information. The person may submit a request to the Administrator to reconsider this intention and may provide additional information in support of the trade secret designation. The Administrator shall notify the person in writing of the decision which will become effective no sooner than 15 days after the date of such notice.

§ 90.13 Recordkeeping requirements.

(a) ATSDR shall maintain a record of all health assessments and health effects studies. The Administrator shall, at his or her discretion, determine the contents of the record. At a minimum, the record shall include:

(1) The final ATSDR report of the health assessment or health effects study;

(2) Nonconfidential data and other information upon which that report is based or which was considered by ATSDR;

(3) Nonconfidential data or other information submitted by interested persons pertaining to the health assessment or health effects study;

(4) The protocol for the health effects study;

(5) A list of the individuals responsible for external peer review of the report of a health effects study, their comments, and ATSDR's response to the comments; and

(6) For health effects study, the notice announcing the availability of a draft final report for public review and comment, all comments received in response to the notice, and any responses to the comments by ATSDR.

(b) The record may contain a confidential portion which shall include all information determined to be confidential by the Administrator under this part.

(c) The Administrator may determine other documents are appropriate for inclusion in the record for health assessments or health effects studies.

(d) Predecisional documents, including draft documents, are not documents upon which ATSDR bases its conclusions in health assessments or health effects studies, and are not usually included in the record for health assessments or health effects studies.

(e) The record for ATSDR health assessments and health effects studies will be available for review, upon prior request, at ATSDR headquarters in Atlanta, Georgia.

(f) Nothing in this section is intended to imply that ATSDR's decisions to conduct health assessments or health effects studies, or the reports of health assessments or health effects studies, are subject to judicial review.

§ 90.14 Documentation and cost recovery.

(a) During all phases of ATSDR health assessments and health effects studies, documentation shall be completed and maintained to form the basis for cost recovery, as specified in section 107 of CERCLA.

(b) Where appropriate, the information and reports compiled by ATSDR pertaining to costs shall be forwarded to the appropriate EPA regional office for cost recovery purposes.

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federal register

Tuesday
February 13, 1990

Part V

Environmental Protection Agency

Asbestos; Publication of Identifying Information; Notice

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ENVIRONMENTAL PROTECTION AGENCY

[OPTS-62085; FRL-3687-9]

Asbestos; Publication of Identifying Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice provides summaries of the information submitted to EPA by manufacturers and processors of certain asbestos products in accordance with the Asbestos Information Act of 1988 (the Act). It also explains how individuals may obtain more or all of the information submitted to EPA.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-545, 401 M St., SW, Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION:

I. Background

On October 31, 1988, the President signed into law the Asbestos Information Act of 1988, Pub. L. 100-577 (the Act), which requires former and current manufacturers and processors of certain asbestos products to submit information identifying their products to EPA and requires EPA to organize and publish the submitted information. EPA issued a notice in the **Federal Register** of April 18, 1989 (54 FR 15622), which explained how and where these manufacturers and processors were to submit the information required by the Act. On August 7, 1989, EPA issued a notice in the **Federal Register** (54 FR 32430) which established a deadline of October 6, 1989, for these manufacturers and processors to submit to EPA the information required by the Act. On September 20, 1989, EPA issued a notice in the **Federal Register** (54 FR 38736) which informed submitters of information under the Act that EPA will not accept claims of business confidentiality.

II. Summaries of Information Submitted to EPA

Most of the manufacturers which submitted information to EPA provided a summary of the required information in the order that the Agency requested in Unit II of the April 18, 1989 **Federal Register** notice. EPA requested summaries from the manufacturers, because the Agency anticipated that the total amount of information submitted would be too voluminous to publish easily. That has proven to be the case. Therefore, EPA has decided to publish in this **Federal Register** notice only summaries of the information submitted. Instructions on how to obtain any or all additional information submitted to EPA are available in Unit III of this notice.

In some cases, EPA has reorganized the submitted information into a uniform summary format for inclusion in this **Federal Register** notice. However, the substance of the information submitted to EPA has not been altered.

Summaries of the information submitted to EPA before November 17, 1989 are included below in alphabetical order by name of manufacturer:

1. The Amtico Division of American Biltrite Inc.

(a) *Name and address of manufacturer.* The Amtico Division of American Biltrite Inc., 3131 Princeton Pike, Lawrenceville, NJ 08648. Prior to American Biltrite's purchase of the assets for producing vinyl asbestos tile and asphalt tile in Hamilton Township, NJ from Bonafide Mills Inc. on January 1, 1961, Bonafide Mills manufactured vinyl asbestos tile, asphalt tile (containing asbestos), and sheet vinyl flooring utilizing an "asbestos felt backing" at this same location. American Biltrite Inc. has no records regarding dates or patterns of vinyl asbestos tile manufactured by Bonafide Mills prior to American Biltrite's purchase on January 1, 1961. Prior to American Biltrite's purchase of the assets for producing sheet vinyl flooring in Norwood, MA from New London Mills in 1974, New London Mills manufactured sheet vinyl flooring utilizing an "asbestos felt backing" at this same location. American Biltrite has no records regarding dates or patterns of sheet vinyl flooring produced by New London Mills prior to American Biltrite's purchase in 1974.

(b) *Years of manufacture.* 1961 through 1980.

(c) *Types or classes of products.* Vinyl asbestos floor tile, asphalt tile (containing asbestos), and sheet vinyl flooring (utilizing an asbestos felt backing).

(d) *Other identifying characteristics.* Vinyl asbestos floor tile (produced January 1, 1961 through early December 1985) was available in a variety of colors, patterns, and surface textures. Many of the same colors, patterns, and surface textures produced prior to December 1985, which contained asbestos, have subsequently been produced in the non-asbestos tile construction after December 1985 and have the same visual appearance as the former asbestos-containing tile.

Asphalt tile containing asbestos (produced January 1, 1961 through 1970) was also marketed as plastic asphalt floor tile. It was available in a variety of colors, patterns, and surface textures, including: travatile, dot, cork, and marbleized.

Sheet vinyl flooring (produced January 1, 1962 to 1968, and 1974 through 1980) utilized an "asbestos felt backing" (flooring felt containing asbestos) bonded to the under side of the vinyl sheet flooring. It was available in a variety of colors, patterns, and surface textures; among the styles were: Casa Royale, Sun Court, Sunfire, Serenata, Natural State, Forum, Chatam Square, Royal Clan, Suntide, Contessa, and Kings Inn.

(e) *Additional information.* Additional information is available.

2. Armstrong World Industries, Inc.

(a) *Name and address of manufacturer.* Armstrong World Industries, Inc., formerly known as Armstrong Cork Company, P.O. Box 3001, Liberty and Charlotte Streets, Lancaster, PA 17604. Predecessors: Forms + Surfaces, Inc., Box 5215, Santa Barbara, CA 93150; and The W. W. Henry Company, 5608 Soto Street, Huntington Park, CA 90255.

(b) *Years of manufacture.* 1909 through April 1987.

(c) *Types or classes of products.* Thermal system insulation material, fire-resistant vapor barrier and adhesive for cork, resilient floor tile, lining felt and backing for sheet vinyl, asphalt "cutback" floor tile adhesive, acoustic cement, and decorative wall treatment.

(d) *Other identifying characteristics.* Nonpareil High Pressure Covering, Block, and Cement (produced 1909 to 1932 by Armstrong) were high temperature thermal system insulations for pipe covering and block and cement. These products were last offered more than 50 years ago. The only formula information available to Armstrong is that which is taken from the United States Patent Office documents.

LT Cork Covering (produced with asbestos 1956 to 1959 by Armstrong) was a low temperature thermal system cork insulation. It was a wrap-around insulation consisting of wedge-shaped cork segments cemented to a laminate consisting of aluminum foil and asbestos paper. It is unique in its appearance and can be easily distinguished visually by its physical structure.

Armaspray (produced 1966 to 1968 by Armstrong) was a spray- on thermal system insulation.

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CC Navy Sealer (LT Sealer) (produced approximately 1942 to 1962 by Armstrong) was a fire-resistant vapor barrier and adhesive for cork. CC Navy Sealer was light tan in color and had a trowel and brush consistency; LT Sealer was white and had a trowel and brush consistency.

Vinyl Composition Tile (produced with asbestos 1954 to June 1981 in a commercial grade and 1954 to 1982 in a residential grade by Armstrong) was a resilient floor tile made of non- friable material. Visual identification may be possible using designated pattern book volumes.

Rubber Tile (produced with asbestos 1955 to 1966 by Armstrong) was a resilient floor tile made of non-friable material. Visual identification may be possible using designated pattern book volumes.

Asphalt Tile (produced 1931 to 1972 by Armstrong) was a resilient floor tile made of non-friable material. Visual identification may be possible using designated pattern book volumes.

Hydrocord (produced 1955 to 1983 by Armstrong) was a lining felt and backing for sheet vinyl made of non-friable material.

S–89 (produced with asbestos 1965 to January 1983 by Armstrong) was an asphalt "cutback" floor tile adhesive. It was non-friable, black in color, and had a dried consistency of a heavy-bodied tar.

S–90 (produced with asbestos 1934 to January 1983 by Armstrong) was an asphalt "cutback" floor tile adhesive. It was non-friable, black in color, and had a dried consistency of a heavy-bodied tar.

Acoustic Cement, also known as 314 Acoustic Cement, (produced as an asbestos-containing material 1945 to 1953 by Armstrong) was an adhesive for acoustical tile installation. It was used for chemical bonding of the acoustic ceiling tiles to a structural member.

"Bonded Bronze" Panels (produced 1970 to 1971 by Forms + Surfaces) used a commercially available asbestos cement board as a backing material and had an end use as decorative wall treatment. Forms + Surfaces was not the manufacturer of the asbestos cement board and, therefore, the type and percentage of asbestos and other formula information is unknown.

#232 Asphalt Cutback Adhesive (produced with asbestos November 1965 to April 1987 by The W. W. Henry Company) was a floor tile adhesive. It was a non-friable asphalt cutback adhesive, black in color with a dried consistency of a heavy- bodied tar. Formula information for #232 Asphalt Cutback Adhesive is as follows: 63% asphalt by weight, 5% chrysotile asbestos, and 32% solvent.

(e) *Additional information.* Additional information is available.

3. The BFGoodrich Company

(a) *Name and address of manufacturer.* The BFGoodrich Company, 3925 Embassy Parkway, Akron, OH 44313.

(b) *Years of manufacture.* Approximately 1945 through 1963.

(c) *Types or classes of products.* Floor tile.

(d) *Other identifying characteristics.* Self-explanatory by class description.

(e) *Additional information.* No additional information is available.

4. The Celotex Corporation

(a) *Name and address of manufacturer.* The Celotex Corporation, P.O. Box 31602, Tampa, FL 33631–3062. Predecessors: Panacon Corporation, Briggs Manufacturing Corporation, Philip Carey Corporation, Smith & Kanzler Company, Glen Alden Corporation, and Philip Carey Manufacturing Company.

(b) *Years of manufacture.* 1906 through 1984.

(c) *Types or classes of products.* Surfacing material, thermal system insulation (pipe coverings and block, cements, accessory products), and miscellaneous materials (boards, other).

(d) *Other identifying characteristics.* Spraycraft surfacing material (produced 1969 to 1971) was 35% asbestos, 60% mineral wool, 2.5% white cement, 2.5% clay.

The following were pipe covering and block products:

85% Magnesia (produced 1906 to 1961) was 85% magnesia, 11 to 15% asbestos (filter molded);

Super Light 85% Magnesia (produced 1951 to 1958) contained normal carbonate magnesium, 15% asbestos (precision molded);

Alltemp (produced 1954 to 1958) was 60% perlite, 20% magnesia plastic, 10% bentonite clay, 10 to 12% asbestos;

Careytemp (produced 1958 to 1969, asbestos removed 1969) was 90% perlite, 6 to 7% asbestos and binders;

Paper Pipe Products (produced 1906 to the early 1970's) contained approximately 60% asbestos, 25% organic fiber, 15% silicate. Product names: Aircel, Careycel, Carocel, Defendex, Excel, Glosscell, Multi-Ply.

Asbestos Sponge contained 60% asbestos, 2 to 3% asbestos sponge, organic felt, and silicate.

Fyrex contained 60+% asbestos, organic material, and silicate.

Other Pipe Coverings (produced 1906 to February 1967): Tempcheck—20% magnesium plastic, 60% diatomaceous earth, 20% asbestos; Hi-temp #19—80% diatomaceous earth, 20% asbestos; Hi-temp #12 and #15—60% diatomaceous earth, 20% magnesia plastic, 20% asbestos; Careytemp Aluminum Jacketed and Traced Pipe Insulation—Careytemp with aluminum or stainless steel jacket; Careytemp 2000—93.6% diatomaceous earth, 6.4% asbestos; Dual Careytemp—2% bentonite clay, 17% starch, 19% phenolic resin, 10% asbestos; 62% perlite.

The following were cement products:

707 Cement (produced 1906 to 1960) contained 43% asbestos, 57% ground gypsum;

Super 606 Cement (produced 1906 to 1960) contained 20% bentonite, 10% kaolin clay, 10% asbestos, 60% mineral wool;

100 Cement (produced 1906 to 1967) contained 55% asbestos, 50% gypsum;

303 Cement (produced 1906 to 1967) contained 55% asbestos, 35% gypsum, 10% kaolin clay;

Careytemp Finishing Cement (produced 1966 to 1968) contained cement, bentonite clay, perlite, 22% asbestos, limestone, silica, wetting agent;

MW–0 Cement (produced 1950 to 1952) contained 70% mineral wool, 10% asbestos, 20% bentonite clay;

MW–0 Cement (produced 1940 to 1967) contained 90% mineral wool, 10% asbestos;

LF–0 Asbestos Cement (exact date manufacture began is unknown; manufactured up to 1967) contained 60 to 70% asbestos, kaolin clay, hardeners;

Vitricel Cement (#10 and #19) (produced 1940 to 1967) contained 15 to 25% asbestos, 50% cement/slate flour;

A–01 Cement (produced 1906 to 1967) contained 100% asbestos;

7M–0 Asbestos Shorts Cement (produced 1950 to 1977, brokered) contained 100% asbestos.

The following are accessory products:

45-pound Asbestos Waterproof Jacket (produced 1906 to 1982) contained 85% asbestos, asphalt, organic paper fillers;

Asbestos Rope and Wick (produced 1925 to 1945) contained 85% asbestos, 15% cotton fiber;

Asbestos Papers and Roll Boards (produced 1906 to February 1982) contained 60 to 80% asbestos, organic fiber, silicate;

Asbestos Tank Jackets (produced 1906 to 1945) contained 60% asbestos, 25% organic fiber, 15% silicate;

Thermalite (produced 1906 to 1937) contained 85% asbestos, 15% sodium silicate;

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Firefoil Board and Panel (produced 1940 to 1960) contained 60% asbestos, 25% organic fiber, 15% silicate;

Vitricel Asbestos Sheets (produced 1941 to 1960) contained 60% asbestos, organic fiber, silicate, waterproofing solution;

Thermotex-B (produced 1906 to 1984) contained 14% asbestos, asphalt and mineral stabilizer;

228 Fibrated Emulsion (manufacture began 1906, exact date manufacture stopped is unknown) contained bentonite clay, asphalt, 3.6% asbestos;

Insulation Seal (produced 1930 to 1984) contained 20% asbestos, asphalt cutback, naphtha, mineral spirits;

Fire Resistant Insul Seal (years of production unknown) contained 20% asbestos, asphalt and chlorinated solvent;

Fibrous Adhesive (1906 to 1984) contained 85% sodium silicate, 15% asbestos;

BTU Cement (produced 1930 to 1965) contained 25 to 30% asbestos, asphalt cutback;

Careytemp Adhesive (produced 1961 to 1968) contained 80% silicate, 15% asbestos, 4.8% diatomaceous earth, 2% wetting agent.

The following are miscellaneous materials:

Thermo-bord (produced 1925 to 1969) contained non-asbestos insul covered with A–C sheets (20% asbestos);

Industrial A–C Boards (produced 1925 to 1970) contained 78% cement, 22% asbestos;

Cemesto Board (produced 1930's to early 1960's) was similar to Thermo-bord;

Marine Panel (produced 1941 to 1950) contained Aircel and asbestos cement (60% asbestos);

Millboards (produced 1906 to February 1982) had various formulations: 65 to 97% asbestos and cement, clay, or starch;

Careyduct (produced 1940 to 1955) contained 60 to 85% asbestos, 15 to 40% starch;

Carey Asphalt Floor Tiles (produced 1930's to 1975) contained 40% asbestos, 60% asphalt and sand;

Careyduct Adhesive (produced 1940 to 1955) contained 15% asbestos, 85% sodium silicate;

Ceiling Tiles (produced 1960 to 1975) contained 1.5 to 3% asbestos, 70 to 72% mineral wool, 18% clay, 7% starch, and 1 to 2% wax.

(e) *Additional information.* No additional information is available.

5. Congoleum Corporation

(a) *Name and address of manufacturer.* Congoleum Corporation, P.O. Box 3127, Trenton, NJ 08619.

(b) *Years of manufacture.* 1947 through 1983.

(c) *Types or classes of products.* Counter tops, asphalt tile, vinyl asbestos tile, 6 foot sheet flooring, sheet flooring with asbestos felt.

(d) *Other identifying characteristics.* Counter tops (produced 1952 to 1960) were available in a variety of patterns and styles, including: Vinyl Top, Nairon Top, Viscount, and Marble.

Asphalt Tile (produced 1952 to 1971) was available in a variety of patterns and styles, including: Gala, Corkette, Tweed Texture, Featherveining, and Sequin.

