the enforcement procedures otherwise provided, he shall inform the affected employees and official in charge of the establishment of the danger and require immediate abatement, including withdrawal of employees from the dangerous circumstances.

§ 1960.26 Notices of hazards.

(a) Each agency will establish a procedure for issuing notices of hazards discovered upon inspection. Notices will describe with particularity the nature of the hazard, including a reference to the standard or other requirement involved. The notice will also fix a reasonable time for the abatement of the hazard. A copy of the notice will be sent to the official in charge of the establishment.

(b) If a notice of hazard is issued as a result of a request for inspection under § 1960.24(a) or a notification of hazard under § 1960.24(c), a copy of the notice of hazard will also be sent to the employee or representative of employees who made such request or notification.

(c) Upon receipt of any notice of hazard, the official in charge of an establishment will immediately post such notice, or a copy thereof, unedited, at or near each place a hazard referred to in the notice occurred, except as provided below. Where, because of the nature of the establishment operations, it is not practicable to post the notice at or near each place of hazard, such notice will be posted, unedited, in a prominent place where it will be readily observable by all affected employees. For example, where establishment activities are physically dispersed, the notice may be posted at the location to which employees report each day. Where employees do not primarily work at or report to a single location, the notice may be posted at the location from which the employees operate to carry out their activities. The official in charge of an establishment will take steps to ensure that the notice is not altered, defaced, or covered by other material.

(d) Each notice of hazard, or a copy thereof, will remain posted until the hazard has been abated, or for 3 working days, whichever is later.

§ 1960.27 Correction of hazards.

(a) The procedures for correcting hazards will include reinspection by the office of the designated safety and health official to determine whether the correction was made. If upon reinspection the correction was not made, the designated safety and health official shall make this fact known to the head of the agency for appropriate action.

(b) If in the judgment of the designated safety and health official abatement of a safety or health hazard will not be possible within 30 working days, the official in charge of the establishment will submit an abatement plan to the designated safety and health official with a copy thereof to the head of the agency and to the Secretary of Labor. Such plan will contain an explanation of the circumstances of the delay in abatement, a proposed timetable for the abatement, and a summary of steps being taken in the interim to protect employees from being injured by the hazard. A copy of the plan will be sent to the safety and health committee of the agency for appropriate comment. The head of each agency will inform the Secretary of Labor at regular intervals to be determined by the Secretary as to the progress made in carrying out the abatement plan. Any changes in the abatement plan will require the submission of a new plan in accordance with the provisions of this section.

Subpart E—Federal Agency Internal Evaluation

§ 1960.28 Duties of Federal agencies.

Each agency shall conduct an annual detailed internal evaluation of its occupational safety and health program. Basic guidelines for this evaluation will be issued periodically by the Office of Federal Agency Safety Programs. These internal evaluations shall be utilized by each agency for the purposes set forth in the applicable statutes and Executive Order No. 11612, as described in § 1960.1, and shall be maintained and made available by each agency for review by the Office of Federal Agency Safety Programs.

Signed at Washington, D.C., this 24th day of September 1973.

JOHN H. STENDER,
Assistant Secretary of Labor.

[FR Doc.73-20707 Filed 9-27-73;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 121, 128, 133]

ASBESTOS PARTICLES IN FOOD AND DRUGS

Notice of Proposed Rulemaking

The Commissioner of Food and Drugs has received a petition from the Center for Science in the Public Interest, 1779 Church Street NW., Washington, D.C. 20036, and the Environmental Defense Fund, 1525 18th Street NW., Washington, D.C. 20036, requesting promulgation of regulations under the Federal Food, Drug, and Cosmetic Act to prohibit the adulteration of food and drugs with asbestos. Petitioners request that the Commissioner publish in the FEDERAL REGISTER "immediately (within 30 days)" the following proposed regulations:

1. Subpart F of Part 121 is amended by adding the following section:

§ 121.___ Filters containing asbestos.

"Foods that have come into contact with filters made wholly or partially of asbestos may reasonably be expected to become contaminated with asbestos particles which may be injurious to health when ingested. Accordingly, any food or food additive produced, manufactured, processed or prepared using a filter made wholly or partially of asbestos shall be deemed to be adulterated in violation of section 402(a) of the Act.

2. Part 133 is amended by adding the following sections:

§ 133.___ Filters containing asbestos.

Drugs passed through filters made wholly or partially of asbestos may reasonably be expected to become contaminated with asbestos particles which may be injurious to health when injected or ingested. Accordingly, any drug or drug component produced, manufactured, processed or prepared using a filter made wholly or partially of asbestos shall be deemed to be adulterated in violation of section 401(a) of the Act.

