the Commissioner has decided to await clarification of the degree of other types of contamination and the possible health effects of such other particulates prior to developing applicable regulations. A call for scientific information in this regard will be published in the FEDERAL REGISTER in the future.

8. One comment objected to the requirement of proof of reduction of asbestos fibers by the use of subsequent non-asbestos-containing filters in the manufacture of a parenteral drug or drug ingredient when submitting a request for approval of a process in which asbestos filters are used. This and one other comment claimed that the National Institute for Occupational Safety and Health (NIOSH) analytical method, as well as other analytical methods for determination of asbestos-form fibers in parenteral drugs, is inadequate quantitatively to demonstrate reduction and is immensely difficult to perform.

The Food and Drug Administration and other government agencies are presently attempting to develop reproducible, practical and useful methodologies for these analyses, and amendments to these regulations will be promulgated upon the satisfactory completion of this research. The Commissioner has decided that until these studies are completed, the evidence for reduction of asbestos-form fiber content need not be obtained if adequate downstream filtration is accomplished. Thus, the requirement of proof of reduction of asbestos fiber content is omitted and the use of a non-fiber-releasing filter of 0.22 micron maximum pore size is added to this regulation (0.45 micron maximum, if the manufacturing conditions so dictate).

9. One comment claimed that it is inappropriate to control all types of asbestos filters uniformly, as asbestos filters are composed primarily of chrysotile which is less hazardous to human health than amphiboles.

The Commissioner concludes that this differential in hazard has not been established for parenterally administered asbestos. Studies by Reeves et al. (Ref. 17) have demonstrated mesotheliomas in rats and rabbits from pleural and peritoneal injections of both chrysotile and crocidolite fibers. Further studies have been initiated by the Food and Drug Administration on the effects of parenteral injections of chrysotile fibers in experimental animals.

10. One comment indicated that, in the study of parenteral administration of asbestos to animals by Schmahl (Ref. 11), the tumors that occurred were not related to asbestos since they were sarcomas rather than mesotheliomas.

Although mesotheliomas are closely related to inhalation of asbestos, there also has been an association of carcinoma of the lung with asbestos inhalation. As with other carcinogens, several types of tumors may occur as a result of exposure to a particular carcinogen depending upon the route of exposure. The Commissioner therefore concludes that the data in this reference are valid and may possibly implicate asbestos in the development of these malignant tumors of soft tissues, namely, sarcomas.

11. One commenter presented data demonstrating that membrane filtration was capable of removal of all asbestos particles from his asbestos-filtered product (beer) as measured by electron microscopy. However, even though the container for this product was subjected to a final rinse by municipal water, the packaged product contained a significant number of asbestos fibers. Similarly, the Food and Drug Administration has found asbestos particles in parenteral drugs produced by manufacturers who do not use asbestos filters in their processes.

These indications of substantial contamination of the product from typical liquid containers have led the Commissioner to conclude that cleansing and rinse water for the containers for parenteral drugs shall be filtered through non-fiber-releasing filters equivalent to those required for post-asbestos-filter filtration to remove inherent fiber contamination.

12. The Environmental Impact Analysis Report (ELAR) and other relevant materials have been reviewed and it has been determined that the proposed use will not have a significant environmental impact. Copies of the ELAR are available in the office of the Assistant Commissioner for Public Affairs, Rm. 15B-42, or the office of the Hearing Clerk, Rm. 4-65, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

The indications to references set forth in the preamble are to the following, which are on display in the office of the Hearing Clerk:

1. "Parenteral Preparations, Pyrogens," in Remington's Pharmaceutical Sciences, 14th ed., Chapter 82, p. 1542, 1970.

2. Mason, T. J., F. W. McKay and R. W. Miller, "Asbestos-Like Fibers in Duluth Water Supply: Relation to Cancer Mortality," "Journal of the American Medical Association," 228:1029, May 20, 1974.

3. Comment from Asbestos Research Council, March 1, 1974.

4. Cunningham, H. M. and R. Pontefract:

(a) "Asbestos Fibers in Beverages and Drinking Water," "Nature" 232:332-333, 1971.

Union Carbide trial exhibit UC-1354: H. B. Rhodes to Peter Zschunke (Grace GmbH) on FDA Asbestos Filter Rule... Published by AsbestosClaims.Law
ACL Doc 16493 · Page 17 of 28 asbestosclaims.law/library/16493/17

(b) "Symposium on Industrial Chemicals & Food Contaminants," "Journal of the Association of Official Analytical Chemists," 56:976–981, 1973.