Vinyl Asbestos Tile (produced 1959 to 1975) was available in a variety of patterns and styles, including: Thru Style, Grandview, Corinthian, Selected Color Series, Cameo, Samara, Fontenay, Shelburne, Regalwood, Sunburst, Bedford Slate, Canyon Stone, English Brick, Park Ridge, Sonoma, Caribbean, Catalina, Woodgrain, Cimarron, Parthenon, Capella, Orion, El Camino, Feathervein, Brushwood, Sparklewood, Gala, Vinylstone, Romanaire, Rondelle, Dominique, Woodgrain, Travertine, Ranch Tile, Corsicana, Corinthian, Dominique, Carillon, Manorwood, Aztec, San Paulo, Libra, Capella, Venus, Orion, Fontenay, Ventura, and Shelburne.

Tile (produced 1952 to 1962) was available in a variety of patterns and styles, including: Standard, Venetian, Designer, Bermuda Hues, Tiffany Vinyl Tile, Translucent Vinyl Tile, Vinyl Dynasty Tiles and Tile Inserts, Berylstone, Sequin, Venetian, and Marble.

Asbestos Sheet Flooring (produced 1974 to 1977; 1981 to 1983) was available in a variety of patterns and styles, including: Ultraflor, Ultraflor Majestic, Ultraflor Regal, Reflection, Fashionflor, Prestige, Dynasty, Pavillion, Spring, Highlight, Cushionflor Supreme, Villager, Pacemaker, Profile, and Flor-Ever.

6 Foot Sheet Flooring (produced 1952 to 1954) was available in a variety of patterns and styles, including: Vinylflor, Berylstone, Marble, and Picnic.

Sheet Flooring with Asbestos Felt (produced 1965 to 1980) was available in a variety of patterns and styles, including: Pebble, Brick, Colony Square, Georgian Marble, Persian Tile, Casa Grande, Town & Country, Williamsburg Brick, The Rembrandt, The Stuart, The Degas, The Goya, Caliente, Hampstead Brick, Royal Court, Westbury, Fairmont, Topaz, La Mesa, Colonnade, Majesty, Espana, Pennhurst, Camelot, Italian Terrazzo, and Willowbrook.

(e) *Additional information.* Additional information is available.

6. Eagle-Picher Industries, Inc.

(a) *Name and address of manufacturer.* Eagle-Picher Industries, Inc., 580 Walnut Street, Cincinnati, OH 45202. Corporate Predecessors: The Eagle-Picher Company, The Eagle-Picher Lead Company.

(b) *Years of production.* 1930 through 1971.

(c) *Types or classes of products.* Insulating cement, insulating and finishing cement.

(d) *Identifying characteristics.* Super "66" asbestos-containing insulating cement, formerly called Eagle "66," was manufactured from 1930 to August 1971. Super "66" was an insulating cement which dried to a grayish-white color with dark mineral wool fiber nodules of generally uniform size (¼" to ½"), evenly dispersed through the binder, and compressible and resilient when pressed between the fingers. Super "66" was formulated as follows: 42 to 67% granulated mineral wool (dark) fiber nodules by weight; 22 to 33% (1931 to 1963) and 44 to 52% (1963 to 1971) bentonite clay by weight; 8 to 10% (1931 to 1963) and 3 to 4% (1964 to 1971) chrysotile asbestos fibers by weight; less than 5% other ingredients by weight.

One-Cote Insulating and Finishing Cement was manufactured from 1960 to August 1971. One-Cote was a hydraulic setting insulating and finishing cement which dried to a smooth, white to off-white, hard finish with high compressive strength and abrasion resistance. It contained dark mineral wool fiber nodules of generally uniform size (⅛" to ⅜"), evenly disbursed through the binder, and compressible and resilient when pressed between the fingers. One-Cote was formulated as follows: 19 to 31% granulated mineral wool (dark) fiber nodules by weight; 27 to 33% portland cement by weight; 5 to 18% (1960 to 1966) and 23 to 35% (1967 to 1971) bentonite clay by weight; 24 to 30% (1960 to 1966) and 7 to 14% (1967 to 1971) diatomaceous earth by weight; 5 to 6% (April 1960 to 1967) and 2 to 5% (1968 to August 1971) chrysotile asbestos fibers by weight (product did not contain asbestos prior to April 1960 or after August 1971); less than 4% other ingredients by weight.

Eagle-Picher has developed an extensive set of analytical procedures and testing protocols specifically designed for precise identification of distinguishing characteristics of Eagle-Picher's Super "66" and One-Cote in the laboratory setting. For further information and assistance in performing the analytical procedures

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contact James A. Ralston at the address provided above in 6(a).

(e) *Additional information.* No additional information is available.

7. Fibreboard Corporation

(a) *Name and address of manufacturer.* Fibreboard Corporation, 1000 Burnett, Galaxy Office Park, Concord, CA 94520. Formerly Fibreboard Paper Products and Pabco Corporation.

(b) *Years of production.* 1920 to 1971.

(c) *Types or classes of products.* Block, pipe- covering, and cement thermal insulation, thermal insulating cement, floor covering, cement products, roof paint, floor- coating asphalt saturated felts or roll roofings with asbestos- containing base sheets, caulking compounds, plastic cements, gypsum board, taping and finishing compounds, insulating tape, and gaskets and packings.

(d) *Identifying characteristics.* Prasco, a block, pipe-covering, and cement thermal insulation manufactured from about 1928 to 1957, contained 85% diatomaceous earth and binders and about 15% asbestos (color: yellow or red).

85% magnesia block, pipe-covering, and cement thermal insulation manufactured from about 1928 to 1966, contained about 85% or more basic magnesium carbonate and 15% or less asbestos (color: white).

Caltemp (or Caltherm), a block, pipe-covering, and cement thermal insulation manufactured from about 1952 to 1968, contained about 88% calcium silicate and about 12% asbestos (color: pink until mid-1960's, then white or gray).

Supercaltemp, a block, pipe-covering, and cement thermal insulation manufactured from the late 1960's until 1971, contained calcium silicate and other non-asbestos material increasing from about 88% to 96½%, and asbestos material decreasing from about 12% to 3½% (color: white or gray).

FI thermal insulating cement, manufactured from about 1963 to 1966, contained about 95% calcium silicate and binders and about 5% asbestos (color: pink until mid-1960's, then white or gray).

No. 127 thermal insulating cement, manufactured from about 1966 to 1971, contained about 95% calcium silicate and binders and about 5% asbestos (color: white or gray).

Aircell or asbestos paper insulation, manufactured prior to 1948, was composed of asbestos paper and sodium silicate (color: grayish).

Kaylo, LK Insulation, and Pyrocal, block and pipe-covering thermal insulation, under rebrand agreements and specifications for Owens-Corning Fiberglas, Armstrong Contracting and Supply, and PPG Industries, respectively, were manufactured 1960 to 1971, 1964 to 1971, and 1968 to 1971.

Pabco Floron floor covering, manufactured from about 1952 to 1954, contained about 15% asbestos.

Colorok, Stormlap, Pabflex, and Stonite asbestos-cement products, manufactured from about 1948 to 1963, contained portland cement and about 15–20% asbestos.

Alumishield roof paint, manufactured from about 1946 to 1968, and Gripdeck floor-coating, manufactured from about 1942 to 1968, contained paint vehicles, pigments, and about 5 to 10% asbestos.

Asphalt-saturated felts or roll roofings, manufactured sporadically from 1920 to 1968 at various locations, may have had asbestos-containing base sheets.

Caulking compounds, plastic cements, and roof coatings manufactured until 1968 may have contained about 5 to 10% asbestos.

Flamecurb gypsum board, manufactured from about 1951 to 1960, contained a small percentage of asbestos.

Gypsum board and lath, manufactured for a few months in 1954, contained 0.2 to 0.3% asbestos.

Taping and finishing compounds, manufactured from about 1951 to 1960, contained about 5 to 10% asbestos.

Insulating tape manufactured in the 1940's may have contained some asbestos.

Gaskets, packings, and a product called Asbestofelt manufactured by a predecessor prior to 1948 may have contained some asbestos, and said predecessor may have sold some asbestos- cement roofing, siding, refractories, textiles, paper, millboard, or other materials manufactured by others which may have contained some asbestos.

(e) *Additional information.* Additional information is available.

8. The Flintkote Company

(a) *Name and address of manufacturer.* The Flintkote Company, 100 The Embarcadero, Third Floor, San Francisco, CA 94105.

(b) *Years of manufacture.* 1945 through 1982.

(c) *Types or classes of products.* Vinyl asbestos floor tile, floor tile cements.

(d) *Other identifying characteristics.* Vinyl Asbestos Floor Tile (produced 1945 to November 1980) was manufactured and sold in hundreds of patterns and color combinations. The amount of chrysotile fiber contained in the product varied, but generally ranged from 5 to 25%. No physical or chemical testing protocol is known for Flintkote floor tile, however, it can be identified through visual inspection by persons knowledgeable in the trade.

GF–8/R–14–C Floor Tile Cements (produced 1945 to approximately 1982) contained chrysotile. The amount of chrysotile fibers contained in these products ranged from approximately 5 to 11%. No physical or chemical testing protocol is known for Flintkote floor tile cements.

9. GAF Building Materials

(a) *Name and address of manufacturer.* GAF Building Materials Corporation, 1361 Alps Road, Wayne, NJ 07470. Predecessor: The Ruberoid Company.

(b) *Years of manufacture.* 1928 through 1981.

(c) *Types or classes of products.* Pipe covering, asbestos paper and millboard products, and insulating cements.

(d) *Other identifying characteristics.* Calsilite (produced from approximately 1944 to June 1947 for the U.S. Navy; from July 10, 1947 to March 7, 1949 by Ruberoid on an experimental basis; from March 7, 1949 to 1967 by Ruberoid on a commercial basis; in 1967 by Aniline & Film Corporation on a commercial basis; and from 1968 to October 1971 by GAF Corporation on a commercial basis) was a pipe covering and block insulation. Calsilite was a lightweight, hard, calcium silicate insulation designed to withstand temperatures up to 1250 °F. Calsilite pipe covering was manufactured in 3 foot lengths and in varying thicknesses. It was available in half-sectional pieces, and, at various times, in three-segmental and regular segmental shapes, for assembly around a pipe in single or double layers. Pipe covering normally was provided with standard weight cotton or canvas jackets applied with silicate of soda. No "T's," elbows or joints were produced. Flat Calsilite blocks were manufactured, at various times, in 18" or 36" lengths, in widths from 3" to 36", and in thicknesses up to 4". Six-inch wide curved segmental blocks, capable of contouring more easily for insulation of large pipes and circular vessels, also were available. Calsilite was manufactured by a "pan-molding" method until 1964 when Ruberoid began using a "filter-press" method or process.

Pan-molded Calsilite was grayish-white and relatively smooth, with some small holes. Calsilite filter press was grayish-white with screen marks on the outer surfaces. Calsilite-Hi, developed in or around 1960, could withstand temperatures up to 1,800 °F. In the mid-

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to-late 1960's, Ruberoid developed Calsilite SS, an "inhibited" product designed specifically to prevent stress corrosion and cracking of stainless steel piping. In addition to formula changes made in connection with product development, the Calsilite formula was adjusted often in order to compensate for changes in the quality and availability of raw materials.

Asbestos Paper and Millboard Products (produced by Ruberoid from 1928 to 1967, by General Aniline & Film Corporation in 1967, and by GAF Corporation from 1968 to 1981). Asbestos paper was designed to be used alone or in the manufacture of other products. It was manufactured in various thicknesses, according to customer specifications. Asbestos paper had a temperature limit of 250 °F. Its primary constituent was chrysotile asbestos, generally a mixture of grades 5 to 7. Other constituents included sulphite pulp, diatomaceous earth, and starch, although in the early years of manufacture this product may have consisted only of chrysotile and starch (which was sometimes in the form of tapioca).

Rollboard was an asbestos paper product, consisting of plies of asbestos paper bonded together without glue to create thicknesses varying from 1/16" to 1/8". Rollboard had a temperature limit of 250 °F.

Millboard was a stiffer product than asbestos paper or rollboard and was manufactured in sheets of varying thicknesses according to customer specifications. Millboard consisted generally of chrysotile asbestos, (usually grades 5D, 5R, and 6D), sulphite pulp and often other constituents, bonded with portland cement and/or starch. In later years, at least as early as 1974, latex was added as a binder.

Corrugated asbestos paper was designed to be used alone or in the manufacture of other products. It was made in three types: ¼" thickness per ply (4 plies per inch); ⅛" thickness per ply (6 plies per inch); and 1/16" thickness per ply (8 plies per inch). It was manufactured by adhering 36" to 37½" wide flat sheets of asbestos paper (usually 6 lb. paper) with silicate of soda to sheets of the same paper which had been corrugated using characteristic "Roman Arch" shaped corrugations, 26 to 28 to the inch. Its constituents were those of the asbestos paper from which it was constructed. Corrugated asbestos paper was sold in 250 and 500 square foot rolls.

Air Cell was a corrugated asbestos paper product manufactured from 1928 to approximately 1958. It was constructed of layers to the thickness specified by the customer of 36 or 37½" wide flat asbestos paper which was adhered to corrugated asbestos paper with silicate of soda. The corrugations of this product had a characteristic "Roman Arch" shape. As of 1938, the corrugated paper component had 28 corrugations per lineal foot. Each ply was ¼" thick and air cell came in three standard thicknesses—2-ply, 3-ply, and 4-ply. Air cell pipe covering, sheets and blocks were sold. Often a canvas, cloth, or pyroxiline jacket was applied to the outer surface of air cell pipe covering with an adhesive, usually a starch or cereal paste. 2½ brass lacquered bands were provided for each canvas-jacketed section of air cell pipe covering to hold it to the pipe. With the pyroxiline jacket, three 1" wide black japan bands were supplied with each section. Air cell had a temperature limit of 250° to 350 °F. Prior to 1935, air cell may have been sold only under the name "Celasbestos," which was available in 5, 6, 7, and 8-ply versions and well as 1–4 ply versions.

Watocell was a corrugated asbestos paper product manufactured as Watcocel from 1928 to 1934, as Supercell from 1935 to 1942, and as Watcocell from 1942 to 1960. In 8-ply per inch Watcocell, the corrugations were 1/16" thick; in 6-ply, the corrugations measure about ⅛" thickness. Watcocell was sold in rolls, sheets, and blocks. Watcocell's temperature limit was 250 °F.

Imperial insulation was manufactured from at least 1936 to approximately 1960. It had a temperature limit of 500° to 700 °F. Imperial paper consisted of two plies of flat asbestos paper which were passed through an indenting roll resulting in a waffle-like appearance with closely spaced square indentations.

Imperial pipe covering was wound on a mandrel to achieve the desired thickness and canvas-covered. In early years of production, layers of Imperial may have been stapled together or stitched with strands of wire rather than wound on a mandrel. Imperial sheets and blocks were made of layers of Imperial paper glued to the desired thickness with a fireproof glue, such as silicate of soda. This product was sold with a canvas, asphalted felt, or pyroxylin jacket.

Aristo Insulation was listed for sale in and around 1940, but the years of manufacture of Aristo Insulation are unknown. It was a corrugated asbestos paper product with carefully measured indentations and 23 to 25 laminations per inch of thickness. Its temperature limit was 700° to 750 °F. The asbestos paper used in this product was treated with a surface treatment, possibly Bennett size. This product was sold in a standard thickness of one inch, but often was used in thicknesses up to and exceeding three inches. Standard canvas and waterproof jackets were available for this product.

Sponge felt was manufactured from 1936 to approximately 1960. It consisted of asbestos sponge paper made by imbedding small pieces of sponge into asbestos paper. Its temperature limit was 750 °F. It was sold in 36" wide rolls, sheets, and blocks which were produced in the same manner as Imperial products.

Woolfelt, a wool or rag felt insulation manufactured from 1928 to approximately 1959, did not contain asbestos, but was sometimes sold with an asbestos paper liner or backing paper. Tar-lined woolfelt was sold with a tar paper liner which did not contain asbestos. Twin-purpose woolfelt was sold with a liner of asphalt coated asbestos paper.

Anti-Sweat Pipe Covering was manufactured until approximately 1958, and intended exclusively for residential use on cold water pipes. At least as early as 1936 this product was composed of an inner layer of asphalt-saturated asbestos paper followed by a ½" layer of woolfelt, two layers of asphalt- saturated asbestos paper, another ½" layer of woolfelt, and two final layers of asphalt-saturated asbestos paper. The outermost layer had a flap extending at least 3 inches beyond the longitudinal joint. GAF does not know whether a jacket was ever provided with this product. This product was sold in 36" wide rolls and had a temperature limit of 50 °F.

Frost-Proof Pipe Covering was apparently constructed of a layer of felt made from cattle, goat, or other animal hair with layers of asphalt-saturated asbestos paper and a layer of woolfelt. Its years of manufacture, appearance, and temperature limit are unknown to GAF.

Range Boiler Jacket consisted of a series of plies of corrugated asbestos paper built up to the required thickness on mandrels that were the same size as the range boilers the product was designed to fit. The corrugated paper used was a coarse variety with 4 plies per inch of thickness. These jackets were furnished in two sections—upper half and lower half. Five extra-wide bands were provided to attach the jacket to the range boiler. The outside surface was painted or covered with canvas. GAF does not know the years of manufacture of this product.

115 Insulation Cement was a chrysotile asbestos product which, in some instances, was produced at Ruberoid/GAF's Vermont facility and in

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other instances was purchased from various other asbestos suppliers and resold. Some of the product purchased from other suppliers may have been milled again at Ruberoid/GAF's Vermont facility prior to resale. Asbestos insulation cements produced at GAF's Vermont facility could generally be distinguished from asbestos insulation cements produced by other manufacturers inasmuch as the Vermont product was a slip chrysotile asbestos rather than a cross vein asbestos and was generally of a lower grade and contained a greater percentage of impurities, such as dirt and rock particles. It is believed that this product was sold from at least as early as 1937 to 1975. It is believed that the "115" designation was employed from approximately 1950 to 1975 and the designation "Grade B" was also employed in years prior to 1950. The basic ingredients of this cement product were: chrysotile determined to pass the 0–0– 1–15 Quebec test, and impurities (dirt, rock, earth). The particular formulas utilized by entities which purchased this product for construction are not known by GAF, but this product was normally mixed with portland cement, water, and/or other substances.