§ 133.___ Talc containing asbestos.

Talc is a naturally occurring hydrous magnesium silicate which may reasonably be expected to be contaminated with asbestos particles. Asbestos particles may be injurious to health when ingested or injected. Accordingly, it is not considered good manufacturing practice to add talc, directly or indirectly, as a component in the production, manufacture, processing or preparation of any drug, unless the manufacturer or processor of the drug first demonstrates by appropriate tests that the talc so used is free of asbestos particles. Any drug or drug component containing talc which has not been demonstrated to be free of asbestos particles shall be deemed to be adulterated in violation of section 501(a) of the Act.

Petitioners also request that the Commissioner "immediately (within 30 days from the receipt of this petition)" promulgate as a final regulation a zero tolerance for asbestos particles in talc intended for use as a food additive, pursuant to the proposal published in the FEDERAL REGISTER of August 12, 1972 (37 FR 16407), and take whatever other action the Commissioner deems necessary to eliminate contamination of food and drugs with asbestos.

A complete copy of the petition and its attachments may be reviewed at the office of the Hearing Clerk, Food and Drug Administration, Rm. 6-86, 5600 Fishers Lane, Rockville, MD 20852, during working hours, Monday through Friday.

The Commissioner has carefully reviewed the petition, its attachments, and other available information, and has reached the following conclusions. Each conclusion indicates the source reference upon which the conclusion is based and copies of all referenced material are available from the office of the Hearing Clerk.

"Asbestos" is a generic term for a number of hydrated silicates that, when crushed or processed, separate into flexible fibers made up of fibrils. Although there are many asbestos minerals, only six are of commercial importance. Chrysotile, a tubular serpentine mineral, accounts for 95 percent of the world's production. The others, all amphiboles (crystals with 3 groups of metal ions), are amosite, crocidolite, anthophyllite, tremolite and actinolite. These asbestos minerals differ in their metallic elemental content, range of fiber diameters, flexibility, harshness, tensile strength, surface properties, and other attributes that determine their industrial uses and which may affect their respirability, deposition, retention, translocation and biologic reactivity (Ref. 1).

Many products such as cement, flooring, shingles, pipes, filters, textiles, etc., contain asbestos of one kind or another.

There are great variations among such products with respect to the chances of fiber release during the use of the product. The likelihood of such fiber release depends predominantly on the ease with which the fibers can be dislodged and on the degree to which the use of the product destroys the fibers. Almost all asbestos fiber used in the United States for manufacturing products becomes tightly bound within the products and usually undergoes little actual abrasion or wear before being discarded. Asbestos cement products (accounting for most of the asbestos used in the United States), shingles and floor tiles are in this category. Some asbestos-containing products, such as brake linings, are subjected to great friction; their rate of wear is considerable, and at times they are almost completely worn away. In the case of brake linings, the application of force is so intense and the heat created so great that most chrysotile fibers are destroyed by being converted into another substance which is non-fibrous. Nevertheless, an appreciable percentage (1 to 3 percent) remains as fibrous asbestos, and fiber release from products such as asbestos cloth, paper and sprayed fireproofing materials is a serious source of emission. This usually occurs in densely populated areas. Most of the pipes delivering drinking water are of a mixture of cement and asbestos.

Solid wastes produced during manufacture of asbestos-containing products, use of such products, and demolition can be emission sources. These waste materials are usually disposed of without regard to their potential as emission sources. Alternate methods of disposal often result in commingling of asbestos-containing wastes with municipal wastes in open dumps and thus create a long-term emission source.

Asbestos fibers thus are ubiquitous in air, water and a large percentage of the earth's crust. The amount of this material which additionally is added to the environment and to food and drugs by the use of asbestos filters is not known. Therefore it is obvious that the presence of asbestos in these products is only one small source of exposure.

Asbestos inhalation has been known to be an occupational hazard in workers in asbestos mines. The asbestos is inhaled and lodges in the lungs causing the development of a fibrotic disease known as "asbestosis." Asbestosis, or abestotic pneumonoconiosis, was the first clearly demonstrated adverse effect of asbestos in man. It is characterized by a pattern of roentgenographic changes in the lung consistent with diffuse interstitial fibrosis of variable degree and at times with fibrosis and calcification of the pleura; clinical changes that include fine rales, finger clubbing and shortness of breath, each of which may be absent in an individual case; and physiologic changes consistent with a restrictive lung disorder (Refs. 2 through 8).