5. Pontefract, R., and H. M. Cunningham, "Penetration of Asbestos through the Digestive Tract of Rats," "Nature," 243:352–353, 1973.

6. Davis, J. M. G., Institute of Occupational Medicine Edinburgh, Scotland, unpublished report.

7. Bonser, G. M., and D. B. Clayton, "Feeding of Blue Asbestos to Rats," 1967 Annual Report, British Empire Cancer Campaign for Research, p. 242.

8. "Report of the Advisory Committee on Asbestos Cancers to the Director of the International Agency for Research on Cancer," "British Journal of Industrial Medicine," 30:180–185, 1973.

9. Kleinfeld, M., J. Messite, and M. H. Zaki, "Mortality Experiences Among Talc Workers: A Follow-up Study," "Journal of Occupational Medicine," 16:345–349, 1974.

10. Nicholson, W. H., C. J. Maggiare and I. J. Selikoff, "Asbestos Contamination of Parenteral Drugs," "Science," 177:171–173, 1972.

11. Schmahl, D., "Carcerogene Wirking von Asbest bei Implantation von Ratten," "Zeitschrift fur Krebsforschung," 62:561–567, 1958.

12. Roe, F. H. C., R. L. Carter, M. A. Walters and J. S. Harrington, "The Pathological effects of Subcutaneous Injections of Asbestos Fibers in Mice: Migration of Fibers to Submesothelial Tissues and Induction of Mesotheliomas," "International Journal of Cancer," 2:628–633, 1967.

13. Kanazawa, K., M. S. C. Birbeck, R. L. Carter and F. J. C. Roe, "Migration of Asbestos Fibers from Subcutaneous Injection Sites in Mice," "British Journal of Cancer," 24:96–106, 1970.

14. "Symposium on Occupational Exposure to Fibrous Glass," sponsored by National Institute for Occupational Safety and Health, University of Maryland, June 26–27, 1974.

15. Stanton, Mearl F., "Fiber Carcinogenesis: Is Asbestos the Only Hazard?" "Journal of the National Cancer Institute," 52:633 (1974).

16. "Occupational Exposure to Asbestos," Criteria document, U.S. Public Health Service, National Institute for Occupational Safety and Health, Chapter VIII, pg. 6, 1972.

17. Reeves, A. J., H. E. Puro, R. G. Smith and A. J. Vorwald, "Experimental Asbestos Carcinogenesis," "Environmental Research," 4:495–511, 1971.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 501, 502, 701, 52 Stat. 1049–1051, 1055–1056, as amended; 21 U.S.C. 351, 352, 371) and under the authority delegated to the Commissioner (21 CFR 2.120), Part 133 is amended as follows:

1. By amending § 133.8 by adding new paragraph (j), to read as follows:

§ 133.8 Production and control procedures.

* * * * *

(j) Use of asbestos-containing or other fiber-releasing filters: (1) Filters used in the manufacture, processing or packaging of components of drug products for parenteral injection in humans shall not release fibers into such products. No asbestos-containing or other fiber-releasing filter may be used in the manufacture, processing or packaging of such products unless it is not possible to manufacture that drug product or component without the use of such a filter. Filtration, as needed, shall be through a non-fiber-releasing filter. For the purposes of this regulation a non-fiber-releasing filter is defined as a nonasbestos, nonglass fiber filter which, after any appropriate pretreatment such as washing or flushing, will not continue to release fibers into the drug product or component which is being filtered. A fiber is defined as any particle with length at least three times greater than its width.

(2) If use of a fiber-releasing filter is required, an additional non-fiber-releasing filter of maximum pore size of 0.22 microns (0.45 microns if the manufacturing conditions so dictate) shall subsequently be used to reduce the content of any asbestos-form particles in the drug product or component. Use of an asbestos-containing filter with or without subsequent use of a specific non-fiber-releasing filter is permissible only upon submission of proof to the appropriate bureau of the Food and Drug Administration that use of a non-fiber-releasing filter will, or is likely to, compromise the safety or effectiveness of the drug.

(3) Substitution for a fiber-releasing filter shall be achieved on or before September 14, 1976. If such substitution is not achieved on or before March 14, 1976, the manufacturer of the drug product for parenteral injection who requires the additional 6 months to develop new manufacturing procedures so as to utilize non-fiber-releasing filters in place of fiber-releasing filters shall submit monthly reports to the appropriate bureau of the Food and Drug Administration indicating progress in substituting the new filters. Such a substitution shall be shown to have been effected without loss of the safety or effectiveness of the drug.