214 Insulation Cement was also a chrysotile asbestos product which, in some instances, was produced at GAF's Vermont facility and in other instances was purchased from various other asbestos suppliers and resold. Some of the product purchased from other suppliers may have been milled again at Ruberoid/GAF's Vermont facility prior to resale. Ruberoid/GAF's Vermont product was a lower grade cement which contained a greater percentage of impurities, such as dirt and rock particles, making it lightly mottled and giving it an overall darker appearance. It is believed that this product was sold from at least as early as 1937 to 1975. It is believed that the "214" designation was employed from approximately 1950 to 1975 and the designation "Grade BB" was also employed in years prior to 1950. The basic ingredients of this cement product were: chrysotile determined to pass the 0–0–2–14 Quebec test, and impurities (dirt, rock, earth). The particular formulas utilized by entities which purchased this product for construction are not known by GAF, but this product was normally mixed with portland cement, water and/or other substances.

Calsilite Insulation Cement was a combination of chrysotile asbestos fiber, ground Calsilite pipe covering or block, and portland and other cements. It is believed that this product was made with Vermont-produced asbestos and thus contained certain impurities, such as rock, dirt and earth particles. This product was never widely or frequently sold. To the extent that such sales took place, they ceased completely in or around 1960.

Grade AA Insulating Cement was manufactured by Ruberoid using a high grade of pure asbestos fiber together with suitable binding materials that had low conductivity. It was designed to yield a hard, durable surface. Its temperature limit was 1,200 °F.

Grade A Insulating Cement was a factory-prepared cement consisting of fibers which were not as long as those used in the better grade AA, together with suitable binding materials. Its temperature limit was 1,000 °F.

Grade H F—Hard Finish—was a hard finish cement designed to be used as a final protective coating over other coats of cement. It had a smooth, glossy, hard finish. Grade HF was recommended to be applied in a ¼" thick layer. It had a temperature limit of 1,500 °F and was a prepared cement manufactured by Ruberoid.

Grade H. T.—High Temperature—Cement was designed to withstand temperatures of 1,600° to 1,800 °F. This material was not designed to be used for finishing purposes.

Grade 203 Insulating Cement was a 100% chrysotile cement which had a screen test of approximately 0–0–1–16 which made it the lowest grade cement sold by Ruberoid/GAF.

Satin Finish Cement consisted of 87% chrysotile, 10% portland cement, and 3% Medusa cement.

Grade A–11 Insulating Cement consisted of vermiculite, chrysotile, and binding substances. It was recommended for temperatures up to 1,500 °F, or 1,800 °F if the applicator did not intend to reclaim the material. Grade A–11 was designed to be an insulation material, not a finishing cement.

Coverkote was designed to be a weatherproofing coating for insulated surfaces, rather than an insulating cement. It was a combination of emulsified asphalt and 25 to 28% chrysotile. It was a black plastic material particularly designed for protection of insulation on large tanks and vessels and for insulated equipment such as smoke breechings and ducts. The temperature limit for Coverkote was 400 °F.

Rock Wool Cement was apparently available from Ruberoid in the late 1940's and early 1950's. It consisted of a mixture of rock wool and chrysotile asbestos and had a temperature limit of 1,500 °F.

(e) *Additional information.* Additional information is available.

10. General Refractories Company

(a) *Name and address of manufacturer.* General Refractories Company, Valley Forge Corporate Center, 2661 Audubon Road, Valley Forge, PA 19403. General Refractories Company purchased certain assets from Ohio Lime Company, located in Woodville, OH in August 1967 and formed OLC.

(b) *Years of manufacture.* 1955 through 1973.

(c) *Types or classes of products.* Hydraulic setting insulating castable, paste-like silicate cement, acoustical plaster, decorative spray coating.

(d) *Other identifying characteristics.* Litecast 30 (produced 1962 to 1968; 1970 to 1973 by General Refractories Company) was a hydraulic setting insulating castable. Constituent composition of Litecast 30 by weight of each constituent: 40% expanded Perlite Grade P–38; 23% chrysotile asbestos 7K 15; 36% Lumnite Cement; and 1% bentonite. Litecast 30 was shipped dry in 30 lb. valve type bags. It was mixed with water, then cast or sprayed onto a furnace surface for use in the aluminum and petrochemical industry. Litecast 30 was manufactured at the Company's facilities in Sproul, PA and in Troup, TX.

Fibrous Adhesive (produced 1955 to 1972 by General Refractories Company) was a paste-like silicate cement used to hold refractory insulating block to which General added 14% chrysotile asbestos. Constituent composition of Fibrous Adhesive by weight of each constituent: 86% Sodium Silicate; 14% chrysotile asbestos. Fibrous Adhesive was sold in 1 gallon, 32 gallon, or 55 gallon drums, 24 or 36 drums per pallet.

Mute Acoustical Plaster (produced from October 1961 to May 1964 by OLC) contained approximately 15% asbestos. It was packaged for sale in 10 lb. Kraft paper sewn end bags with blue lettering.

Decorative Spray Coating, "DSC," (produced from approximately February 1969 to January 1973 by OLC) contained 16.4% asbestos, consisting of asbestos short fibers, purchased from Cary of Canada. DSC was packaged in 50 lb. bleached Kraft paper bags with red lettering. Total production of DSC was a little over 300 tons.

(e) *Additional information.* No additional information is available.

11. Georgia-Pacific Corporation

(a) *Name and address of manufacturer.* Georgia-Pacific

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Corporation, 133 Peachtree Street, N.E., P.O. Box 105605, Atlanta, GA 30348. Predecessor: Bestwall Gypsum Company.

(b) *Years of manufacture.* 1956 through 1977.

(c) *Types or classes of products.* Acoustical plaster, joint compounds, textures, and specialty products.

(d) *Other identifying characteristics.* Trowel Applied Acoustical Plaster was manufactured from 1956 to 1959. It was off-white in color, if not painted, and was applied on smooth or textured surfaces, normally ceilings. The components of this product were approximately 2.5% asbestos; 28% gypsum; and 70% pumice.

Machine Applied Acoustical Plaster was manufactured from 1958 to 1963. It was off-white in color, if not painted, and was applied on smooth or textured white surfaces; normally ceilings. The components of this product were approximately 25 to 30% asbestos; 13 to 15% clay, and 50 to 60% perlite.

Dry Mixed Joint Compound was manufactured from 1956 to 1977. It was off-white in color, if not painted, and was applied on smooth or textured white surfaces. Normally, it was applied over bedding or taping compounds over joints, fastener heads, corners, and entire areas of a gypsum board on interior walls and ceiling surfaces. The components of this product were approximately 2.5 to 7% asbestos; 50 to 90% calcium carbonate (limestone); or 80 to 90% calcium sulfate (gypsum); 5 to 20% mica; and 2 to 6% casein and/or vinyl binder(s).

Wet Mixed Joint Compound was manufactured from 1963 to 1977. It was off-white in color, if not painted, and was applied on smooth or textured surfaces. Normally the texture was applied as a taping, finishing, or texturing material over joints, fastener heads, corners and entire areas of gypsum board in walls and ceilings. The components of this product were approximately 1.5 to 5% asbestos; 45 to 70% calcium carbonate (limestone); or 45 to 70% calcium sulfate (gypsum); 5 to 10% mica; 2 to 5% vinyl binder(s); and 30 to 40% water.

Textures were manufactured from 1956 to 1974. The color appeared white to off-white with aggregate particles providing a rough surface. Normally the texture was applied as a decorative finish over drywall, sprayed-on or trowel applied. The components of this product were approximately 2 to 12% asbestos; 25 to 90% calcium carbonate (limestone), or 25 to 90% calcium sulfate (gypsum); 5 to 15% clay; 4 to 30% expanded perlite; 10 to 15% expanded vermiculite; 2% shredded expanded polystyrene; 2 to 9% casein, vinyl and/or starch binder(s); and 7 to 15% mica.

Patching was manufactured from 1956 to 1975. This product was off-white, unless painted, and smooth. It was normally applied to repair plaster cracks and holes in wall and ceiling surfaces. The components of this product were approximately 2% asbestos, and 98% calcium sulfate (gypsum).

Spackling was manufactured from 1956 to 1971. This product was off-white and smooth. It was normally applied to patch fine cracks in plaster surfaces. The components of this product were approximately 5% asbestos; 70% calcium carbonate (limestone); 16% mica; and 2 to 4.5% casein or vinyl binder(s).

Laminating Compound was manufactured in 1969. It was white to off-white in color, and was normally applied between two layers of gypsum board in special multi-layer applications. The components of this product were approximately 4% asbestos; 80% calcium carbonate (limestone); and 2 to 8% vinyl binder(s).

Drywall Adhesive was manufactured in 1972. It was white to off-white in color; and was normally applied between gypsum board and framing member. The components of this product were approximately 1% asbestos; 80% calcium carbonate (limestone); and 2 to 8% organic binder(s).

(e) *Additional information.* No additional information is available.

12. H. K. Porter Co., Inc.

(a) *Name and address of manufacturer.* H. K. Porter Co., Inc., Porter Building, Pittsburgh, PA 15219. (Predecessor of Emhart Glass of Laclede Christy Clay Products Company, P.O. Box 580, Owensville, MO 65066.)

(b) *Years of manufacture.* 1970 through 1973.

(c) *Types or classes of products.* Wet cement.

(d) *Other identifying characteristics.* Porter Bonding Mortar #20.

(e) *Additional information.* No additional information is available.

13. Kaiser Cement Corporation

(a) *Name and address of manufacturer.* Kaiser Cement Corporation, 1333 North California Blvd., Suite 445, Walnut Creek, CA 94596-1209. Formerly Kaiser Cement & Gypsum Corporation (1964 to 1979), and Permanente Cement Company (1939 to 1964).

(b) *Years of manufacture.* 1944 through 1946, and 1959 through 1979.

(c) *Types or classes of products.* Plastic gun cement, plastic cement, masonry cement, stucco.

(d) *Other identifying characteristics.* Kaiser Permanente Plastic Gun Cement (produced 1959 to 1976) was a grey powder composed primarily of portland cement and plasticizing and air-entraining agents. Sold in sacks, the product was used to make stucco for building exteriors and was applied by gun with a plastering machine. The product contained a small amount of chrysotile asbestos. Plastic gun cement was sold primarily in California, but also in several other Pacific Coast States and Nebraska.

Kaiser Permanente Plastic Cement (Hand) (produced 1961 to 1973) had the same composition and use as plastic gun cement, with the exception that it was applied manually with a trowel. The distribution area for sales of this product was the same as for the plastic gun cement.

Kaiser Permanente Masonry Cement (produced 1973) was sold in 78 lb. bags and used as mortar in building construction. The product's ingredients included a trace amount of chrysotile asbestos, probably less than 1% when product was applied, and was primarily composed of a combination of portland cement and air-entraining additives. This masonry cement was manufactured and sold in the Phoenix, AZ area.

Plastite (produced 1944 to 1945) was sold in 100 lb. sacks, and used to make manually applied stucco for building exteriors. The product was primarily composed of portland cement, adhesive, plasterizing and water repellant agents, and contained a small amount of asbestos. It was sold in Northern California and in Washington.

(e) *Additional information.* No additional information is available.

14. Kaiser Gypsum Company, Inc.

(a) *Name and address of manufacturer.* Kaiser Gypsum Company, Inc., 1333 North California Blvd., Suite 445, Walnut Creek, CA 94596–1209.

(b) *Years of manufacture.* 1952 through 1976.

(c) *Types or classes of products.* Texture paints, joint compounds, joint compound premixes, mineral fiber acoustical ceiling tile and lay-in board, specialized surface- finish products.

(d) *Other identifying characteristics.* Cover-Tex, Spray-Tex, Spray Cover-Tex, and Kaiser-Tex were produced 1952 to 1967. These texture paints were sold by the bag in dry powder form and were composed of casein, limestone, mica and a small amount of chrysotile asbestos.

Cover-Tex Wall Texture, (TSS), (produced 1968 to 1975) was similar to the other texture paints described

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above. K-Spray Ceiling Texture (KSV or KSP and KSS) were produced 1961 to 1975. Ceiling texture paints were manufactured in dry form and had the same primary composition as the texture paints described above.

Joint Compound-Powder, Finishing Compound-Powder, One-Day Joint Compound-Powder, and 3-Purpose Compound-Powder were produced 1953 to 1975. Joint compounds were sold by the bag in dry form and were primarily composed of casein or polyvinyl, clay, talc, limestone and mica, with a small amount of chrysotile asbestos.

Premix Joint Compound, Premix Finishing Compound, Dual Purpose Premix Compound, and Premix Topping Compound were produced 1959 to 1976. Joint compound premixes were sold in paste form in cartons or pails and composition was essentially the same as dry form with the addition of a liquefying agent.

Kaiser Mineral Fiberboard UL-Fire Rated (Underwriters' Laboratories, Inc. Design) was produced 1963 to 1974. Mineral fiber acoustical ceiling tile and lay-in board contained a small amount of chrysotile asbestos and was primarily composed of mineral wool and various wool fibers, clays and starch. Sold in boxes, the face side had a fissured or swirl, or pin-punched design for acoustical treatment.

"Laminating Compound," an adhesive for laminating wallboard to wallboard or to sound deadening board, was primarily composed of soya flour and limestone.

"Filler Compound," for covering radiant heat system ceiling surfaces, was primarily composed of limestone and mica.

"Radiant Heat Compound," for covering radiant heat cables stapled to ceiling surfaces, was primarily composed of sand and white portland cement.

"Radiant Heat Surfacing Compound," for covering radiant heat cables embedded in ceiling surfaces, was primarily composed of silica, flour and mica, as was "Radiant Heat Scrimless Surfacing Compound."

"Radiant Heat Joint Compound," for filling cracks and embedded tape grooves in radiant heat gypsum wallboard ceiling surfaces, was primarily composed of casein, clay, mica and limestone.

"X-Terior Premix Prefill Compound," for prefilling joints in gypsum wallboard, was primarily composed of raw gypsum, PVA emulsion and mica.

"X-Terior Premix Wall Texture Compound," for providing surface texture to gypsum wallboard installed on building exteriors only, was primarily composed of limestone, acrylic emulsion, and mica. The only form of asbestos used in these products was chrysotile.

(e) *Additional information.* No additional information is available.

15. Keene Corporation

(a) *Name and address of manufacturer.* Keene Corporation, 200 Park Avenue, New York, NY 10017. Former subsidiary: Keene Building Products Corporation ("KBPC"). KBPC's corporate predecessors: Baldwin-Ehret-Hill, Inc. ("BEH"), a Pennsylvania Corporation; Ehret Magnesia Manufacturing Company ("EHRET"), a Pennsylvania Corporation; Baldwin Hill Company ("B-H"), a New Jersey Corporation.

(b) *Years of manufacture.* 1904 through approximately 1972.

(c) *Types or classes of products.* Pipe and block covering, cement, insulation materials, insulated pipe, spray-on acoustical coverings, acoustical ceiling tiles.

(d) *Other identifying characteristics.* 85% Magnesia (Thermalite) Pipe and Block Covering (produced 1904 to 1964 by Ehret and BEH) was a molded insulation for use on hot surfaces having temperatures up to 600 °F. Little information exists on the product, and the best estimate is that it was composed primarily of magnesium carbonate (85%). Although there has been diverse testimony on the product, the best information is that up until World War II it contained 10 to 15% asbestos fiber, composed primarily of amosite and a small amount of chrysotile. Thereafter, it contained 10 to 15% amosite. It was manufactured in cylindrical sections and in curved segments. It was also made in the form of blocks. The product was packaged in corrugated cardboard boxes according to size. The remnants from the molding and shaping process were sold as 85% Magnesia Cement or Thermalite Cement for use in sealing joints between the block and pipe covering, which was packaged in multiwall open mouth paper bags in 60 lb. weights and 75 lb. barrels (85% Magnesia Cement) and in multiwall open mouth paper bags in 50 lb. weights (Thermalite Cement). Investigation of this product is ongoing.

No. 1 Plus Cement/No. 1 Cement (produced 1938 to 1971 by B– H, BEH, and KBPC) was a dry mixture of spun mineral wool granules, bentonite clay binder, chrysotile asbestos fiber (7.5%) and other ingredients. Mixed with water and applied with a trowel, it formed a thermal insulation capable of withstanding temperatures from 1,800° to 2,100 °F. Asbestos was removed from this product in 1971. The product was packaged in paper bags by 40 or 50 lb. weights. For approximately 1 year around 1970, a Military Formulation of No. 1 Plus Cement was manufactured. Investigation of this product is ongoing.

Mono-Block (produced 1941 to 1968 by B–H and BEH) was a lightweight, moisture-resistant, non-corrosive, incombustible and chemically stable insulation product. Mono-Block contained 0.95% amosite asbestos, which amount was removed in 1968. The product was packaged in corrugated cardboard boxes according to size. Investigation of this product is ongoing.

Thermasil Pipe & Block Covering and Cement (produced 1956 to 1972 by Ehret, BEH, and KBPC) was a lightweight, molded, hydrous calcium silicate insulation, manufactured from a blend of special inorganic ingredients, reinforced with amosite asbestos fibers. Although one witness testified it contained chrysotile, the best available information is that Thermasil contained approximately 10% amosite asbestos fiber from 1956 to February 1969. The amount was reduced to approximately 8.6% until 1970, when the amount was further reduced to 2%. In November 1972, all remaining amounts of asbestos fiber were removed and KBPC purchased a license to manufacture an asbestos-free calcium silicate product. The product was packaged in corrugated cardboard boxes according to size. The remnants from the molding process were sold as Thermasil cement. Investigation of this product is ongoing.