In these workers in asbestos mines, malignancies of the lung and of the body lining tissues, namely lung cancer and mesothelioma, occur at rates greater than in persons not so occupationally exposed. There is a 5 to 7 fold increase in lung cancer in asbestos workers which is noted as early as 10 to 14 years after onset of exposure and is significant at 20 years (Refs. 9 through 15). Seven percent of deaths in asbestos workers are caused by pleural and peritoneal mesothelioma (Refs. 16 through 33). This is a marked increase since this tumor is extremely rare in the general population. There is suggestive evidence concerning an increase in the rate of gastrointestinal malignancies in asbestos workers (Ref. 34).

There is considerable evidence that most human lungs harbor thousands or millions of asbestos fibers although most people do not have asbestosis (Refs. 35 through 37). This is due to the ubiquity of the substance. Some of these fibers are chrysotile asbestos, and amphiboles are probably present also. This number of fibers is relatively small in most persons not occupationally exposed to asbestos compared with the numbers found in the occupationally exposed. The systematic application of quantitative techniques, measuring both coated and uncoated fibers, is needed to define a gradient of accumulated fibers for correction with incidence of disease, on the one hand, and history of environmental exposure, on the other.

The methodology for quantification of asbestos fibers of varying sizes is such that the results obtained in one laboratory may vary substantially from those in another. An inter-agency governmental task force together with other scientists working in this field is currently attempting to develop standard technology which can be applied to the identification and qualification of asbestos fibers. The Environmental Protection Agency is currently investigating four separate techniques in order to establish the best method for identification, quantification, sizing and typing of asbestos particles and fibers. At present, the National Institute for Occupational Safety and Health (NIOSH) recommends, as a technique for sampling of air, a method based on counting fibers greater than 5 microns in length using phase contrast illumination at 430x magnification with a 4 millimeter objective (Refs. 38 and 39). This technique is currently recommended for liquid materials until more accurate and sensitive practical methods are developed. However, as indicated below, another method is proposed for analysis of asbestos fibers in a material such as talc.

The evidence concerning the possible hazard from ingestion of asbestos particles is contradictory and inconclusive:

In an unpublished study by L. M. Swinburn (Ref. 40), asbestos particles were fed once a week to SPF Wistar rats for 16 and 18 weeks. The material was administered in butter. Although the particles were of the size range known to produce tumors by other modes of administration, no tumorgenic effect was noted. With a single large dose, the fibers were totally cleared by the gastrointestinal tract in 48 hours and no asbestos was detected in the animal tissues at the end of 1 week. The gastroinstestinal tract of the rat seemed to provide an effective barrier to penetration.

In a published study by W. E. Smith, *et al.* (Ref .41), hamsters maintained on a diet of 1 percent chrysotile or amosite through life had no gastrointestinal tumors.

A report by Westlake, Spjut and Smith (Ref. 42) indicates that the rat colonic mucosa is penetrated by chrysotile after feeding a diet containing 5 percent asbestos for 3 months.

Cunningham and Pontefract (Ref. 43 and 44) injected chrysotile fibers (9.4 and 94 x 10^9) directly into stomachs of rats. Fibers were found in blood and other organs, 2-4 days after treatment. Control rats, although having no asbestos in blood, also had high levels of asbestos in tissues.

These workers found that, whereas the tap water in Ottawa (having a filter plant) contained about 2 million fibers per liter, the quality of fibers in soft drinks and alcoholic beverages purchased in the Ottawa area ranged from 1 to 12 million fibers per liter. Even with the technical problems of methodology, this seems to indicate that in some beverages the asbestos content may be about the same as in water, whereas, in others, it may be increased. Thus, it is reasonable to conclude that water and many other beverages for human consumption contain substantial amounts of asbestos fibers.

There is some evidence that asbestos filters may remove some asbestos material. In a preliminary experiment performed by the Food and Drug Administration, asbestos was added to distilled water and dispersed evenly by the action of an ultrasonic generator. Electron microscopy of this material clearly showed large numbers of asbestos fibers. This material was then filtered through an asbestos filter, and electron microscopic examination of the filtered material showed a reduction in the number of asbestos fibers.