2. By revising § 133.9 to read as follows:

§ 133.9 Product containers and their components.

Suitable specifications, test methods, cleaning procedures, and when indicated, sterilization procedures shall be used to assure that containers, closures, and other component parts of drug packages are suitable for their intended use. Containers for parenteral drugs, drug products or drug components shall be cleansed with water which has been filtered through a non-fiber-releasing filter equivalent to that indicated in § 133.8(j)(2). Product containers and their components shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug or its components beyond the official or established requirements and shall provide adequate protection against external factors that can cause deterioration or contamination of the drug.

Effective date. This order shall be effective April 14, 1975.

(Secs. 501, 502, 701, 52 Stat. 1049–1051, 1055–1056, as amended; (21 U.S.C. 351, 352, 371))

Dated: February 28, 1975.

A. M. Schmidt,
Commissioner of Food and Drugs.

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ACL Doc 16493 · Page 18 of 28 asbestosclaims.law/library/16493/18

CHRYSOTILE ASBESTOS IN PLASTICS

John L. Myers

"CALIDRIA" ASBESTOS

UNION CARBIDE CORPORATION
MINING AND METALS DIVISION
NIAGARA FALLS, NEW YORK

Presented on May 14, 1974 at the 32nd Annual Technical Conference of the Society of Plastics Engineers in San Francisco.

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INTRODUCTION

Asbestos has received a great deal of attention and publicity in recent years, especially after it was designated a "target health hazard" by OSHA and a "hazardous air pollutant" by the EPA. Many of the articles on asbestos by the press have been emotionally oriented or distorted and in some cases stories have been sensationalized, based on obvious misinterpretation of facts. The use of half-truths or unsubstantiated statements has led to general confusion and the unfair castigation of asbestos and products containing asbestos. The purpose of this paper is to put the matter of asbestos use and asbestos hazards in a logical and practical perspective. In this paper the different types of asbestos and their many uses are discussed along with government regulations controlling the use of asbestos. The health hazards associated with asbestos, both occupational and environmental, and some industrial experience with air sampling and dust control measures are also covered.

WHAT IS ASBESTOS?

Asbestos is a commerical or generic term used to describe six naturally-occurring "asbestiform" minerals that are fibrous, hydrated metal silicates. The six varieties are divided into two classes, serpentine and amphibole, based on their crystal structure. Chrysotile is the only member of the serpentine class while the amphiboles include crocidolite, amosite, anthophyllite, tremolite and actinolite. Chrysotile is by far the most used variety and accounts for over 95% of U.S. consumption, as noted in Table I.

Crocidolite, also known as blue asbestos, is imported from South Africa. Because of its high mechanical strength and good resistance to acids and alkalis, it is used to reinforce a limited variety of plastics where its pronounced color is not objectionable. Amosite, also imported from South Africa, is used primarily in thermal insulation. Although there are some deposits of anthophyllite in the U.S., most of it is imported from Finland. It is used primarily as a filler for polypropylene and in insulating materials. A comparison of the four varieties of asbestos which are of commercial importance is presented in Table II. It should be noted that there are significant differences between chrysotile and the amphiboles with regard to chemical composition and certain physical properties.

WHERE IS ASBESTOS USED AND WHY?

Asbestos has served mankind for over 100 years in a broad variety of applications. The general areas in which asbestos is used in the United States are shown in Table III. Based on information from asbestos producers and consumption surveys, it is estimated that the plastics industry uses about 1/3 of the 800,000 tons consumed annually, which makes it the largest single user of asbestos fiber.

The largest uses of asbestos by the plastics industry are in vinyl/asbestos floor tile and in phenolic molding compounds. It is also used in other plastics such as polypropylene, polyester, nylon, melamine, epoxy, silicones and vinyls. Asbestos provides

According to the 33-member Advisory Committee on Asbestos Cancers of the International Agency for Research on Cancer (a division of the World Health Organization):

> "There is evidence of an association of mesothelial tumours with air pollution in the neighbourhood of crocidolite mines and of factories using mixtures of asbestos fibre types. The evidence relates to conditions many years ago. There is evidence of no excess risk of mesotheliomas from asbestos air pollution which has existed in the neighbourhood of chrysotile and amosite mines. There are reported differences on incidence of mesothelioma between urban and rural areas, the causes of which have not been established. There is no evidence of a risk to the general public at present." (5)

The same body quoted above has also concluded that there is at present no evidence of lung damage by asbestos to the general public; and such evidence as there is does not indicate any risk of cancer resulting from asbestos fibers present in water, beverages, food or in the fluids used for the administration of drugs.