Military Formulation of Super Powerhouse Cement (produced 1957 to 1971 by B–H, BEH, and KBPC) contained 5% chrysotile asbestos and was developed to conform to government specification. This product was manufactured and sold exclusively for U.S. government military installations. The commercial formulation without asbestos continued in production. Both products were dry, mixtures containing spun mineral-wool, hydraulic setting binders, clays and other ingredients. Asbestos was removed from the military formulation in 1971. Super Powerhouse Cement was sold in dry mixture in 50 lb. bags. Investigation of this product is ongoing.

Enduro Pipe Covering and Block Cement (produced 1924 to 1955 by Ehret) consisted of specially selected pre-calcined diatomaceous earth, clays, and asbestos fibers. Enduro is believed to have contained a blend of 1.1% No. 373 chrysotile asbestos and 8.7% amosite fiber. The dry formula of this product was sold as Enduro Cement. Investigation of this product is ongoing.

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Durant Insulated Pipe (produced 1938 to 1945 by Durant) was a piping system exclusively for outdoor and underground use. Durant was metal piping insulated with 85% magnesia and then protected with a thick layer of a special high melting point asphalt which was cast inside of a heavy sheet metal jacket. Investigation of this product is ongoing.

Pyrospray Types I, T & S (produced 1963 to the early 1970's by BEH and KBPC) were packaged in multiwall open mouth paper bags in 40 or 50 lb. weights. Pyrospray Type I was a dry mixture of mineral wool, 32% chrysotile asbestos and inorganic binders and inhibitors which was mixed with water at a nozzle and applied pneumatically. Pyrospray Type T was a combination of dry mineral wool, 15% asbestos and inorganic binders and inhibitors, which was mixed with water at a nozzle and applied pneumatically. Pyrospray Type S (also known as Uni-Coustic) was a dry mixture of mineral wool, 22% chrysotile asbestos, and hydraulic setting binders and inhibitors, which was mixed with water at a nozzle and applied pneumatically. Asbestos was removed from all three types of Pyrospray prior to 1972. Investigation of these products is ongoing.

Mono-spray (produced 1963 to 1970 by BEH) was a dry-mixed blend of mineral wool with asbestos fibers and inorganic binders which was mixed with water at a nozzle and applied pneumatically. Mono-Spray contained 13% chrysotile asbestos from 1963 to 1968, and 12.5% chrysotile asbestos from 1968 to 1970. Production was terminated in 1970. The product was packaged in multiwall open mouth paper bags in 40 lb. weights. Investigation of this product is ongoing.

Mono-K (produced from 1964 to 1968 by BEH) is a high temperature insulating material which was manufactured by laminating asbestos-free mineral wool felts to Mono-Block. Mono- Block contained 0.95% amosite asbestos. Mono-K was discontinued for lack of a sales market. Investigation of this product is ongoing. Styltone AF, FR–2, and FR–3 (produced from 1957 to 1972 by B–H, BEH, and KBPC) were acoustical ceiling tiles which are believed to have contained approximately 4.3% amosite asbestos fiber. Sales of asbestos containing Styltone ceased in 1972. Styltone AF, FR–2 and FR–3 was a preformed, natural fissured, ridged mineral fiber acoustical tile for use on mechanical suspension systems. Styletone also was produced as a non-asbestos containing product from 1957 to 1975. Investigation of this product is ongoing.

(e) *Additional information.* No additional information is available.

16. Kentile Floors Inc.

(a) *Name and address of manufacturer.* Kentile Floors Inc., 58 Second Avenue, Brooklyn, NY 11215.

(b) *Years of manufacture.* 1907 through 1986.

(c) *Types or classes of products.* Resilient flooring—tiles and sheet goods.

(d) *Other identifying characteristics.* Kentile Asphalt Tile: Asbestos Filler; Standard size: 9″×9″; Thickness: ⅛″ and 3/16″ (heavy duty); Border size: 18″×24″; Edging: 1″×18″; 25 Tile Colors; 3 Styles: Regular marbleized Kentile noted for its uniform marbleization, Carnival Kentile noted for multi-color mottling, and Corktone Kentile which has a cork look.

KenFlex Vinyl Asbestos Tile: Blend of vinyl and asbestos fibers; Size: 9″×9″; Thickness: 1/16″ and ⅛″ (heavy duty); Styles include: Regular, Carnival, Corktone, Terrazzo Style, Woven Tones, Woodgrain KenFlex Vinyl Asbestos Tiles.

Kentile Vinyl Sheet Flooring: Styles vary in width of rolls and thickness.

(e) *Additional information.* Additional information is available.

17. Mannington Mills, Inc.

(a) *Name and address of manufacturer.* Mannington Mills, Inc., P.O. Box 30, Salem, NJ 08079.

(b) *Years of manufacture.* 1963 through 1983.

(c) *Types or classes of products.* Cushioned vinyl floor covering sheet goods, counter top coverings.

(d) *Other identifying characteristics.* The following styles of cushioned vinyl floor covering sheet goods contained asbestos backing: Royal Air (produced from approximately 1967 to 1977; unavailable 1967, 1968, 1977, and 1978); Marquis (produced from approximately 1968 to 1983); Vinyl-Ease 100 (produced from approximately 1968 to 1983; unavailable 1971 and 1973); Million Air (produced from approximately 1970 to 1983); Vega (produced from approximately 1970 to 1983; unavailable 1971 and 1973); Aristocon (produced from 1974 to 1983); Lustrecon (produced from approximately 1976 to 1983); Classicon (produced from approximately 1975 to 1983; unavailable 1976); Decora (produced from approximately 1975 to 1983; unavailable from 1976 to 1983); Architect's Choice (produced from 1977 to 1983; unavailable 1977); Duracon (produced 1981 to 1983); Special "Y" (produced 1980 to 1981; unavailable 1980 and 1981); Price Buster (produced 1981 to 1983; unavailable 1981 to 1983); Boca (produced 1983; unavailable).

The following styles from Mannington Mills Inc.'s Vinyl-1 line contained asbestos backing: Estoril (produced 1967 to approximately 1970; unavailable 1967 and 1968); Laurentian (produced 1966 to approximately 1970; unavailable 1967 to 1969); Tahiti (produced 1963 to 1967; unavailable 1963, 1965 to 1967); Pebble Beach (produced 1963 to 1971; unavailable 1963, 1967 to 1971); Castanet (produced 1964 to approximately 1970; unavailable 1967 to 1970); Costa Bella (produced 1966 to 1971; unavailable 1966 to 1968, and 1971); Marvel Air (produced 1969 to 1971; unavailable 1971); Villa Madrid (produced 1969 to 1971; unavailable 1971).

The following styles of Mannington Mills, Inc. products also contained asbestos: Counter Top (produced 1963 to 1972; unavailable 1971 and 1972); Casina (produced 1969 to 1971; unavailable 1969 to 1971); Sea Isle (produced 1969 to 1971; unavailable 1969 to 1971); Marvel Air (produced 1969 to 1971; unavailable 1971).

(e) *Additional information.* Additional information is available.

18. Manville Corporation

(a) *Name and address of manufacturer.* Manville Corporation, P.O. Box 5108, Denver, CO 80217 (1982 to the present). Predecessor: Johns Manville Corporation, Ken-Caryl Ranch, Denver, CO 80217 (1972 to 1981), 22 East 40th Street, New York, NY 10016 (1907 to 1971).

(b) *Years of manufacture.* 1891 through 1983.

(c) *Types or classes of products.* Packing, insulation, construction materials, friction materials, asbestos-cement pipe, and asbestos fiber.

(d) *Other identifying characteristics.* Chempac: 2012, 2011, 2009, 2008, 2006, 2013, 2014, 2024, 2005, 2004, 587, and Valve Stem Packing (produced 1891 to 1983) was a packing which contained white asbestos yarns, 0 to 90%; blue asbestos yarns, 0 to 90%, commercial grade T asbestos, 0 to 90%; TFE, 0 to 10%; mineral oil, 0 to 1%; wax and oil, 0 to 1%. Description: braid-over-braid, square cross section; braided in the interlocked pattern; twisted to form a round cross section.

Interlocked: 255, 253, 263, 270, 257, 254, 2009 (produced 1891 to 1983) was a packing which contained white asbestos yarns, 60 to 98%; petroleum base wax, 0 to 35%; petroleum base oil, 0 to 1%; neoprene cement, 0 to 35%; inorganic fillers, 0 to 10%; copper wire 0 to 10%; graphite finish, 0 to 1%. Description: square cross section; a resilient braided packing, its construction of interlocking

braided asbestos yarn prevents unraveling or coming apart.

Centripac: 4, 7, 11, 18, 19, 2018, 2021, 2036, 350, 351, 2022 (produced 1891 to 1983) was a packing which contained white asbestos yarns, 0 to 90%; blue asbestos yarns, 0 to 90%; petroleum base wax, 0 to 35%; petroleum base oil, 0 to 1%; mineral oil, 0 to 2%; inorganic fillers, 0 to 10%; lead ribbon, 0 to 10%; copper wire, 0 to 10%; graphite finish, 0 to 1%. Description: square plaited cross section.

Thermacore: 398, 397, 399 (produced 1891 to 1983) was a packing which contained white asbestos yarns, 50 to 90%; inconel wire, 0 to 10%; neoprene, 0 to 30%; mica, 0 to 1%; graphite finish, 1 to 2%. Description: braid-over asbestos/plastic core, with a square cross section.

Rajah: 6, 2 (produced 1891 to 1983) was a packing which contained white asbestos yarns, 95 to 98%; natural and buna-S rubbers, 0 to 2%; graphite finish, 1 to 2%. Description: braid-over-braid, with square or round cross-section.

Mogul: 223, 222 (produced 1891 to 1983) was a packing which contained white asbestos yarns, 95 to 98%; light petroleum base oil, 1 to 2%; graphite finish, 1 to 2%. Description: braid-over-braid, and calendered to a square cross-section.

Braided: 2020, 10 Jewett, 55, 2053, 323, 14, 322, 2017 (produced 1891 to 1983) was a packing which contained white asbestos yarns, 0 to 98%; blue asbestos yarns, 0 to 98%; petroleum base waxes, 0 to 2%; petroleum base oils, 0 to 2%; inert inorganic fillers, 0 to 2%; copper wire, 0 to 5%; lead ribbon, 0 to 10%; neoprene base cement, 0 to 5%; graphite finish, 0 to 2%. Description: Braid-over-braid, and calendered to a square cross-section.

Asbestos-metallic: 344, 360, 379, 392, 393 (produced 1891 to 1983) was a packing which contained white asbestos yarns, 25 to 60%; blue asbestos yarns, 25 to 60%; copper mesh, 45 to 60%; antimony-lead ribbon, 45 to 60%; lead-alloy ribbon, 45 to 60%; aluminum foil, 45 to 60%; lead foil, 45 to 60%, petroleum base oil, 0 to 2%; hydrocarbon waxes, 0 to 2%; graphite, 1 to 2%. Description: constructions include braid-over-braid, square plaited twisted foil, knitted mesh, spiral and others.

Asbestos fabrics: 166 Kearsarge, 167 Superheat Steam, 168 Kearsarge (produced 1891 to 1983) were packings which contained asbestos cloth, 90 to 94%; natural and buna-S rubber compound, 5 to 8%; graphite finish, 0 to 2%; mica, 0 to 1%. Description: Square cross-section.

Groove: 17, 790, 872, 216 (produced 1891 to 1983) was a packing which contained white asbestos yarns, 98 to 100%; copper wire, 1 to 2%; copper wire mesh, 0 to 2%; buna-S cement, 0 to 1%; graphite finish, 0 to 1%. Description: braided, square, or rectangular cross-section.

Inconel mesh core groove: 164, 163 (produced 1891 to 1983) was a packing which contained asbestos yarns, 90 to 94%; inconel mesh, 5 to 10%, buna-S and neoprene cement, 0 to 5%; viton cement, 0 to 5%; graphite finish, 0 to 2%. Description: asbestos cloth wrapped around inconel core, form to a square or rectangular form.

Folded groove: 176, 177, 128, 129 (produced 1891 to 1983) was a packing which contained asbestos cloth, 94 to 98%; buna-S cement, 0 to 4%; copper wire, 0 to 2%. Description: asbestos cloth wrapped around asbestos rope, or asbestos folded core, in square or rectangular cross-section.

165 Moulded autoclave packing (produced 1891 to 1983) was a packing which contained asbestos yarns, 90 to 94%; buna-S and neoprene rubbers, 3 to 6%; inconel wire, 1–5 to 4%. Description: variety of cross-sectional shapes. Supplied also in rings.

124 Tubular gasketing (produced 1891 to 1983) was a packing which contained asbestos cloth, 94 to 96%; brass wire, 2 to 4%; lead insert, 2 to 4%; natural and buna-S rubber cement, 2 to 4%. Description: round cross-section with hollow core.

Thermo-Pac rope: 500, 750, 1000, Blue (produced 1891 to 1983) was a packing which contained asbestos fibers, 0 to 100%; blue asbestos fiber, 0 to 98%; nylon thread, 0 to 1%. Description: soft, twisted, felted strands.

Braided rope: 566, 702, 733, 787, 788, 873, 857, 869 (produced 1891 to 1983) was a packing which contained 95 to 98% asbestos fibers. Description: braided jacket over twisted core, or jacket, with round or square cross-section.

Asbestos wick: 4180, 4197, 4198, 4199, 195, 535 (produced 1891 to 1983) was a packing which contained 95 to 99% asbestos fibers. Description: twisted strands of rovings or felted strips of asbestos, ¼" to ⅜" in size. Twisted rope: 4185, 4186, 4188, 4196, 4200 (produced 1891 to 1983) was a packing which contained 95 to 99% asbestos fibers. Description: asbestos roving twisted together, into ⅜" and up.

Gasketing tape: 122, 121, 119, 2032, 132, 131, 142, 141, Besto-Tak, 120 (produced 1891 to 1983) was a packing which contained asbestos fibers, 80 to 98%; natural and buna-S rubber cement, 0 to 4%; TFE, 0 to 5%; silicone cement, 0 to 5%; adhesive backing. Description: Strip of woven or folded asbestos material sometimes wire-inserted and impregnated with sealants; used to seal joints or closure in mechanical equipment; for applications where design does not permit use of cut or preformed gaskets.

Tadpole tapes: 123, 191, 150, 151, 152, 153, 154, 155, 156, 157, 160, 192 (produced 1891 to 1983) were packings which contained asbestos rope, 0 to 30%; asbestos cloth, 50 to 70%; brass wire, 0 to 5%; inconel mesh, 0 to 5%; inconel wire, 0 to 5%; natural and buna-S rubber, 0 to 10%; neoprene base compound, 0 to 10%; silicone rubber, 0 to 10%; aluminum finish, 0 to 2%; teflon suspensoid, 0 to 5%. Description: Tadpole packing is made by wrapping a core with asbestos cloth cover. The edges of the cloth are stitched or cemented together to form a tail structure.

Compressed asbestos sheets: style 60, 61, 70, 70C, 71, 78, 86A, 52, 76 (produced 1891 to 1983) were packings which contained white chrysotile asbestos, 60 to 80%; SBR rubber compound, 0 to 20%; neoprene compound, 0 to 20%; nitrile, buna-N compound, 0 to 20%. Description: compressed asbestos sheets, with thickness from 1/64" to ¼".

Felted asbestos sheets: 219, 83 B (produced 1891 to 1983) were packings which contained white chrysotile asbestos, 95 to 98%; inorganic binder, 2 to 5%. Description: asbestos sheets, with thicknesses from ⅛" to ½".

Flexible asbestos firewall sheets: 95, 96, 89, 88 (produced 1891 to 1983) were packings which contained asbestos fabric, 90 to 98%; brass wire, 0 to 2%, inconel, 0 to 2%, neoprene compound, 0 to 10%; fluoro elastomer compound, 0 to 10%. Description: flexible flameproof asbestos sheets, supplied in three thicknesses: 3/64", 1/16", ⅛".

Asbestos textiles (produced 1891 to 1983) were packings which contained carded asbestos fibers, 97 to 98%; cotton fiber, 0 to 2%; rayon fiber, 0 to 2%. Description: asbestos fiber twisted, woven or felted into cloth, yarn, tape, tubing, etc.; usually a small percentage of organic fiber such as cotton or rayon is woven in with the asbestos.

Molded packings: Conepac, Cumpac, Uneepac, O-ring, V-ring, Clipper seal (produced 1891 to 1983) were packings which contained asbestos fibers, 0 to 40%; elastomer compound, 0 to 40%; natural rubber compound, 0 to 40%; inorganic fillers, 0 to 20%. Description: packing precision-molded from rubber compounds, often combined with asbestos fiber, cotton duck, etc. Furnished in three basic shapes: Type "A", Type "U", and hat-shaped.

Clutch facings: HDM, STM, Spiral Wound, Gear Tooth, SWAB, UHS, Asbestos-Metallic (produced 1892 to 1972) were friction materials which contained asbestos fiber, 40 to 50%;

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friction particles, 20 to 30%; brass chips, 2 to 10%; phenol-elastomer compound, 15 to 25%. Description: Metallic facings designed for truck, car and other industrial applications. They are engineered to resist high temperatures, fade or slipping and wear on mating surfaces; has good spin strength and torque capacity.

Brake blocks: high, medium and low friction levels, Asbestos Metallic, Trailiners, Trukliners (produced 1892 to 1972) were friction materials which contained asbestos fiber, 20 to 30%; brass chips, 10 to 15%; phenol-elastomer compound, 40 to 50%. Description: molded blocks of friction element for commercial service on trucks, buses, and industrial equipment.