Nicholson and his colleagues (Ref. 45) investigated a number of samples of parenteral drugs and found asbestos fibers. Based on their report a study was undertaken by the Food and Drug Administration concerning contamination of parenteral drugs with asbestos. Although the data are still preliminary, the following observations are pertinent. Parenteral drug samples were collected from a number of firms. Based on phase contrast microscopy, 11 of 13 samples had clear-cut evidence of the presence of asbestos, one sample was questionably positive, and one was negative. The number of fibers ranged from 2 to 27 in the positive specimens of variable sample size. Using electron microscopy, 12 of the 12 samples examined were positive. Quantitation is not yet complete.

In this survey, seven of 13 manufacturers of parenteral drugs do not use asbestos filters; four firms use such filters followed by final membrane type filters (one of these uses asbestos filters for its rinse water without final filtration of such water); and two firms use asbestos filters only for their rinse water, without final filtration.

The preliminary report of these studies is on display at the Office of the Hearing Clerk. Any other scientific data in this regard should be submitted to the Hearing Clerk.

Certain parenteral drugs, such as blood fractionation products, may be filtered several times through asbestos filters. Thus far, it is not known with certainty whether the more viscous products could be successfully processed through terminal membrane filters without compromising safety, identity, strength, quality or purity. The precise effect of asbestos pad filtration on removal of pyrogens (Ref. 46 and 47) is not completely known at the present time. Currently the Food and Drug Administration is surveying the industry for information concerning the use of asbestos filters. Results of this survey will be incorporated in the public record.

Although the major experimental studies of asbestos have involved inhalation of fibers so as to simulate occupational exposure, several studies have been performed to investigate the effect of parenteral inoculation of asbestos fibers. In 1958, Schmähl (Ref. 48) reported that implantation of asbestos fibers and crumbs in either the subcutaneous tissue or in the peritoneum lead to the development of malignant tumors (sarcomas) in 11 of 30 rats which survived longer than 15 months after such implantation. Roe and his colleagues (Ref. 49, 50, 51) have performed a number of studies in which asbestos fibers were injected subcutaneously (Ref. 49) into the flanks of mice. In the first experiments, crocidolite, amosite and chrysotile asbestos fibers were used and each animal was injected twice subcutaneously in both flanks with 10 milligrams of fibers in saline with an interval of five weeks between the injections. Seven of seventy-one mice which survived 40 weeks or more developed injection site tumors. In addition, one mouse developed a mesothelioma of the peritoneum underlying the injection site. The injection site sarcomas were produced by all three types of fibers. In addition, Roe *et al* (Ref. 49) showed that the asbestos fibers were widely disseminated from the local injection sites being deposited rather selectively on the serosal surfaces of the abdominal organs and the retroperitoneal structures as well as on the pericardium, diaphragm, pleura and adjacent parts of the lungs and heart. These serosal surfaces reacted vigorously to the presence of the asbestos fibers and in 10 of 71 mice, malignant mesotheliomas of the thorax and/or abdomen developed. In a later study (Ref. 51) Kanazawa *et al* showed that, after subcutaneous injection of asbestos fibers in mice, fibers could be found to have disseminated to regional and distant lymph nodes, spleen, kidneys and occasionally to brain tissue suggesting that some asbestos may enter the circulation.

Thus, there is experimental evidence that parenteral administration of asbestos fibers may lead to wide dissemination of such fibers in animals and to the development of local malignant tumors as well as malignant mesotheliomas of the pleura and peritoneum similar to those that occur after inhalation of asbestos fibers.

The problem of asbestos in the total environment, to which the worldwide scientific community is addressing itself, is very complex. The Environmental Protection Agency has published in the FEDERAL REGISTER of April 6, 1973 (38 FR 8820) national emission standards for asbestos milling and manufacturing based on the determination that asbestos is a hazardous air pollutant. This standard has been developed despite the fact the EPA also recognizes that a "standardized reference method has not been developed to quantitatively determine the content of asbestos in a material."

The present status of this problem is summarized by the report of a committee prepared subsequent to a meeting sponsored by the International Agency for Research on Cancer (Ref. 52). The Food and Drug Administration's review of this report indicates the following areas of further research are necessary:

(1) Further epidemiology, particularly with respect to past exposure to asbestos and cancer of sites other than lung, pleura, and peritoneum.

(a) Assessment of excess cancer risks following exposure to only one type of fiber.

(b) Investigation of whether reduction of asbestos exposure in lungs below those causing asbestosis abolishes excess risk of carcinoma.

(c) Investigation of evidence of an increased risk of cancer resulting from asbestos in water, beverages, food, or liquids used for the administration of drugs.

(2) Development of methods of quantitative assessment, size analysis and characterization of particles and fibers.