While there seems to be general agreement that the public is not in any present danger from asbestos, it is also recognized that excessive, long-term occupational exposure can cause serious health problems. Also, if man-made emissions are not controlled, then environmental contamination could approach harmful levels. During the past two years, significant legislation has been enacted by the Federal Government to reduce and control occupational exposure to asbestos fibers and to minimize fiber emissions to the environment. Additional standards or regulations have been proposed or enacted by many state and local governments.

SUMMARY OF OSHA REGULATIONS

The Williams-Steiger Occupational Safety and Health Act of 1970 became effective on April 28, 1971, with the following Congressional purpose: "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." The Act established the Occupational Safety and Health Administration (OSHA) within the Department of Labor, which has responsibility for administration and enforcement. Research and related functions are handled by the Department of Health, Education and Welfare (HEW) through the National Institute of Occupational Safety and Health (NIOSH). Five million employers and 60 million of the nation's 80 million workers are covered by OSHA. Specifically excluded from coverage are government employees and operations which are protected under other Federal health and safety laws. In a news release issued January 4, 1972, OSHA announced a Target Health Hazards Program aimed at improving health factors associated with working conditions. The following five substances were designated to be the focus of initial and concerted efforts by OSHA and NIOSH: Asbestos, Cotton Dust, Silica, Lead and Carbon Monoxide.

At the present time new standards have been established only for asbestos; although, of the 8,000 toxic substances on the

exposed. On March 31, 1971, asbestos, along with beryllium and mercury, was identified as a "hazardous air pollutant" by the Administrator of the EPA. National Emission Standards for asbestos were then published by the EPA in the Federal Register, Vol. 38, No. 66 - Friday, April 6, 1973. Although no numerical emission standards were established, operating criteria are prescribed to prevent or limit asbestos emissions to the outside air from asbestos mills, roadways, certain manufacturing operations, building demolition, and the spray-on application of materials used to insulate or fireproof equipment and machinery. The law further requires that spray-on materials used to insulate or fireproof buildings, structures, pipes, and conduits shall contain less than 1% asbestos on a dry weight basis. This should significantly reduce emissions to which the general public may be exposed, especially in large urban areas.

"...the Administrator (of the EPA) has determined that, in order to provide an ample margin of safety to protect the public health from asbestos, it is necessary to control emissions from major man-made sources of asbestos emissions into the atmosphere, but that it is not necessary to prohibit all emissions.

In this determination, the Administrator has relied on the National Academy of Sciences' report on asbestos, which concludes: 'Asbestos is too important in our technology and economy for its essential use to be stopped. But, because of the known serious effects of uncontrolled inhalation of asbestos minerals in industry and uncertainty as to the shape and character of the dose-response curve in man, it would be highly imprudent to permit additional contamination of the public environment with asbestos. Continued use at minimal risk to the public requires that the major sources of man-made asbestos emission into the atmosphere be defined and controlled.'" (7)

WHAT IS INDUSTRY DOING?

The Asbestos Information Association/North America reports that, during the past 30 years, the asbestos industry has spent millions of dollars to improve mining, milling, and manufacturing methods (8). The establishment of safer working conditions has been a prime target and this work continues unabated and in close association with government agencies and independent medical researchers (9). The ultimate goals of the asbestos industry are:

- Reduction of work-area dust to minimum levels.
- Protection of workers from asbestos-related diseases.
- Maintenance of environmental emissions at levels low enough to preclude public endangerment.

AIR SAMPLING

In order to comply with OSHA Standards and to determine the need for dust control measures, air monitoring should be conducted in areas where asbestos is regularly handled or used. OSHA Standards require that "all determinations of airborne concentrations of asbestos fibers shall be made by the membrane filter method at 400-450X (magnification) (4 millimeter objective) with phase contrast illumination." (10) The equipment for collecting air samples costs less than $400 and is readily available. A phase

this product serves a fair portion of the asbestos market. Pellets not only reduce dust during conventional handling but they are also available in bulk hopper cars and can be transferred and used in totally enclosed systems. Barring leaks in the system, dust in work areas is virtually eliminated. Used in bulk, asbestos pellets also reduce shipping costs, eliminate warehouse storage and handling, facilitate automation, reduce clean-up, and eliminate bag handling and disposal. The pellets contain no binder and are friable enough to be dispersed in dry form or in aqueous or resinous systems with conventional high-shear grinding equipment (13).