Brake linings: Custom Four Star, WK (produced 1892 to 1972) were friction materials which contained asbestos fiber, 45 to 60%; friction particles, 20 to 30%; phenol-elastomer compound, 30 to 40%. Description: molded materials that can be drilled, bonded, and rivetted on braking shoe for cars and trucks.

Railroad brake block and lining: Cobra (produced 1892 to 1980) were friction materials which contained asbestos fiber, 45 to 60%; friction particles, 0 to 30%, metallic chips, 0 to 10%; phenol-elastomer compound, 40 to 50%. Description: an incombustible mineral, found in nature, which separates into fibers. Sold in fiber form packaged in bags.

Transite Ring-Tite water pipes (produced 1929 to 1983) were asbestos-cement pipes which contained asbestos fibers, 15 to 25%; silica flour, 25 to 35%; portland cement, 45 to 55%. Description: asbestos-cement pipes of various diameter sizes.

Transite electrical ducts: Conduit Type II, Korduct Type II (produced 1929 to 1983) were asbestos-cement pipes which contained: asbestos fibers, 15 to 25%; silica flour, 25 to 35%, portland cement, 45 to 55%. Description: asbestos-cement pipes from 2" in diameter to 6" in diameter.

Transite telephone ducts (produced 1902 to 1983) were asbestos-cement pipes which contained: asbestos fibers, 15 to 25%; silica flour, 25 to 35%; portland cement, 45 to 55%. Description: asbestos-cement pipes from 2" in diameter to 6" in diameter.

Magnesia, 85% High Temperature Insulation: Pipe covering and block form (produced 1902 to 1970) was an insulation which contained: asbestos fibers, 12 to 18%; ground clay, 2 to 5%; basic magnesia carbonate, 85 to 90%. Description: white pipe covering and block form.

Superex M & Superex 1900: Pipe covering and block form (produced 1922 to 1972) was an insulation which contained asbestos fibers, 8 to 14%; celite, 55 to 60%; magnesia, 25 to 35%. Description: grey-white pipe covering and block forms, used for high temperature insulation.

Thermobestos: Pipe covering and block form (produced 1939 to 1973) was an insulation which contained asbestos fibers, 5 to 10%; diatomaceous earth, 45 to 50%; quicklime, 40 to 46%. Description: white pipe covering and block forms.

Asbestos Millboard: C, 101, 102, 103, 104, 105, 106, 106–B, 106–H, 219, Type A, XXX (produced 1878 to 1980) was an insulation which contained asbestos fibers, 65 to 75%; clay and lime, 15 to 25%; starch, 2 to 8%; sodium silicate, 2 to 5%. Description: sheets or board furnished in thicknesses 1/32" to 1/2".

Asbestos-Binder cements: 0352, 300, 301, 302, 304, 319, 340, 352, 364, 400, 450, 500, 678, Superex, 85% Magnesia (produced 1930 to 1973) was an insulation which contained asbestos, 10 to 100%; diatomaceous earth, 0 to 30%; clay, 0 to 30%; portland cement, 0 to 30%; mineral wool, 0 to 30%. Description: off-white to grey in color. Packaged in cans or pails.

Putty-like Sealing Compound: Albaseal, Body Sealer, Branchtite, Duxseal, Nordseal, Stove Putty, TranolSeal, Navaseal, Uniseal (produced 1957 to 1977) was an insulation which contained asbestos, 25 to 65%; butane polymer, 0 to 40%; calcium carbonate, 0 to 20%; titanium dioxide, 0 to 5%; carbon black, 0 to 1%; castor oil, 0 to 40%; magnesium oxide, 0 to 1%; chlorinated paraffin, 0 to 55%; stearic acid, 0 to 1%. Description: Pugs-packaged in fiberboard cartons.

Asbestos Pipe Blanket (produced 1898 to 1960) was an insulation which contained asbestos fiber, 95 to 98%. Description: blanket.

Asbestos Roll Fire Felt: Vitro Firefelt, Gold Line (produced 1891 to 1973) was an insulation which contained asbestos fiber, 95 to 98%. Description: felt.

Asbestos Sponge Felted (produced 1890 to 1961) was an insulation which contained asbestos fiber, 95 to 98%. Description: felt. Asbestos Turbine Blankets (produced 1951 to 1973) were insulation which contained asbestos fiber, 95 to 98%; stainless steel tufting discs, 1 to 2%; monel wire, 1 to 2%. Description: blanket.

Asbestos Weatherproof Felt: 50 Asbestos Weatherproofing, 15A Asbestos Jacket, 45A Asbestos Jacket, 7700 Coated Asbestos Jacket (produced 1931 to 1969) was an insulation which contained asbestos fiber, 95 to 98%. Description: felt and jacket.

White Surface Asbestos Jacket (produced 1931 to 1968) was an insulation which contained asbestos fiber, 95 to 98%. Description: felt.

Asbestos Felts-Corrugated: Vitrobestos, VitroFire Felt (produced 1907 to 1959) was an insulation which contained asbestos fiber, 95 to 98%. Description: corrugated felt.

Neoprene coated asbestos: Thermotape, Thermowrap (produced 1951 to 1964) was an insulation which contained asbestos fiber, 95 to 98%; neoprene, 2 to 5%. Description: neoprene coated pad and blanket.

Asbestos Firefelt, Asbestos Firetard (produced 1891 to 1962) was an insulation which contained asbestos, 95 to 98%; inorganic binder, 2 to 5%; asphalt, 0 to 10%. Description: asbestos felt.

Asbestos paper and rollboard: Armaturo, Doublex, Fibroid, Long Fiber, Microbestos, Non-Burn, Welding Paper (produced 1900 to 1965) was an insulation which contained asbestos, 40 to 99%; inorganic binder, 1 to 60%.

Fibrous adhesive (produced 1930 to 1981) was an insulation which contained asbestos fiber, 15 to 20%; sodium silicate, 80 to 85%. Description: off-white liquid, packaged in cans, pails, or drums.

Refractory cement: Firelite Furnace Cement, Heat Treating Cement (produced 1954 to 1973) was an insulation which contained asbestos fiber, 1 to 3%; silica sand, 55 to 65%; sodium silicate, 25 to 35%; clay, 4 to 6%; water, 1 to 3%. Description: liquid, packaged in cans, pails, or drums.

Asbestos Bitumen cement: Insulkote, Duplex, Asbestile, Laptite (produced 1952 to 1984) was an insulation which contained asbestos fiber, 5 to 10%; asphaltic emulsion, 0 to 30%; limestone, 0 to 20%; clay, 0 to 3%, asphalt, 0 to 45%; mineral spirits, 0 to 35%. Description: black thick liquid, packaged in cans, pails, or drums.

Asbestos calcium silicate sheet: Marimet 45, Marinite, Marinite 23, 36, 65, Metal Veneered, Veneered, Molten Metal, Imperial, Heat Treated 30 (produced 1936 to 1978) was an insulation which contained asbestos fiber, 25 to 65%; lime, 20 to 36%, diatomaceous earth, 20 to 35%; clay, 10 to 15%. Description: grey-brownish sheet.

Molded: Min-K 1301, 2000, 500, Min-Klad; Blanket: Min-K Flexible, High Temp, Standard (produced 1958 to 1974) was an insulation which contained asbestos fiber, 5 to 20%; colloidal silica, 70 to 80%; carbon black, 0 to 10%; titanium dioxide, 0 to 20%; phenol-formaldehyde resin, 0 to 6%; silicon metal powder, 0 to 20%; glass clothes, 0 to 30%; glassfiber thread, 0 to 4%.

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Description: solid form for molded Min-K and flexible blankets.

Electrical insulation paper and millboard: Quinorgo, Quinorgobord, Quinterra, Quinterrabord, Quintex, Quintexbord (exact date manufacture began is unknown; manufactured up to 1975) was an insulation which contained asbestos fiber, 80 to 95%; starch, 8 to 12%; kraft pulp, 0 to 10%; nitrile rubber, 0 to 10%. Description: paper and board that has good electrical insulation properties.

Marinite veneer-aluminum: Reeferite (produced 1950 to 1974) was an insulation which contained asbestos fiber, 25 to 35%; portland cement, 40 to 45%; silica, 25 to 30%; aluminum sheet, 1 to 3%. Description: solid sheet.

Molded Insulation: Sonite (produced 1969 to 1974) was an insulation which contained asbestos fiber, 3 to 8%; colloidal silica, 85 to 95%; phenol-formaldehyde resin, 3 to 8%. Description: Molded solid used for acoustical insulation.

Molded felt sheet and molding compound: Thermomat (produced 1963 to 1970) was an insulation which contained asbestos fiber, 90 to 98%; phenol-formaldehyde resin, 2 to 5%. Description: in sheet or tape form.

Asbestos cement sheet: Marine Veneer, Pallite, Transite Core Plate, Dekeran Transite Board (produced 1938 to 1978) was an insulation which contained asbestos fiber, 5 to 50%; portland cement, 40 to 45%; silica, 25 to 30%. Description: asbestos- cement sheet or board.

Asbestos-cement: corrugated and flat transite, transite acoustical panel (produced 1930 to 1982) was a construction product which contained asbestos fiber, 25 to 35%; portland cement, 40 to 45%; silica, 25 to 30%.

Asbestos-cement Architectural Panel: Splitwood, Stonehenge, Transitop, Transifoam, Thermocore, Thermostone, Agean, Santone (produced 1907 to 1982) was a construction product which contained asbestos fiber, 25 to 50%; portland cement, 30 to 50%; silica, 10 to 15%; pigment, 2 to 10%; wood fiber 0 to 25%; asphaltic compounds, 0 to 25%; expanded polystyrene board, 0 to 10%, fesco board, 0 to 10%. Description: Gray or colored, flat or perforated panels.

Asbestos-cement extrusion products: ACE Stone, Colorsil, Corspan, Facespan (produced 1907 to 1976) were construction products which contained asbestos fiber, 25 to 50%; portland cement, 30 to 50%; silica, 10 to 15%. Description: Flat or wedge shaped window sills, stools.

Asbestos-cement sheet: Asbestoboard, Asbestos Ebony, Chemstone, Colorceran, Colorlith, Electrobestos, Flexboard (produced 1934 to 1987) was a construction product which contained asbestos fiber, 40 to 70%; portland cement, 15 to 50%; dry asphalt size, 0 to 8%; pigment, 0 to 12%. Description: Gray or colored smooth sheets or boards.

Asbestos-cement shingles: Cedargrain, Salem Colonial, Salem American, Durosbestos, Rock-Shakes, Western Shade Corrgrain, Deepgrain, Trugrain (produced 1907 to 1976) was a construction material which contained asbestos fiber, 15 to 30%; portland cement, 20 to 60%; silica, 15 to 50%; pigment, 5 to 10%. Description: roof and sidewall shingles.

Asbestos Roofing felts: Centurian, Blue Chip Felts, Asbestos finishing felts, coated asbestos base felts, ventsulation felts (produced 1907 to 1979) was a construction product which contained asbestos fiber, 50 to 70%; asphalt saturant, 30 to 50%; inorganic filler, 0 to 10%; sand, 0 to 20%. Description: asphalt-impregnated asbestos felts.

Asbestos-asphalt roofing shingles: Fire-Glass Seal-O-Matic, Fire-King Seal-O-Matic, Flexbetos, FGA, Townsend Seal-O-Matic (produced 1907 to 1979) were construction products which contained asbestos fiber, 30 to 50%; fiberglass, 20 to 40%; asphalt saturant, 30 to 50%; inorganic filler, 0 to 5%; sand, 0 to 10%. Description: asphalt-impregnated asbestos-fiberglass- reinforced shingles.

Asbestos-vinyl floor tile: Terraflex, Terraschip, Allegro, Seastone, Granada, Larado, Abode (produced 1933 to 1969) was a construction product which contained asbestos fiber, 30 to 50%; Gilsonite, 5 to 15%; Vinyl resin, 20 to 30%; plasticizer, 10 to 20%; inorganic fillers, 20 to 40%; pigments, 0 to 20%. Description: vinyl floor tiles of various colors and design backed with asbestos reinforced asphalt adhesive. Asbestos fiber available in over 60 standard and special grades. Each designation defines a distinct grade that is suitable for certain industrial applications. These grades are further defines as to textural characteristics. It is used in a variety of products such as textiles, paper, plastics, cement products, friction materials, coatings, caulkings, to name a few. Produced 1912 to 1983. Contained 80 to 100% asbestos fiber. Description: Asbestos fiber is inorganic, fibrous, strong, flexible, and nonflammable. It bulks, reinforces, adds flexibility, provides dimensional stability, and resists time, weather, and fire.

(e) *Additional information.* No additional information is available.

19. National Gypsum Company

(a) *Name and address of manufacturer.* National Gypsum Company, 4500 Lincoln Plaza, 500 North Akard Street, Dallas, TX.

(b) *Years of manufacture.* 1933 through 1972.

(c) *Types or classes of products.* Acoustical plasters, acoustical treatment, fireproofing.

(d) *Other identifying characteristics.* Rockwall Acoustic Plaster (produced 1936 to 1940) contained the following ingredients: molding plaster, 35.5% (by weight); pumice, 53.2%; asbestos, 6.4%; cork, 2.5%; retarder, 2%, fiber, 2.1%.

Standard Gold Bond Macoustic (produced 1933 to 1936) contained the following ingredients: asbestos, 39.90% (by weight); rock wool, 9.98%; slag, 24.94%; stucco, 24.94%; aluminum sulphate, 0.05%; retarder, 0.20%. This product was available in colors; the pigments used are not listed in the above formula or accounted for in calculations.

New Smooth Trowel Finish Macoustic (also called New Trowel Finish Macoustic and Trowel Finish Macoustic) had varied formulations. The formula for September 27, 1935 was: pumice, 34.94% (by weight); cork, 11.98%; asbestos, 17.97%; hydrated finish lime, 24.96%; keenes cement, 9.99%; soap bark powdered, 0.15%. The formula for October 8, 1936 was: pumice, 35.95% (by weight); cork, 11.98%; asbestos, 3.99%; hydrated finish lime, 29.96%; keenes cement, 14.98%; soap bark powdered, 0.15%; ground paper, 1.50%; wood fiber, 1.50%. The formula for March 8, 1937 was: pumice, 35.30% (by weight); cork, 11.98%; asbestos, 5.99%; hydrated finish lime, 29.96%; keenes cement, 14.98%; soap bark powdered, 0.15%; ground paper, 1.50%; wood fiber, 1.50%. The formula for October 7, 1943 was: pumice, 42.42% (by weight); cork, 14.47%; asbestos, 7.49%; hydrated finish lime, 12.47%; keenes cement, 18.71%; ground paper, 1.88%; wood fiber, 1.88%; Nacconal Hg, 0.19%. This product was available in colors; pigments used are not listed in the above formulas or accounted for in calculations.

Macoustic Plaster (produced 1942 to 1947) had varied formulations over the years. The formula for October 5, 1942 was: moulding plaster, 33.47% (by weight); pumice, 54.39%; asbestos, 10.88%; wood fiber, 0.84%; Naccanol Hg, 0.16%; retarder, 0.25%. The formula for January 23, 1946 was: moulding plaster, 29.24% (by weight); pumice, 62.38%; asbestos, 5.85%; wood fiber, 2.34%; retarder, 0.16%; Duponol Me Dry, 0.04%. The formula for February 18, 1946 was: moulding plaster, 29.43% (by weight); pumice, 60.17%; asbestos, 7.85%; wood fiber, 2.35%; retarder, 0.16%; Duponol Me Dry, 0.04%. The formula for December

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30, 1947 was: moulding plaster, 28.62% (by weight); pumice, 61.07%; asbestos, 7.63%; wood fiber, 2.29%; powdered locust gum, 0.25%; arctic syntex M beads, 0.08%; Dowicide G, 0.05%. This product was available in colors; the pigments are not listed in the above formulas or accounted for in calculations.

Perlite Macoustic (also called Perlite Acoustical Plaster and Acoustical Plaster) contained the following ingredients: stucco, 48.63% (by weight); asbestos, 12.97%; wood fiber, 3.89%; perlite, 33.72%; powdered locust gum, 0.43%; arctic syntex M beads, 0.27%; Dowicide G, 0.08%; retarder, as required. This product was available in colors; pigments used are not listed in the above formula or accounted for in calculations.

Thermacoustic (produced 1949 to 1957) had varied formulations. The formula for August 10, 1949 was: mineral wool, 80% (by weight); asbestos, 12%; starch, 8%. The formula for December 22, 1949 was: mineral wool, 79.84% (by weight); asbestos, 11.98%; starch, 7.98%; cut fungicide, 0.2%. The formula for January 24, 1951 was: mineral wool, 70.67% (by weight); asbestos, 18.90%; portland cement, 4.52%; starch, 5.75%; cut fungicide, 0.16%. The formula for January 12, 1953 was: mineral wool, 70.67% (by weight); asbestos, 18.90%; portland cement, 4.52%; starch, 4.96%; cut fungicide, 0.99%. The formula for August 23, 1956 was: mineral wool, 65.09% (by weight); asbestos, 21.16%; portland cement, 4.88%; starch, 2.85%; cut fungicide, 1.22%; diethylene glycol, 1.95%; vegetable cellulose adhesive, 2.85%.

Fire-Shield Plaster (produced 1958 to 1970) was also known as Steel Deck Fireproofing Plaster for Spray. The product had varied formulations over the years. The formula for August 27, 1958 was: perlite, 36.89% (by weight); stucco, 50.44%; asbestos, 12.61%; Monad G, 0.05%. The formula for February 4, 1959 was the same. The formula for April 11, 1960 was the same, except for the asbestos content, which increased to 24.37% (by weight), and the Monad G content, which increased to 0.06%. The formula for May 1, 1968 was the same. The formula for September 30, 1968 was: perlite, 23.74% (by weight); stucco, 50.23%; asbestos, 24.35%; bentonite, 1.52%; Monad G, 0.15%.