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The Commissioner recognizes that it is not possible to eliminate all sources of asbestos contact with food and drugs. Asbestos is used in virtually all pipes carrying drinking water, in buildings in which food and drugs are manufactured, and in many filtering systems used in the manufacture of food and drugs, and is found in some substances, notably water and talc, used in the manufacture and processing of food and drugs. Nevertheless, the Commissioner also recognizes that asbestos fibers perform no functional purpose in talc and are an unnecessary contaminant. It is therefore reasonable to require precautions to be taken in the manufacure of food and drugs, as part of good manufacturing practices, to assure that the amount of asbestos fibers in any food or drug is reduced to the minimum feasible level. Accordingly, the Commissioner has concluded to take the following action:

1. In view of the demonstrated hazard in animals from injection of asbestos fibers, the Commissioner is proposing that the good manufacturing practice (GMP) regulations for drugs be amended to require that filtration procedures for parental drugs shall utilize either a non-asbestos-containing or non-fiber-releasing filter such as a membrane filter or, if an asbestos-containing filter is necessary, 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.

2. The Commissioner intends to promulgate a final regulation for talc under § 121.2006 as soon as a method for determining asbestos fibers in food-grade talc is validated. Such a method is proposed below, as part of a republication of the earlier proposal in which no methodology was specified. The Commissioner concludes that a final regulation for talc under Part 121 cannot be promulgated until a reproducible and accurate method can be specified for compliance purposes.

3. The Commissioner is also proposing that any talc used in the manufacture or processing of drugs meet the specifications for this substance that will be imposed by § 121.2006.

4. The Commissioner realizes that the issues raised in this notice are complex and have widespread ramifications. Comment is requested on all aspects of the public health significance of ingestion and injection of asbestos fibers. Since adoption of any new filtration requirements may require use of additional equipment, comment on the availability of appropriate equipment, the need for use of asbestos-containing filters as contrasted with filters which contain no asbestos, and the time needed to obtain and begin using non-asbestos-containing final filters such as membrane filters, is also requested. Finally, comment on methods of quantitative assessment, size analysis, and characterization of particles and fibers, is essential in order to develop final methods on which accurate and fair compliance can be based.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 402, 502, 701, 52 Stat. 1046–1047, as amended, 1050–1051, as amended, 1055–1056, as amended; 21 U.S.C. 342, 352, 371) and under authority delegated to him (21 CFR 2.120), the Commissioner of Food and Drugs proposes to amend Title 21 of the Code of Federal Regulations as follows:

1. In Part 121 by amending § 121.101 (d)(8) by alphabetically adding to the table a new item and in paragraphs (h) and (i) by revising the entry for "talc", to read as follows:

§ 121.101 Substances that are generally recognized as safe.

* * * * *

(d) * * *

Product	Tolerance	Limitations or restrictions
* * *	*	* *
(8) Miscellaneous and/or general purpose food additives.	------------	
* * *	*	* *
Talc (free of asbestos fibers as determined in § 121.2006).	------------	In chewing gum base and as an antisticking agent in forms used in molding food shapes.
* * *	*	* *

(h) * * *

Talc (free of asbestos fibers as determined in § 121.2006).

* * * * *

(i) * * *

Talc (free of asbestos fibers as determined in § 121.2006).

* * * * *

2. In Part 121 by amending Subpart E by adding the following new section:

§ 121.2006 Talc.

(a) Talc is a naturally occurring hydrous magnesium silicate subject to a prior sanction for use in coating polished rice. It is found in natural deposits that may be contaminated with asbestos fibers.

(b) Good manufacturing practice requires that talc be free from asbestos fibers to the maximum extent practicable. Accordingly, any food or food-packaging material containing talc that is not free from asbestos fibers as determined by the method set out in paragraph (c) shall be deemed to be adulterated in violation of section 402(a)(1) of the act.

(c) The following method shall be used to determine compliance with this section:

(1) The various kinds of asbestos are distinguished from talc and from each other by their refractive indices, other optical crystallographic properties, and morphology as determined with a polarizing microscope (Methods of the Association of Official Analytical Chemists, 11th Ed., 1970, Sections 36.541–36.543, p. 717–721).[1] Talc occurs mainly in the form of thin plates, which may appear fibrous when seen edgewise in microscopic view. Beta and gamma indices of talc vary from about 1.575 to 1.590, beta being very close to gamma. All of the principal refractive indices of chrysotile are less than 1.590. Chrysotile asbestos is therefore distinguishable from fibrous looking talc particles in a 1.574 refractive index liquid and the other five amphibole types of fibrous asbestos from talc in a 1.590 refractive index liquid. The table of optical crystallographic properties for talc and the asbestos minerals in subparagraph (3) shows refractive indices which are usually encountered in these minerals, but occasional samples may have indices which are somewhat higher or lower. For practical measurement of optical properties shown in the table, particles identified by this method should be at least 5 μm or longer.