Several types of special packaging are currently available and suppliers consider customer requests for unusual requirements. The floor tile industry can obtain asbestos in plastic bags which can be added directly to the compounding operation. Asbestos in bleached paper bags assembled with water-soluble glue and printed with water-dispersible ink can be added directly to paper-making furnishes or acoustical ceiling tile formulations. Water-proof bags are available to permit slurrying of the asbestos in the bag. Wider use of shrink-filming is being offered to reduce dust during bag handling, transportation and storage.

Although "wetted" asbestos is not generally available, most suppliers are working with customers to provide "dustless" products. When justified by market demand, asbestos can be treated with water, mineral spirits, glycol or other materials compatible with the application or system.

CONCLUSION

Asbestos is one of industry's many raw materials which involves a potential hazard when not used with reasonable respect and care. Although all forms of asbestos are recognized as hazardous to health when inhaled excessively, there is growing evidence that crocidolite and amosite are more hazardous than chrysotile. Fortunately the plastics industry uses primarily chrysotile asbestos and in most products the fibers are locked-in to prevent airborne contamination. Although asbestos dust levels are generally lower than expected, industry continues to expend large amounts of time and money to further improve the quality of the workplace. Although the general public is not currently in danger, occupational controls are required to prevent future environmental contamination.

Chrysotile asbestos is an important and necessary raw material, vital to the nation's safety and economy; and, with proper control, it can be used safely and in compliance with government regulations. Medical, scientific, government, and industrial personnel must continue to work closely together to establish reasonable exposure limits, provide safe work areas, and eliminate any possibility of public endangerment.

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ACL Doc 16493 · Page 23 of 28 asbestosclaims.law/library/16493/23

TABLE I

APPARENT U.S. CONSUMPTION OF ASBESTOS, TONS*

(% of Total Shown in Parentheses)

Year	Total	Chrysotile	Amosite	Crocidolite
1967	720583	686044(95)	12558(1.7)	14917(2.1)
1968	817363	775711(95)	20467(2.5)	13965(1.7)
1969	784321	749708(96)	14618(1.9)	10558(1.3)
1970	728131	695770(96)	14261(2.0)	8936(1.2)
1971	758571	729272(96)	14580(1.9)	6953(0.9)
1972	808554	791020(98)	7125(0.9)	5374(0.7)

*Information based on import and production data from United States Bureau of Mines Minerals Yearbooks.

TABLE II

COMPARATIVE DATA FOR ASBESTOS MINERALS

	CHRYSOTILE	CROCIDOLITE	AMOSITE	ANTHOPHYLLITE
FORMULA	$3MgO \cdot 2SiO_2 \cdot 2H_2O$	$Na_2O \cdot Fe_2O_3 \cdot 3FeO \cdot 8SiO_2 \cdot H_2O$	$1.5MgO \cdot 5.5FeO \cdot 8SiO_2 \cdot H_2O$	$7MgO \cdot 8SiO_2 \cdot H_2O$
COMPOSITION,%				
SiO_2	37-44	49-53	49-53	56-58
MgO	39-44	0-3	1-7	28-34
FeO	0-6	13-20	34-44	3-12
Fe_2O_3	0-5	17-20	-	-
Al_2O_3	0-2	-	2-9	0-2
H_2O	12-15	2-5	2-5	1-6
CaO	0-5	-	-	-
Na_2O	-	4-8	-	-
$CaO+Na_2O$	-	-	0-3	-
CRYSTALS	Fine Fibers	Brittle Fibers	Prismatic Crystals	Prismatic Crystals
COLOR	Gray/Green	Blue	Gray/Brown	Gray
TEXTURE	Soft/Silky	Harsh	Harsh	Harsh
FLEXIBILITY	Very Good	Good	Good	Poor
HARDNESS, Mohs	2.5-4	4	5.5-6	5.5-6
FIBER DIA., Å	180-300	600-900	600-900	600-900
TENSILE, Mpsi	800	600	200	<4
SURFACE CHG.	Positive	Negative	Negative	Negative
RES. TO ACID	Poor	Good	Good	Very Good
RES. TO ALK.	Good	Good	Fair	Good

Source: Modern Plastics Encyclopedia(1972-3), and Encyclopedia of Chemical Technology, Volume 2, p. 136(1948).

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ACL Doc 16493 · Page 25 of 28
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ACL Doc 16493 · Page 26 of 28
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ACL Doc 16493 · Page 28 of 28
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