White Spray-On Acoustical Plaster (produced 1955 to 1956) had two formulations. The formula for October 6, 1955 was: perlite, 59.32% (by weight); bentonite, 15.21%; asbestos, 7.60%; limestone, 15.21%; titanium dioxide, 2.09%; Monad G, 0.57%. The formula for December 15, 1955 was: perlite, 59.04%; bentonite, 15.14%; asbestos, 7.57%; limestone, 15.14%; titanium dioxide, 2.08%; Monad G, 0.57%; sodium nitrite, 0.47%.

Superwhite Sprayolite (produced 1956 to 1968) had varied formulations. The formula for April 6, 1956 was: perlite, 59.04% (by weight); bentonite, 15.14%; asbestos, 7.57%; calcium carbonate, 15.14%; asbestos, 7.57%; calcium carbonate, 15.14%; titanium dioxide, 2.08%; Monad G, 0.57%; sodium nitrate, 0.47%. The formula for September 3, 1956 was: perlite, 58.87% (by weight); bentonite, 15.09%; asbestos, 7.55%; calcium carbonate, 15.09%; titanium dioxide, 2.08; Monad G, 0.57; sodium nitrite, 0.47%; boric acid, 0.28%. The formula for January 21, 1958 was the same. The formula for March 27, 1958 was: perlite, 63.20% (by weight); bentonite, 13.50%; titanium dioxide, 1.86%; Monad G, 0.51%; sodium nitrate, 0.42%; boric acid, 0.25%. The formula for July 30, 1958 was perlite, 58.37% (by weight); bentonite, 12.47%; asbestos, 9.35%; calcium carbonate, 18.71%; Monad G, 0.47%; sodium nitrite, 0.39%; boric acid, 0.23%.

Gold Bond Acoustical Plaster Type C (produced 1952 to 1956) was also called Gold Bond Acoustical Plaster High Humidity. The formula for this product was: asbestos, 6.95% (by weight); Monad G, 0.35%; white portland cement, 23.17%; pumice, 69.52%.

(e) *Additional information.* Additional information is available.

20. Owens-Corning Fiberglas Corporation

(a) *Name and address of manufacturer.* Owens-Corning Fiberglas Corporation ("OCF"), Fiberglas Tower, Toledo, OH 43659.

(b) *Years of manufacture.* 1938 through 1972.

(c) *Types or classes of products.* Asbestos paper facing for blankets of fiberglass insulation, asbestos yarn ties, high temperature insulation, insulating cement, finishing cement.

(d) *Other identifying characteristics.* Blankets of fiberglass insulation with an asbestos paper facing were produced 1938 to 1941. OCF did not manufacture the asbestos paper, but offered, as a special order option, to sew it on to blankets of its fiberglass insulation.

Asbestos yarn ties were produced 1938 to approximately 1952. OCF sold fiberglass blankets which had a metal mesh attached to the blanket. The metal mesh was affixed to the fiberglass insulation blanket by wire ties. Yarn ties were offered as a special order option for this product.

Kaylo high temperature insulation (produced 1958 to 1972) contained 15% asbestos, quicklime, silica, diatomaceous earth, clay, chromite, limestone, and sodium silicate.

Unarcoboard, later called Fyrcor, (produced 1970 to 1972) was a high temperature industrial insulation, produced in sheet form. It contained a small amount of amosite asbestos and was generally grayish/white in color.

Insulating cement (produced for 6 months in 1951) may have contained asbestos. The modulated insulation was dry mixed with refractory type materials.

Asbestos-containing finishing cement (produced 1940 to 1949) was a light density fibrous material combined with asbestos fibers and suitable binders.

(e) *Additional information.* No additional information is available.

21. Pfizer Inc.

(a) *Name and address of manufacturer.* Pfizer Inc., 235 East 42nd Street, New York, NY 10017. Predecessor: Gibsonburg Lime Products Co. (GLPC).

(b) *Years of manufacture.* January 19, 1962 through December 31, 1964 by GLPC; December 31, 1964 through approximately December 31, 1972 by Pfizer Inc.

(c) *Types or classes of products.* Kilnoise acoustical ceiling plaster.

(d) *Other identifying characteristics.* The formula for Kilnoise was 89.1% hydrated dolomitic lime, 9.9% chrysotile asbestos, 0.25% fiberglass, and 0.75% Duponol (sodium lauryl sulfate). Kilnoise was a white (on rare occasions, cream or buff) powder mixed with water, then trowelled on by hand over gypsum brown coat. After being applied to approximately ¼" thickness, Kilnoise was brush stippled and nail perforated by hand while wet, and then allowed to dry to a hard, uniformly textured surface, which could thereafter be painted if desired. Kilnoise was not a spray-on insulation material.

Rapid screening test: To a 300-mg sample of the building material add 2 to 3 drops of dilute (1 N) hydrochloric acid. If there is not an immediate evolution of gas (carbon dioxide), the sample is not Kilnoise and no further testing is necessary. (Note: If there is only a very small amount of gas evolution, the binder may contain hydrated lime that has reacted with carbon dioxide in the air to form small amounts of carbonate. Lime- based material, however, may be differentiated from dolomitic material on the basis of its greater alkalinity.)

(e) *Additional information.* Additional information is available.

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22. Rhone-Poulenc Ag Company

(a) *Name and address of manufacturer.* Rhone-Poulenc Ag Company, or "Rhone-Poulenc", P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. Predecessor: Achem Products, Inc., formerly American Chemical and Paint Company and Benjamin Foster Company (office address from 1930 to 1946: 1411 Walnut Street, Philadelphia, PA), (factory address from 1930 to 1946: 31st Street and Magazine Lane, Philadelphia, PA), (office and factory address 1946 to 1976: 4635–37 West Girard Avenue, Philadelphia 31, PA).

(b) *Years of manufacture.* Early 1930's through 1976.

(c) *Types or classes of products.* Adhesives, coatings and sealants, and mastics.

(d) *Other identifying characteristics.* The following products which contained small amounts of encapsulated asbestos were manufactured and sold by the Benjamin Foster division of Amchem Products, Inc. and/or its predecessors in interest and may have been used in the construction industry:

Adhesives: Thermas Extruded Heat Transfer Cement (designed 1955); Black Spot Adhesive (designed 1959); INSULFAS (designed 1941); Fibrous Adhesive (designed 1942, 1966, 1957); Fire Resistive Adhesive (designed 1943); Fire Resistive Insulation Adhesive (designed 1959); Metal Adhesive (designed 1959); Black Adhesive; C.C. Adhesive; Fire Resistive Linoleum Adhesive; Cement, Adhesive, Fire Retardant, Type 1; Steel Floor Plate Adhesive, Part A; Insulation Adhesive, Part B; Adhesive Sealer, Charcoal Gray, Part A; Adhesive Sealer, Part A; Adhesive Sealer, White, Part A; Mariner Adhesive; Cold Storage Adhesive; Adhesive; Foster IBM Asphalt Fibre Roof Cement; Black Cat Roof Cement (Asphalt with Asbestos); Foster IBM Red Plastic Roof Cement; Foster IBM Green Plastic Roof Cement; Foster IBM Green Fibre Roof Coating Cement.

Mastics: Sealfas Mastic (designed 1959); Sealfas Mastic, Sand (Temporary) (Low Temperature Grade) (designed 1959); Sealfas Mastic, Mediterranean, Blue (Low Temperature Alt.) (designed 1959); Sealfas Mastic, Sand, (designed 1959); Sealfas Mastic, White, (designed 1959); SEALFAS G–P–M Mastic; Cork-filled Mastic (designed 1959); C.I. Mastic; Fire Resistive Mastic; C.I. Mastic, Aluminum; Fire Resistive Mastic, Aluminum; STACKFAS Mastic (designed 1960); Safetie H. I. Mastic (designed 1955); Hilastic Mastic (designed 1958); Fire Resistive Asphalt Material (designed 1965); Safetie C. I. Mastic (designed 1964); H. I. Mastic (designed 1941); Low Temperature H. I. Mastic (designed 1962); Climastic MASTIC; Sealfas Mastic; Sealfas G–P–M Mastic; Cork-Filled Sealfas; Sealfas Mastic Trowel; Cork Filled Fire Resistive Mastic; Fire Resistive Mastic; Safetee Cork-Filled Fire Resistive Asphalt Mastic; O. C. Mastic.

Sealants: Flame Resistant High Velocity Duct Sealant (designed 1960); Asphalt Seam Sealer (designed 1959); Fire Resistive Navy Sealer (designed 1955); Heat Resistant Sealant (designed 1949); FOAMSEAL Sealant (designed 1960); Insulation Sealant (designed 1963); Contraction Joint Sealant (designed 1969); High Velocity Duct Sealer (designed 1962); Flame Resistant High Velocity Duct Sealant Cartridge Grade (designed 1968); Flashing Compound (designed 1960); Elastolar Sealant (designed 1966); Extruded Sealant Tape; Duct Sealer, Gray; Flame Resistant High Velocity Duct Sealant, Gray; Insulation-Sealer Undercoating; Flexible Joint Sealer; Flextra Sealant (Spray); Gray Caulking Compound; Fitting Filler; Foster Black Caulking Compound-Gun Grade; Joint Filler.

Coatings: Protection Kote (designed 1953); Fire Retardant Vapor Barrier (designed 1955); LAGTONE Coating (designed 1962); Tite-Fit Coating; White Insulation Coating; Lagtone (designed 1956); FOAMSEAL Coating (designed 1972); Masonry Coating; Stackfas-Hi Solids; Heat Resistant Metal Coating; Foster IBM Asphalt Fibre Roof Coating; Black Cat Roof Coating (Asphalt with Asbestos); Foster IBM Red Fibre Roof Coating.

(e) *Additional information.* Additional information is available.

23. The Sherwin-Williams Company

(a) *Name and address of manufacturer.* The Sherwin- Williams Company, 101 Prospect Ave., N.W., Cleveland, OH 44101. Purchased subsidiary: Dutch Boy Group, 101 Prospect Ave., N.W., Cleveland, OH 44101.

(b) *Years of manufacture.* Before 1972. Records were reviewed back to 1964.

(c) *Types or classes of products.* Cement block fillers.

(d) *Other identifying characteristics.* The coatings are used as a thin film and the asbestos is bound in a resin. There usually is a non-asbestos top coat applied over these coatings. The only way to distinguish these products from other manufacturers' is by purchase records.

(e) *Additional information.* No additional information is available.

24. Tremco Incorporated

(a) *Name and address of manufacturer.* Tremco Incorporated, 3735 Green Road, Beachwood, OH 44122. Also operated by Tremco: Adhesives System Division, BFGoodrich Company, 123 West Bartges, Akron, OH 44311.

(b) *Years of production.* 1930 through the present.

(c) *Types or classes of products.* Extruded Butyl Tapes (produced 1955 to the present by Tremco Incorporated); Acrylic Sealant (produced 1961 to the present by Tremco Incorporated); Polyurethane Coatings & Sealants (produced 1979 to the present by Tremco Incorporated); Butyl Sealants (produced 1960 to the present by Tremco Incorporated); Drying Sealants (produced 1950 to the present by Tremco Incorporated); Non-Drying Sealants (produced 1952 to the present by Tremco Incorporated); Oil Based Paints (produced 1930 to 1973 by Tremco Incorporated); Adhesives (produced 1960 to 1983 by Adhesives Systems Division, BFGoodrich Company).

(d) *Identifying characteristics.* The above products contain chrysotile asbestos; identifying characteristics are unavailable.

(e) *Additional information.* No additional information is available.

25. Union Carbide Corporation

(a) *Name and address of manufacturer.* Union Carbide Corporation, 39 Old Ridgebury Road, Danbury, CT 06817–0001. Predecessor: Calidria Corporation, Bakelite Corporation.

(b) *Years of manufacture.* 1939 through approximately 1974.

(c) *Types or classes of products.* Raw chrysotile asbestos, phenolic resin material.

(d) *Other identifying characteristics.* Calidria (initially sold as Union Carbide Asbestos), (produced 1963 to June 30, 1985), consisted entirely of raw chrysotile asbestos in a unique short fiber form. The chemical formula was $Mg_6(OH)_8Si_4O_{10}$. Union Carbide produced four grades of Calidria asbestos: standard, super standard, high purity, and resin grade; the different grades reflect varying degrees of purity of content. Union Carbide packaged some of the Calidria products which were sold by domestic distributors under the following trade names: Arcovis, Imcobest, Oilbestos, Super Visbestos, Telvis, Univis, Visbestos, and Visquick. Calidria asbestos consisted of raw chrysotile asbestos in a unique short fiber form and can thus be

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distinguished from other chrysotile asbestos by its short fiber length. Calidria asbestos was sold in fibrous and pelletized forms. In appearance, Calidria was grey (pelletized) or white (fibrous) in color and powdery in substance.

Bakelite (produced from approximately 1939 to mid 1974), was manufactured at Union Carbide's Bound Brook Facility, 1 River Road, Bound Brook, NJ 08805. Union Carbide affiliates also manufactured asbestos containing Bakelite in Monterey and Mexico City, Mexico, and in Belleville, Ontario, Canada, however, none of these facilities sold Bakelite to customers in the United States. Prior to Union Carbide, from 1931 until 1939, Bakelite was manufactured by the Bakelite Corporation at the same Bound Brook facility as Union Carbide's Bakelite plant. The Bakelite Corporation and facility at Bound Brook was formed and created from a merger of the Bakelite Company, originally located at Bloomfield, IN; the General Plastics Company, of Perth Amboy, NJ; and the Redmonal Company, of Chicago, IL. Bakelite consisted of a phenolic resin material, sold to customers in a coarse granular (sand-like) form. Bakelite's purchasers consisted of molders who used the intermediate products sold to additional manufacturers. Bakelite customers would heat and melt the powder to create a molten resin (to which some purchasers would add other substances) and then mold, harden and cool the resin into the finished product. Most Bakelite did not contain asbestos. At its peak, asbestos containing Bakelite comprised 40% of the Bakelite produced by Union Carbide. The great bulk of non-asbestos Bakelite contained wood flour as a filler in lieu of asbestos. Asbestos containing Bakelite fell into three classes of Bakelite, which differed on the basis of the quantity and type of asbestos: General Purpose Bakelite, Heat Resistant Bakelite, and High Impact Heat Resistant.

General Purpose Bakelite contained less than 12% asbestos content. The asbestos consisted of short fiber usually purchased from the Carey-Canada Corporation. General Purpose Bakelite was marketed for use in certain electrical devices such as electrical panels, electrical plug receptacles, and electrical switches. General Purpose Bakelite consisted of the following Bakelite product designations (which differed with respect to either resin components or asbestos proportions): BMMA 5138, BMRS 5314, BMMA 5440, BMMA 5330, BMMC 5333, BMMS 5333, BMRS 5440, BMMA 5441.

Heat Resistant Bakelite contained 25 to 30% asbestos content (with one exception noted below). The asbestos consisted of short fiber asbestos usually purchased from the Carey Canada Corporation. Heat Resistant Bakelite was marketed for high voltage electrical switches or switch boxes and consisted of the following product designations: BMMC 2035; BMMA 5303; BMMD 5303; BMRS 2035; BMRS 5303; BMRC 2035; BMMA 5353 (only 10% asbestos).

High Impact Heat Resistant (only manufactured until the mid 1960's) consisted of 50% asbestos. The asbestos consisted of long fiber African Blue (trade name) Asbestos. High Impact Heat Resistant was marketed for use in or with very high voltage industrial electrical switch gear and consisted of the following product designation: BMMZ 5250.

As indicated above, Bakelite was sold in a granular form. Bakelite was brown; however, a pigment was usually added to give it a black appearance. Some of the long-fiber asbestos had a green hue to it. Asbestos containing Bakelite can be distinguished from Bakelite or other phenolics which contained wood flour as a filler by appearance or weight: the asbestos-containing Bakelite had a smoother appearance and a greater specific gravity (by a factor of approximately 1.3). Asbestos containing Bakelite can only be distinguished from phenolics with asbestos or other, non-asbestos, mineral filler (as opposed to wood flour) by an ash chemical analysis.

Any asbestos contained in general purpose Bakelite or Heat Resistant Bakelite was fully encapsulated by the resin in the Bakelite sold by Union Carbide. Any asbestos in High Impact Heat Resistant Bakelite would be encapsulated when the resin was molded, hardened and cooled into the finished product by the purchasers of Bakelite. Therefore, any asbestos in Bakelite found in buildings is encapsulated and thus not respirable.

(e) *Additional information.* No additional information is available.

26. Uniroyal Holdings, Inc., Textile Division

(a) *Name and address of manufacturer.* Uniroyal Holdings, Inc., Textile Division, 455 Chase Parkway, Waterbury, CT 06708-3392. Formerly named U.S. Rubber Company.

(b) *Years of manufacture.* 1941 through 1976.

(c) *Types or classes of products.* Asbestos cloth.

(d) *Other identifying characteristics.* From about 1941 until 1976, Uniroyal's Textile Division made and marketed asbestos-containing cloth containing a significant quantity by weight and volume of chrysotile asbestos fiber. Uniroyal sold this cloth for a great variety of uses, and did not market it specifically as an insulation material for use in buildings. The chrysotile fibers in the cloth were combined with cotton or other natural or synthetic fibers, and the woven cloth was often coated with resin to achieve a smooth and uniform finish. Uniroyal's asbestos cloth, generally light in weight as compared to other manufacturers' asbestos-containing cloth, was graded depending on the percentage of asbestos in the finished product. Generally speaking, the grades were Underwriters, AA and AAA; the range of gauges .023 to .078; and the weight in pounds per square yards ranged from .75 to 2.5, with the predominant sales in the lighter weight fabric.