(2) Weigh out 1 milligram of a representative portion of talc on each of two microscope slides. Mix the talc with a needle to spread evenly over the suitable area on one slide with a drop of 1.574 refractive index liquid, and then the other with 1.590 liquid, and place on each a square or rectangular cover glass sufficiently large so that the liquid will not run out from the edge (ca. 18 mm. square) and will provide a uniform particle distribution. Fibers counted by this method should meet the following criteria: (i) Length to width ratio of 3 or greater (ii) length of 5 μm or greater (iii) width of 5 μm or less. Count and record the number of asbestos fibers found in each 1 milligram as determined from a scan of both slides with a polarizing microscope at a magnification of approximately 400 X. In the 1.574 refractive index liquid, chrysotile fibers with indices less than 1.574 in both extinction positions may be present; in the 1.590 refractive index liquid, the other five amphibole types of asbestos fibers with indices exceeding 1.590 in both extinction positions may be present. Check the extinction and sign of elongation for tentative identification. For specific identification of asbestos fibers, make additional mounts in appropriate refractive index liquids, and refer to the optical crystallographic data in the table. A count of not more than 1000 amphibole types of asbestos fibers and not more than 100 chrysotile asbestos fibers per milligram-slide constitutes the maximum limit for the presence of these asbestos fibers in talc. These limits 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) Optical crystallographic characteristics of asbestos minerals and talc:

EXAMPLES OF REFRACTIVE INDICES (n)

Substance	$n\alpha$	$n\beta$	$n\gamma$	Extinction	Elongation
Actinolite	1.614	1.630	1.641	Inclined	Positive.
	1.615–1.655	1.625–1.665	1.64–1.68		
Amosite	[1] 1.663		1.680		
	[1] 1.675		1.702		
Anthophyllite	1.598	1.623		Parallel	Positive.
	1.598		1.623		
	1.598–1.674	1.605–1.635	1.615–1.697		
	1.608		1.631		
	1.619	1.630	1.640		
	1.619–1.633	1.630–1.642	1.640–1.657		
	1.629	1.635	1.640		
	1.633	1.638	1.652		
Chrysotile	1.493	1.504	1.517	Parallel	Positive.
	1.508	1.512	1.522		
	1.529–1.559	1.530–1.564	1.537–1.567		
	1.53 –1.54		1.54 –1.55		
	1.542		1.555		
	1.542	1.543 (calc.)	1.555		
	1.546	1.550	1.557		
	1.546	1.557	1.557		
	1.548	1.560	1.560		
Crocidolite		1.695		Parallel	Negative.
	1.693	1.695	1.697		
	1.697	1.700	1.703		
Talc	1.538–1.545		1.575–1.590	Parallel or 2° or 3°	Positive.
	1.539	1.589	1.589		
	1.539	1.589	1.589		
	1.539	1.589	1.589		
	1.540	nearly-n	1.575		
	1.541	1.585	1.585		
	1.544	1.592	1.592		
		1.594	1.594		
	1.545	1.584	1.584		
Tremolite	1.599	1.613	1.625	Inclined	Positive.
	1.599	1.613	1.625		
	1.599–1.612	1.613–1.626	1.625–1.637		
	1.600	1.616	1.627		
	1.602	1.614	1.635		
	1.602	1.618	1.631		
	1.602–1.623	1.613–1.633	1.624–1.650		
	1.604	1.612	1.623		
	1.604	1.617	1.630		
	1.609	1.622	1.630		
	1.609	1.623	1.630		
	1.613	1.621	1.634		

[1] $\frac{n+n}{2}$.

3. In Part 133 by adding the following new paragraph (i) to § 133.6 to read as follows:

§ 133.6 Components.

* * * * *

(i) Talc is a naturally occurring hydrous magnesium silicate which may reasonably be expected to contain asbestos fibers which may be injurious to health. Current methodology cannot assure the absence of asbestos in talc. Accordingly, any drug, drug ingredient, or drug packaging material containing talc that fails to meet the specifications of paragraph (c) of § 121.2006 of this chapter as determined by the method set out in that paragraph shall be deemed to be adulterated in violation of section 501(a) of the Act.