(e) *Additional information.* No additional information is available.

27. United States Gypsum Company

(a) *Name and address of manufacturer.* United States Gypsum Company, 101 South Wacker Drive, Chicago, IL 60606. United States Gypsum Company in NJ was incorporated December 27, 1901 and dissolved August 23, 1920. Avery Gypsum Company in NJ was incorporated August 23, 1920 and dissolved October 14, 1927. United States Gypsum Company in IL was incorporated August 12, 1920 and dissolved December 24, 1936. United States Gypsum Company in DE was incorporated December 24, 1936 and dissolved in August 1952. United States Gypsum Company was incorporated August 1952 and dissolved February 4, 1966. USG Corporation in DE was incorporated February 2, 1966 and dissolved July 1, 1966. The United States Gypsum Company in DE was incorporated August 1, 1966.

(b) *Years of manufacture.* 1930 through 1977.

(c) *Types or classes of products.* Ceiling tile, fireproofing plaster, thermal insulation, rigid block insulation, texture, simulated acoustical ceiling texture, paper and felt, and pipe covering.

(d) *Other identifying characteristics.* Acoustone 120 ceiling tile was produced 1968 to 1976 in Gypsum, OH.

Shadowline ceiling tile was produced 1968 to 1976 in Walworth, MI.

Acoustone 180 ceiling tile was produced 1966 to 1975 in Gypsum, OH.

Red Top Firecode Plaster (D) fireproofing plaster was produced 1962 to 1963 in Boston, MA; 1962 to 1963 in

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Detroit, MI; 1959 to 1964 in East Chicago, IN; 1960 to 1964 in Empire, NY; 1959 to 1964 in Fort Dodge, IA; 1961 to 1964 in Gypsum, OH; 1959 to 1964 in New Brighton, NY; 1962 to 1963 in Oakfield, NY; 1962 to 1963 in Philadelphia, PA; 1961 to 1963 in Sperry, IA; 1962 to 1963 in Stony Point, NY; 1964 only in Hagersville, CAN.

Red Top Firecode "V" Plaster fireproofing plaster was produced 1965 to 1969 in Baltimore, MD; 1962 to 1963 in Boston, MA; 1962 to 1963 in Detroit, MI; 1962 to 1969 in East Chicago, IN; 1962 to 1969 in Empire, NY; 1964 to 1965 in Fort Dodge, IA; 1962 to 1963 in Galena Park, TX; 1962 to 1968 in Gypsum, OH; 1963 to 1967 in Midland, CA; 1962 to 1969 in New Brighton, NY; 1962 to 1963 in Oakfield, NY; 1962 to 1963 in Philadelphia, PA; 1967 to 1968 in Plaster City, CA; 1962 to 1963 in Stony Point, NY; 1963 to 1969 in Sweetwater, TX; 1963 to 1969 in Hagersville, CAN.

Spraydon Standard A fireproofing plaster was produced 1965 to 1971 in Plainfield, NJ; 1965 to 1971 in Torrance, CA.

Spraydon Standard G fireproofing plaster was produced 1968 to 1970 in Plainfield, NJ; 1968 to 1970 in Torrance, CA. Spraydon

Powercote thermal insulation was produced 1969 to 1971 in Plainfield, NJ; Torrance, CA; and Corsicana, TX.

K–Fac Industrial Insulating Block rigid block insulation was produced 1943 to 1950 in East Chicago, IN.

K–Fac 19 rigid block insulation was produced 1970 to 1973 in Greenville, MS.

Pac-Tex Texture Paint was produced 1962 to 1963 in Dallas, TX; 1943 to 1970 in South Gate, CA; 1949 to 1962 in Sweetwater, TX.

A–B Tex Texture Paint was produced 1959 to 1973 in Chamblee, GA; 1935 to 1949 in Gypsum, OH; 1954 to 1973 in Gypsum, OH; 1973 only in Midway, IL; 1935 to 1949 in New Brighton, NY; 1954 to 1968 in New Brighton, NY; 1943 to 1944 in South Gate, CA; 1954 to 1974 in South Gate, CA; 1948 to 1950 in Sweetwater, TX; 1962 to 1963 in Hagersville, CAN; 1973 only in Hagersville, CAN.

Texture Paint was produced 1959 to 1973 in Chamblee, GA; 1964 to 1973 in Dallas, TX; 1930 to 1973 in Gypsum, OH; 1937 to 1973 in New Brighton, NY; 1948 to 1970 in South Gate, CA; 1948 to 1964 in Sweetwater, TX.

Texolite Dry Fill texture was produced 1959 to 1961 in New Brighton, NY.

Texolite Drywall Surfacer, Aggregated, (renamed Drywall Surfacer, Texture XII in 1965) was produced 1963 to 1965 in Dallas, TX; 1961 to 1977 in Gypsum, OH; 1970 to 1972 in Midway, IL; 1963 to 1965 in New Brighton, NY; 1963 to 1965 in South Gate, CA.

Spray Texture Paint (or Finish) was produced 1961 to 1976 in Chamblee, GA; 1961 to 1976 in Dallas, TX; 1960 to 1976 in Gypsum, OH; 1970 to 1976 in Midway, IL; 1966 to 1968 in New Brighton, NY; 1963 to 1973 in South Gate, CA; 1959 to 1961 in Sweetwater, TX.

Multi-purpose Texture Finish was produced 1964 to 1976 in Chamblee, GA; 1963 to 1976 in Dallas, TX; 1965 to 1976 in Gypsum, OH; 1971 to 1976 in Midway, IL; 1965 to 1966 in New Brighton, NY.

Improved Spray Texture B–8 was produced 1963 to 1973 in South Gate, CA.

Sanded, Colored, Texture Paint was produced 1952 to 1953 in New Brighton, NY; 1952 to 1955 in Sweetwater, TX.

Concrete Ceiling Texture was produced 1970 to 1973 in South Gate, CA. Textone Texture Finish was produced 1959 to 1972 in Chamblee, GA; 1962 to 1972 in Dallas, TX; 1928 to 1975 in Gypsum, OH; 1937 to 1972 in New Brighton, NY; 1944 to 1972 in South Gate, CA; 1949 to 1972 in Sweetwater, TX; 1965 to 1977 in Hagersville, CAN.

Texolite Block Filler was produced 1961 to 1966 in Chamblee, GA; 1966 to an unknown date in Dallas, TX; 1958 to an unknown date in Gypsum, OH; 1958 to an unknown date in New Brighton, NY; 1959 to 1966 in South Gate, CA; 1959 to 1966 in Sweetwater, TX.

Sheetrock Smoothcoat texture was produced 1966 to 1974 in Dallas, TX; 1965 to 1974 in Gypsum, OH; 1971 to 1974 in Midway, IL.

Sheetrock Radiant Heat Simulated Acoustical Texture ceiling texture was produced 1970 to 1972 in South Gate, CA.

Special Texture Paint was produced from 1963 to 1964 to Dallas, TX; 1971 to 1972 in Dallas, TX; 1955 only in New Brighton, NY.

Texture XII, Super Vinyl was produced 1970 to 1976 in Gypsum, OH; 1970 to 1976 in Midway, IL.

Aggregated Spray Finish, White texture was produced 1967 to 1968 in Dallas, TX; 1964 to 1968 in Gypsum, OH; 1971 only in Midway, IL.

Smooth Hard Finish texture was produced 1968 to 1969 in South Gate, CA.

Superhard Spray Texture Finish was produced 1968 to 1969 in South Gate, CA.

Exterior Texture Wallboard Finish was produced 1971 to 1973 in Dallas, TX; 1971 to 1972 in South Gate, GA.

Simulated Acoustical Spray Texture/Finish was produced 1964 only in Chamblee, GA; 1963 to 1964 in Dallas, TX; 1959 to 1964 in Gypsum, OH; 1961 to 1964 in New Brighton, NY; 1959 to 1964 in South Gate, CA; 1961 to 1962 in Sweetwater, TX.

"QT" Simulated Acoustical Spray Texture was produced 1963 to 1973 in South Gate, CA.

Imperial "QT" (Spray) Texture Finish-Regular was produced 1964 to 1965 in Dallas, TX; 1967 to 1976 in Dallas, TX; 1964 to 1968 in New Brighton, NY; 1966 only in South Gate, CA; 1968 to 1973 in South Gate, CA.

Imperial "QT (Spray) Texture Finish-LC was produced 1965 to 1968 in Dallas, TX; 1965 to 1968 in Gypsum, OH; 1965 to 1966 in New Brighton, NY; 1965 to 1966 in Hagersville, CAN; 1966 only in Montreal, CAN.

Imperial "QT" (Spray) Texture Finish-NC–LC was produced 1968 to 1976 in Chamblee, GA; 1966 to 1974 in Dallas, TX; 1966 to 1976 in Gypsum, OH; 1966 to 1975 in New Brighton, NY.

Imperial "QT" (Spray) Texture Finish-Extra Hard Fine was produced 1964 to 1974 in Chamblee, GA; 1964 to 1971 in Dallas, TX; 1964 to 1974 in Gypsum, OH; 1964 to 1973 in New Brighton, NY.

Imperial "QT" (Spray) Texture Finish-Vermiculite, Coarse and Regular was produced 1967 to 1976 in Chamblee, GA; 1966 to 1976 in Dallas, TX; 1968 to 1976 in Gypsum, OH; 1970 to 1976 in Midway, IL; 1968 to 1976 in New Brighton.

Imperial "QT" (Spray) Texture Finish-Polystyrene, Coarse and Regular was produced 1967 to 1976 in Dallas, TX.

Imperial "QT" (Spray) Texture Finish-NC4 was produced 1968 to 1972 in Chamblee, GA; 1968 to 1971 in Dallas, TX; 1967 to 1972 in Gypsum, OH; 1970 to 1972 in Midway, IL; 1967 to 1972 in New Brighton, NY.

Ready-Mixed Imperial "QT" Spray Finish was produced 1966 to 1967 in New Brighton, NY.

Asbestos Paper was produced 1938 to 1939 in Jersey City, NJ.

Asbestos Felts and Coverings were produced 1936 to 1939 in Jersey City, NJ.

Commercial Asbestos Paper was produced 1936 to 1939 in Jersey City, NJ.

Asbestos Corrugated Paper-Corrugated Wool Felt was produced 1936 to 1939 in Jersey City, NJ.

Asbestos Air Cell Pipe Covering was produced 1936 to 1939 in Jersey City, NJ.

Corrugated Wool Felt Air Cell Covering was produced 1936 to 1939 in Jersey City, NJ. Wool Felt Pipe Covering was produced 1936 to 1939 in Jersey City, NJ.

Laminated Asbestos & Sponge Pipe Covering was produced 1936 to 1939 in Jersey City, NJ.

Hair & Wool Felt Pipe Covering-Frost Proof was produced 1936 to 1939 in Jersey City, NJ.

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Anti-Sweat Pipe Covering was produced 1936 to 1939 in Jersey City, NJ.

Range Boiler Jackets pipe covering was produced 1936 to 1939 in Jersey City, NJ.

Asbestos Air Cell Board pipe covering was produced 1936 to 1938 in Jersey City, NJ.

Laminated Sponge & Asbestos Board pipe covering was produced 1936 to 1939 in Jersey City, NJ.

Asbestos Cement pipe covering was produced 1936 to 1939 in Jersey City, NJ.

Pyrobestos Pipe Covering Board & Stack Lining was produced 1936 to 1939 in Jersey City, NJ.

(e) *Additional information.* Additional information is available.

28. W.R. Grace & Company

(a) *Name and address of manufacturer.* W. R. Grace & Company, Grace Plaza, 1114 Avenue of the Americas, New York, NY 10036–7794.

(b) *Years of manufacture.* Approximately 1938 through 1978; exact years of production for many of the products are unknown.

(c) *Types or classes of products.* Surfacing material, concrete leveler or block filler, window glazing compound or paste, elastomeric caulking and sealing compounds, extrudable chalking compound, non-staining oil base caulking compound, waterproofing compounds, bonding agent, epoxy based adhesive, epoxy resin floor surfacing, slip resistant coating, exterior masonry coating, acrylic sealant, and waterproofing sealant.

(d) *Other identifying characteristics.* Zonolite Acoustical Plaster (produced 1945 to approximately 1972) was a surfacing material which contained approximately 15 to 20% 7M chrysotile asbestos by weight; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it contained perlite or vermiculite, but not both; it was spray-applied or trowelled on wet; it was light beige or tan in color. Zonolite Acoustical Plaster may also have been marketed as Zonolite Acoustical Plastic, Vermiculite Acoustical Plaster, and Vermiculite Acoustical Plastic; it may have been manufactured in the 1950's with 6D or 7D chrysotile asbestos.

Zono-Coustic (produced 1960 to 1973) was a surfacing material which contained approximately 10 to 14% 7M chrysotile asbestos by weight; it was an acoustical base coat for walls and ceilings; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it contained perlite or vermiculite, but not both; it was spray-applied or trowelled on wet; it was off-white in color. Zono-Coustic may also have been marketed as Zono-Coustic 1, Zono-Coustic 2, Zono-Coustic 3, Zono-Coustic Type Z, and Zono-Coustic (MK-2).

Zonolite Finish Coat (produced 1950 to approximately 1973) was a surfacing material which contained approximately 11 to 14% 7M chrysotile asbestos by weight; was a decorative textured finish for ceilings; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it contained perlite or vermiculite, but not both; it was spray-applied wet; it was white in color. Zonolite Finish Coat may also have been marketed as Zonolite Finish coat, Decorator's White, Zonolite Acoustical Finish, and Zonolite Finish Coat Decorator's White Extra Hard.

Zonolite Spra-Tex (produced approximately 1955 to 1972) was a surfacing material which contained approximately 29 to 36% chrysotile asbestos by weight; it was a decorative textured finish for ceilings; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it contained perlite or vermiculite, but not both; it was spray-applied wet; it was white in color. Zonolite Spra-Tex may also have been marketed as Zonolite Spra-Tex EH.

Econo-White 70 (produced 1956 to approximately 1970) was a surfacing material which contained approximately 13 to 17% 7M chrysotile asbestos by weight; it was an acoustical plaster for walls and ceilings; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it contained perlite or vermiculite, but not both; it was spray-applied or trowelled on wet; it was white in color. Econo-White 70 may also have been marketed as Econo-White Acoustical Texture or Econo-White Super White.

Z–Tex (produced approximately 1958 to 1962) was a surfacing material which contained approximately 13 to 17% 7M chrysotile asbestos by weight; it was a spray acoustical texture product; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it contained perlite or vermiculite, but not both; it was spray-applied wet; it was white or beige in color. Z–Tex may also have been marketed as EZ–Tex.

Zonolite Board of Education Texture (produced approximately 1962 or 1963) was a surfacing material which contained approximately 9 to 12% 7M chrysotile asbestos by weight; it was a textured acoustical plaster coat; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it contained perlite or vermiculite, but not both; it was spray-applied or trowelled on wet; it was white in color. Zonolite Board of Education Texture was manufactured for one job site only.

Zonolite Mono-Kote MK–1 (produced 1958 to approximately 1962) was a surfacing material which contained approximately 10 to 13% 7M chrysotile asbestos by weight; it was a cementitious fireproofing; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it contained perlite or vermiculite, but not both; it was spray-applied or trowelled on wet; it was light beige in color. Zonolite Mono-Kote MK–1 was also sold under the generic name Mono-Kote.

Zonolite Spra-Insulation (produced approximately 1959 to 1973) was a surfacing material which contained approximately 10 to 13% 7M chrysotile asbestos by weight; it was a cementitious insulation and acoustical material for application to metal building interiors; it did not contain commercially added glass fibers, mineral wool or rock wool; it contained perlite or vermiculite, but not both; it was spray-applied or trowelled on wet; it was dark beige in color.

Zonolite Mono-Kote MK–3 (produced 1959 to 1973) was a surfacing material which contained approximately 10 to 14% 7M or 7R chrysotile asbestos by weight; it was cementitious fireproofing, it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it contained perlite or vermiculite, but not both; it was spray-applied or trowelled on wet; it was light beige in color. Zonolite Mono-Kote MK–3 was also sold under the generic name Mono-Kote.

Zonolite High Temperature Cement (produced approximately 1938 to 1970) was a surfacing material which contained approximately 15 to 19% 7D or 6D–20 chrysotile asbestos by weight; it was a cementitious insulation and fireproofing for high temperature applications; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; contained perlite or vermiculite, but not both; it was trowelled on wet; it was light beige in color. Zonolite High Temperature Cement was also marketed as Hi Temp Insulating Cement, Zonolite Hi-Temperature Cement and Zonolite High Temperature Insulating Cement; it was

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marketed primarily for industrial applications.

Ari-Zonolite Texture (produced approximately 1961 to 1964) was a surfacing material which contained approximately 10% chrysotile asbestos by weight; it was a cementitious sprayed texture product; it was used to cover grooves in a pre-wired ceiling board; it did not contain commercially added amphibole asbestos; it was spray-applied wet; it was off-white in color.

Perltex Super-40 Perlite (exact date manufacture began is unknown; manufactured up to approximately 1973) was a surfacing material which contained approximately 6 to 8% chrysotile asbestos by weight; it was a decorative textured coating; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it contained perlite or vermiculite, but not both; it was spray-applied wet; it was white or beige in color; it may also have been marketed as Perltex Perlite or Super-40 Perlite.

Perltex Super-40 SAV (exact date manufacture began is unknown; up to approximately 1973) was a surfacing material which contained approximately 5 to 7% chrysotile asbestos by weight; it was a decorative textured coating; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool, or rock wool; it contained perlite or vermiculite, but not both; it was spray-applied wet; it was white or beige in color. Perltex Super-40 SAV may also have been marketed as Perltex SAV or Super-40 SAV.