4. By adding the following new paragraph (j) to § 133.8 to read as follows:

§ 133.8 Production and control procedures.

* * * * *

(j) Use of asbestos-containing filters: Filters used in the manufacture of a parenteral drug or parenteral drug ingredient shall not release fibers into such products. No asbestos-containing or fiber-releasing filter may be used in the manufacture of a parenteral drug or parenteral drug ingredient unless it is not possible to manufacture that drug or drug ingredient without the use of such a filter. If use of such a filter is required, an additional non-asbestos-containing or non-fiber-releasing filter such as a membrane filter shall subsequently be used to reduce the content of any asbestos-form particles in the drug or drug ingredient. Evidence for reduction shall be based on the use of the methods described in "Criteria for a Recommended Standard—Occupational Exposure to Asbestos," Report of Review Committee, National Institute for Occupational Safety and Health, Publication No. HSM 72–10267 (1972).[2] Use of an asbestos-containing filter without subsequent use of an additional non-asbestos-containing membrane filter is permissible only upon submission of proof to the Food and Drug Administration that use of a non-asbestos-containing membrane

[1] Copies may be obtained from:
Association of Official Analytical Chemists
P.O. Box 540, Benjamin Franklin Station
Washington, DC 20044

[2] Copies may be obtained from:
Superintendent of Documents
U.S. Government Printing Office
Washington, DC 20402

filter will, or is likely to, compromise the safety or effectiveness of the drug.

Interested persons may, on or before December 27, 1973, file with the Hearing Clerk, Food and Drug Administration, Rm. 6-86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding the petition and the Commissioner's proposal. Comments may be accompanied by a memorandum or brief in support thereof. The petition, background information referred to in this proposal, and comments received may be seen in the above office during working hours, Monday through Friday.

Dated September 24, 1973.

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

[FR Doc.73-20711 Filed 9-27-73;8:45 am]

Social and Rehabilitation Service

[45 CFR Part 221]

FAMILIES, CHILDREN, AGED, BLIND, OR DISABLED INDIVIDUALS

Service Programs; Correction

FR Doc. 73-19242, published at page 24872 in the issue dated Monday, September 10, 1973, is corrected by changing:

1. The number "233" in item number two of the preamble, fifth line, to "233⅓";
2. The code designation "221.6(a) (3) (i)" in item number two of the preamble, seventh line, to "221.6(c) (3) (i)";
3. The code designation "211.6(a) (3) (iii)" in item number three of the preamble, fourth line, to "221.6(c) (3) (iii)";
4. The code designation "211.6(a) (3) (vii)" in item number four of the preamble, fourth line, to "221.6(c) (3) (vii)";
5. The code designation "211.7(b)" in item number five of the preamble, fourth line, to "221.7(b)";
6. The code designation "211.9(b) (3)" in item number seven of the preamble, sixth line, to "221.9(b) (3)";
7. The code designation "221.6(a) (3)" in the words of issuance, number three, first line; and in § 221.6(a) (3) itself, first line, to "221.6(c) (3)";
8. The number "8" in § 221.6(a) (4), (now corrected to § 221.6(c) (4)), fourth line, to "6"; and
9. The word "secured" in § 221.9(b) (5), fourth line, to "secure".

Approved September 24, 1973.

THOMAS S. MCFEE,
Deputy Assistant Secretary for Management Planning and Technology.

[FR Doc.73-20726 Filed 9-27-73;8:45 am]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[14 CFR Part 71]

[Airspace Docket No. 73-GL-44]

VOR FEDERAL AIRWAYS

Proposed Alteration

The Federal Aviation Administration (FAA) is considering an amendment to Part 71 of the Federal Aviation Regulations that would alter several VOR Federal Airways in the vicinity of Chicago, Ill., due to the planned decommissioning of the Naperville, Ill., VOR.

Interested persons may participate in the proposed rule making by submitting such written data, views or arguments as they may desire. Communications should identify the airspace docket number and be submitted in triplicate to the Director, Great Lakes Region, Attention: Chief, Air Traffic Division, Federal Aviation Administration, 2300 East Devon, Des Plaines, Ill. 60018. All communications received on or before October 29, 1973, will be considered before action is taken on the proposed amendment. The proposal contained in this notice may be changed in the light of comments received.

An official docket will be available for examination by interested persons at the Federal Aviation Administration, Office of the General Counsel, Attention: Rules Docket, 800 Independence Avenue SW., Washington, D.C. 20591. An informal docket also will be available for examination at the office of the Regional Air Traffic Division Chief.

The proposed amendment would:

1. Realign V-6 from Cordova, Ill., via INT Cordova 087°T(083°M) and DuPage, Ill., 255°T(253°M radials to DuPage. From the INT of Chicago Heights, Ill., 358°T(356°M) and South Bend, Ind., 271°T(271°M) radials to South Bend.
2. Realign V-8 from Cordova, Ill., via INT Cordova 087°T(083°M) and Joliet, Ill., 291°T(289°M) radials to Joliet.
3. Realign V-9 from Joliet, Ill., via INT Joliet 329°T(327°M) and Milwaukee, Wis., 209°T(207°M) radials to Milwaukee.
4. Designate new VOR Federal Airway V-9 west alternate from Pontiac, Ill., via INT Pontiac 345°T(343°M) and Milwaukee, Wis., 209°T(207°M) radials to Milwaukee.
5. a. Realign V-10 from Plano, Ill., intersection direct to Chicago, O'Hare, Ill.
   b. Delete that portion of V-10 which lies between Plano intersection and Niles, Ill., intersection.
6. Delete that portion of V-10N which lies from Naperville via Neptune, Ind., intersection to South Bend.
7. Delete V-97 from Chicago Heights, Ill., via Joliet, Ill., to Woodstock, Ill., intersection.
8. Realign V-97 from Northbrook, Ill., direct to Janesville, Wis.
9. Realign V-100 from Rockford, Ill., to Northbrook, Ill., via INT Rockford 080°T(077°M) and Northbrooks 292°T (290°M) radials.
10. Delete V-116 from Joliet, Ill., to Neptune, Mich., intersection.
11. Delete V-116S from Naperville, Ill., via Grand Beach, Ind., to Keeler, Ind.
12. Realign V-177 from DuPage, Ill., direct to Janesville, Wis.
13. Delete V-218 from Rockford, Ill., to Keeler, Mich.
14. Realign V-227 from Pontiac, Ill., direct to Rockford, Ill.
15. Realign V-429 from Joliet, Ill., via INT Joliet 351°T(349°M) and DuPage, Ill., 185°T(183°M) radials, to DuPage, thence via INT DuPage 346°T(344°M) radials, and Oshkosh, Wis. 187°T(185° M) radials, to Oshkosh.

The Naperville VOR will be decommissioned about June of 1974 due to the increased cost of lease renewal of the Naperville site, and the future detrimental effect that buildings planned for the vicinity would have on the NAVAID. The DuPage VOR will be frequency protected so that it can serve in the airway structure. Some of the airways in this vicinity would be realigned via DuPage in lieu of Naperville.

This amendment is proposed under the authority of Sec. 307(a) of the Federal Aviation Act of 1958 (49 U.S.C. 1348(a)) and Sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in Washington, D.C., on September 20, 1973.

CHARLES H. NEWPOL,
Acting Chief, Airspace and Air Traffic Rules Division.

[FR Doc.73-20703 Filed 9-27-73;8:45 am]

[14 CFR Part 75]

[Airspace Docket No. 73-WE-10]

AREA HIGH ROUTE

Proposed Alteration

The Federal Aviation Administration (FAA) is considering an amendment to Part 75 of the Federal Aviation Regulations that would realign a segment of J-938R from Reno, Nev., to Maple, Calif.

Interested persons may paticipate in the proposed rule making by submitting such written data, views or arguments as they may desire. Communications should identify the airspace docket number and be submitted in triplicate to the Director, Western Region, Attention: Chief, Air Traffic Division, Federal Aviation Administration, 1500 Aviation Boulevard, P.O. Box 92007, Worldway Postal Center, Los Angeles, Calif. 90009. All communications received on or before October 29, 1973, will be considered before action is taken on the proposed amendment. The proposal contained in this notice may be changed in the light of comments received.

An official docket will be available for examination by interested persons at the Federal Aviation Administration, Office of the General Counsel, Attention: Rules Docket, 800 Independence Avenue SW., Washington, D.C. 20591. An informal docket also will be available for examination at the office of the Regional Air Traffic Division Chief.

As part of this proposal relates to the navigable airspace outside the United States, this notice is submitted in consonance with the ICAO International Standards and Recommended Practices.

Applicability of International Standards and Recommended Practices by the Air Traffic Service, FAA, in areas outside domestic airspace of the United States is governed by Article 12 of and Annex 11 to the Convention on International Civil Aviation, which pertain to the establishment of air navigation facilities and services necessary to promoting the