Perltex Super-40 Polycoarse (exact date manufacture began is unknown; manufactured up to approximately 1973) was a surfacing material which contained approximately 4 to 6% chrysotile asbestos by weight; it was a spray texture coating; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it was spray-applied wet; it was white or beige in color. Perltex Super-40 Polycoarse may also have been marketed as Perltex Polycoarse, Perltex Super-40 Poly or Perltex Poly.

Perltex Super-40 Fog (exact date manufacture began is unknown; manufactured up to approximately 1973) was a surfacing material which contained approximately 4 to 7% chrysotile asbestos by weight; it was used as a base coat under paint or decorative textured finish products; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it was spray-applied wet; it was white or beige in color. Perltex Super-40 Fog may also have been marketed as Perltex Fog.

Perltex Spray Surfacer (exact date manufacture began is unknown; manufactured up to approximately 1973) was a surfacing material which contained approximately 6 to 11% 7TF1 or 7RF9 chrysotile asbestos by weight; it was a spray texture coating applied over board, concrete, metal or plaster; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it contained perlite or vermiculite, but not both; it was spray-applied wet; it was white in color. Perltex Spray Surfacer may also have been marketed as PlasterTex, Perltex Super-40 Spray Surfacer, Perltex Super-40, and Gun Coat Spray Surfacer.

Hi-sorb Acoustical Plaster (exact date manufacture began is unknown; manufactured up to approximately 1973) was a surfacing material which contained approximately 8 to 10% 7M chrysotile asbestos by weight; it was an acoustical textured ceiling plaster; it was to be applied over gypsum plaster, portland cement, and lime plaster base coats, and directly to monolithic concrete surfaces; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it was spray-applied or trowelled on wet; it was oyster white or white in color. It was also sold as Hi-Sorb Acoustical Plaster Oyster White and XX White.

Spra-Wyt (produced 1954 to approximately 1973) was a surfacing material which contained approximately 16 to 20% 7M chrysotile asbestos by weight; it was an acoustical finish coat; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it contained perlite or vermiculite, but not both; it was spray-applied wet. Spra-Wyt may also have been marketed as Spra-Wyt Finish, Spra-Whyt Acoustical or Spra-Wyt Acoustical Finish.

Versakote (exact date manufacture began is unknown; manufactured up to approximately 1973) was a surfacing material which contained approximately 5 to 7% chrysotile asbestos by weight; it was a decorative exterior finish; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it contained perlite or vermiculite, but not both; it was spray-applied wet; it was white or beige in color. Versakote may also have been marketed as Perltex Versakote or Prep Coat #4.

Prep Coat #3 (exact date manufacture began is unknown; manufactured up to approximately 1972) was a surfacing material which contained approximately 4 to 5% chrysotile asbestos by weight; it was a decorative exterior finish; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it was spray-applied wet. Prep Coat #3 may also have been marketed as Perltex Prep Coat #3.

Perlcoustic (years of production unknown) was a surfacing material which contained approximately 15 to 17% 7M chrysotile asbestos by weight; it was an acoustical finish coat; it did not contain commercially added amphibole asbestos or commercially added glass fibers, mineral wool or rock wool; it contained perlite or vermiculite, but not both; it was spray-applied wet.

Concrete Leveler or Block Filler (produced late 1960's to approximately 1973) was a cement-like product used to patch or fill concrete and brick.

Horn Glazing Compound (produced 1966 to 1970) was a commercial window glazing compound or paste; it was off-white in color. Hornflex Sealants (produced 1964 to 1975) were elastomeric caulking and sealing compounds; they were a gray heavy paste and a brown viscous liquid.

Hornseal (produced 1969 to 1975) was an extrudable chalking compound; it was sold in tubes or pails; it was available in various colors, including gray, black, white aluminum, and limestone.

Vulcatex Professional Grade (produced approximately 1972 to 1977) was a polymerized, non-staining oil base caulking compound; it was gray or white in color.

Waterproofing Compounds (produced 1964 to 1977) were sold in the form of a black mastic.

Epoxy Liquid Bonding Agent (produced approximately 1969 to 1975) was a two-component bonding agent; it contained two viscous brown-colored liquids.

Epoxy Base Adhesive (produced approximately 1964 to 1966) was an epoxy based adhesive; it contained two viscous brown colored liquids.

Epoxy Resin Floor Surfacing (produced approximately 1966 to 1971) was an epoxy resin bond coat and seal coat for use on floors; it was applied in two stages; it contained a two-component bond coat and a two-component seal coat; it was available in a wide range of colors including: platinum, cashmere, iroquois, cedar, iron gray, feather green, sand, palmetto, meadowlark, lagoon, beech, graystone, rattan, medium gray, and white.

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Slip Resistant Coating (produced 1966 to 1978) was a viscous liquid slip resistant coating; it was available in gray, green, red, and yellow.

Exterior Masonry Coating (produced approximately 1966 to 1972) was a heavy-bodied liquid exterior masonry coating; it was available in a wide range of colors, including: white, sandstone, tea rose, birch gray, ash gray, shadow green, cedar, baltic, dusty rose, sherwood green, and dove gray.

Acrylic Sealant (produced 1965 to approximately 1969) was a one-component acrylic sealant used for caulking, glazing and sealing joints not subject to abrasion or emersion; it was available in black, white, off-white, limestone, natural gray, and aluminum gray.

Waterproofing Sealant (produced 1969 to 1975) was a sealant accessory product for waterproofing; it was sold as a black extrudable paste.

(e) *Additional information.* No additional information is available.

III. Obtaining Additional Information

In addition to the summaries in unit II of this notice, some submitters provided EPA with such information as product catalogs, product formulas, protocols for samples, and photographs. The availability of additional information about each submission is indicated in paragraph (e) at the end of each summary in Unit II. To assist individuals in ordering any additional information, the following table has been prepared to show the total number of pages in each submission:

NUMBER OF PAGES IN EACH AIA SUBMISSION

Manufacturer	Total pages	Summary pages	Additional information pages
American Biltrite Inc., Amtico Division	264	3	261
Armstrong World Industries, Inc.	562	9	553
The BFGoodrich Company	1	1	0
The Celotex Corporation	4	4	0
Congoleum Corporation	5,594	2	5,592
Eagle-Picher Industries	5	5	0
Fibreboard Corporation	16	11	5
Flintkote Company	4	4	0
GAF Building Materials	571	35	536
General Refractories Company	3	3	0
Georgia-Pacific Corporation	4	4	0
H. K. Porter Company, Inc.	1	1	0
Kaiser Cement	3	3	0
Kaiser Gypsum Company, Inc.	5	5	0
Keene Corporation	7	7	0
Kentile Floors, Inc.	38	1	37
Mannington Mills, Inc.	1,245	2	1,243
Manville Corporation	14	14	0
National Gypsum Company	388	2	386
The Owens/Corning Fiberglas Corporation	3	3	0
Pfizer, Inc.	8	2	6
Rhone-Poulenc Ag Company	190	3	187
The Sherwin Williams Corporation	1	1	0
Tremco, Inc., Adhesives System Division	4	4	0
Union Carbide Corporation	5	5	0
Uniroyal Holding, Inc.	1	1	0
U.S. Gypsum Company	1,090	10	1,080
W. R. Grace & Company	37	37	0
Total	10,068	182	9,886

Copies of the information described above and any additional information submitted to EPA after November 17, 1989, are available for a fee of fifteen cents per page to cover reproduction costs. To obtain additional information, interested individuals should contact the following: ATLIS Federal Services, Inc., EPA/AIA Program, 6011 Executive Blvd., Rockville, MD 20852, (301) 816–0873.

Dated: February 3, 1990.

Linda J. Fisher,

Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 90–3370 Filed 2–12–90; 8:45 am]

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federal register

Tuesday
February 13, 1990

Part VI

Department of Transportation

Federal Aviation Administration

14 CFR Part 73

Proposed Prohibited Areas Over Department of Energy Nuclear Facilities; Announcement of Public Meetings

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Airspace Docket No. 90-AWA-1]

Proposed Prohibited Areas Over Department of Energy Nuclear Facilities

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Announcement of public meetings.

SUMMARY: This document announces a series of meetings to solicit information from the public concerning the establishment or modification of prohibited airspace areas for security and safety purposes at nine Department of Energy (DOE) nuclear weapon facilities.

DATES: Comments must be received on or before May 7, 1990, or 30 days after the close of the last meeting, whichever is later. The public meetings will be held on March 15, 1990, in Columbus, OH; March 20, 1990, in Oak Ridge, TN; March 21, 1990, in Augusta, GA; March 27, 1990, in Westminster, CO; March 28, 1990, in Albuquerque, NM; March 29, 1990, in Amarillo, TX; April 3, 1990, in Richland, WA; April 4, 1990, in Idaho Falls, ID; April 5, 1990, in Livermore, CA.

ADDRESSES: Comments may be mailed in triplicate to:

Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket [AGC-10], Airspace Docket No. 90-AWA-1, Department of Energy/Proposed Prohibited Areas, 800 Independence Avenue SW., Washington, DC 20591.

Comments may be delivered in triplicate to:

FAA Rules Docket, Room 916, 800 Independence Avenue SW., Washington, DC 20591.

Comments may be examined in the Rules Docket weekdays, except Federal holidays, between 8:30 a.m. and 5 p.m.

The public meeting locations are as follows:

Columbus, OH
Date: Thursday, March 15, 1990.
Time: 7:30 p.m.
Location: Broadleigh Elementary School, 3039 Maryland Avenue, Columbus, OH

Oak Ridge, TN
Date: Tuesday, March 20, 1990.
Time: 7:30 p.m.
Location: The American Museum of Science and Energy, 300 S. Tulane, Oak Ridge, TN

Augusta, GA
Date: Wednesday, March 21, 1990.
Time: 7:30 p.m.
Location: Landmark Hotel, 640 Broad Street, Augusta, GA

Westminster, CO
Date: Tuesday, March 27, 1990.
Time: 7:30 p.m.
Location: Ramada Hotel, 8773 Yates Drive, Westminster, CO

Albuquerque, NM
Date: Wednesday, March 28, 1990.
Time: 7:30 p.m.
Location: Holiday Inn—Pyramid, 5151 San Francisco Road NE., Albuquerque, NM

Amarillo, TX
Date: Thursday, March 29, 1990.
Time: 7:30 p.m.
Location: Amarillo College, 2201 S. Washington Street, Amarillo, TX

Richland, WA
Date: Tuesday, April 3, 1990.
Time: 7:30 p.m.
Location: DOE Federal Building, 825 Jadwin Avenue, Richland, WA

Idaho Falls, ID
Date: Wednesday, April 4, 1990.
Time: 7:30 p.m.
Location: Westbank Motel, 475 River Parkway, Idaho Falls, ID

Livermore, CA
Date: Thursday, April 5, 1990.
Time: 7:30 p.m.
Location: Almond Avenue School, Pod A, 1401 Almond Avenue, Livermore, CA

FOR FURTHER INFORMATION CONTACT: Alton D. Scott, Airspace Branch [ATO-240], Airspace-Rules and Aeronautical Information Division, Air Traffic Operations Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: [202] 267-9252.

SUPPLEMENTARY INFORMATION:

Meeting Procedures

(a) The meetings will be informal in nature and will be conducted jointly by representatives of the FAA and the DOE. Each participant will be given an opportunity to make a presentation.

(b) The meetings will be open to all persons on a space-available basis. All efforts will be made to provide a meeting site with sufficient seating capacity for the expected participation. There will be no admission fee or other charge to attend and participate.

(c) Any person wishing to make a presentation to the panel will be asked to sign in and estimate the amount of time needed for such presentation. This will permit the panel to allocate an appropriate amount of time for each presenter. The panel may allocate the time available for each presentation in order to accommodate all speakers. The meeting will not be adjourned until everyone on the list has had an opportunity to address the panel. The meeting may be adjourned at any time if all persons present have had the opportunity to speak.

(d) Any person who wishes to present a position paper to the panel pertinent to the topic of prohibited areas over nuclear weapons facilities for consideration may do so.

(e) Persons wishing to hand out pertinent position papers to the attendees should present three copies to the representatives from the FAA and DOE. The FAA and DOE representatives will retain one copy each, with the third being placed in the meeting files. There should be additional copies of each handout available for other attendees.

(f) The meeting will be recorded by a court reporter. Anyone interested in purchasing the transcript should contact the court reporter directly. A copy of the court reporter's transcript will be filed in the docket.

Materials relating to this subject will be accepted at the individual meetings. Every reasonable effort will be made to hear every request for presentation consistent with a reasonable closing time for the meeting. Written materials may also be submitted up to 30 days after the close of the last meeting.

Agenda

Opening Remarks and Discussion of Meeting Procedures.
Public Presentations.
Closing Comments.

The Proposed Prohibited Airspace Designations

The Department of Energy (DOE) has requested the FAA to establish or modify prohibited airspace over nine DOE nuclear weapons sites for security and safety purposes. The establishment of prohibited airspace would reduce the amount of overflights in the vicinity of DOE facilities, thus providing DOE security forces increased response time to identify an aircraft as either an intentional or accidental intruder, as well as substantially enhancing safety to aircraft, DOE facilities, and personnel through avoidance of potential accidents resulting from DOE facility overflights. The following describes the proposed prohibited airspace that DOE has requested the FAA to designate or modify at nine DOE installations:

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Location	Horizontal boundaries	Altitude surface to—
Portsmouth Gaseous Diffusion Plant, Piketon, OH.	Beginning at lat. 39°03'07"N., long. 83°01'26"W.; to lat. 39°03'07"N., long. 82°58'05"W.; to lat. 38°59'12"N., long. 82°58'05"W.; to lat. 38°59'12"N., long. 83°01'26"W.; to the point of beginning.	5,600 MSL
Oak Ridge Y-12 Plant, TN	Beginning at lat. 35°58'55"N., long. 84°16'51"W.; to lat. 35°59'54"N., long. 84°14'39"W.; to lat. 35°59'26"N., long. 84°13'55"W.; to lat. 35°58'02"N., long. 84°16'34"W.; to the point of beginning.	4,000 MSL
Savannah River Plant, Aiken, SC.	Beginning at lat. 33°23'45"N., long. 81°33'20"W.; to lat. 33°14'30"N., long. 81°29'50"W.; to lat. 33°13'16"N., long. 81°30'45"W.; to lat. 33°08'50"N., long. 81°39'22"W.; to lat. 33°17'12"N., long. 81°47'40"W.; to lat. 33°18'33"N., long. 81°45'45"W.; to lat. 33°19'25"N., long. 81°46'35"W.; to lat. 33°23'00"N., long. 81°46'00"W.; to lat. 33°22'20"N., long. 81°42'55"W.; to the point of beginning.	10,300 MSL
Rocky Flats Plant, Golden, CO	Beginning at lat. 39°55'42"N., long. 105°14'02"W.; to lat. 39°54'38"N., long. 105°09'37"W.; to lat. 39°51'01"N., long. 105°09'53"W.; to lat. 39°51'57"N., long. 105°14'26"W.; to the point of beginning.	10,500 MSL
Los Alamos National Laboratory, NM.	Beginning at lat. 35°47'00"N., long. 106°14'48"W.; to lat. 35°50'03"N., long. 106°21'36"W.; to lat. 35°52'22"N., long. 106°20'42"W.; to lat. 35°52'52"N., long. 106°16'48"W.; to lat. 35°52'30"N., long. 106°14'48"W.; to lat. 35°50'05"N., long. 106°14'48"W.; to lat. 35°47'16"N., long. 106°11'50"W.; to lat. 35°45'30"N., long. 106°15'00"W.; to lat. 35°47'05"N., long. 106°15'05"W.; to the point of beginning.	14,500 MSL
Pantex Plant, Amarillo, TX	Beginning at lat. 35°22'54"N., long. 101°37'04"W.; to lat. 35°22'59"N., long. 101°30'21"W.; to lat. 35°15'08"N., long. 101°30'18"W.; to lat. 35°15'03"N., long. 101°37'04"W.; to the point of beginning.	10,000 MSL
Hanford Site, Richland, WA	Beginning at lat. 46°44'25"N., long. 119°25'00"W.; to lat. 46°39'30"N., long. 119°20'00"W.; to lat. 46°34'10"N., long. 119°20'00"W.; to lat. 46°30'00"N., long. 119°15'00"W.; to lat. 46°23'00"N., long. 119°24'50"W.; to lat. 46°38'00"N., long. 119°43'30"W.; to the point of beginning.	10,000 MSL
Idaho National, Engineering Laboratory Idaho Falls, ID.	Beginning at lat. 43°26'58"N., long. 113°10'35"W.; to lat. 43°26'57"N., long. 112°56'10"W.; to lat. 43°33'15"N., long. 112°35'20"W.; to lat. 43°54'50"N., long. 112°38'00"W.; to lat. 43°54'51"N., long. 112°46'25"W.; to lat. 43°48'16"N., long. 112°50'55"W.; to lat. 43°39'22"N., long. 113°03'20"W.; to lat. 43°36'27"N., long. 113°10'35"W.; to the point of beginning.	10,000 MSL [1]
Lawrence Livermore, National Laboratory, Livermore, CA.	Beginning at lat. 37°45'28"N., long. 121°46'39"W.; to lat. 37°45'28"N., long. 121°38'13"W.; to lat. 37°37'02"N., long. 121°38'13"W.; to lat. 37°37'02"N., long. 121°46'39"W.; to the point of beginning.	3,000 MSL*

*A corridor 2 miles wide with no altitude restrictions exists in the northern portion of this boundary extending from the intersection of ID 88 and ID 22 near the point of the mountain at lat. 43°48'16"N., long. 112°50'55"W.; due east approximatiely 12 miles to a point approximately 1 mile south of circular butte to lat. 43°47'40"N., long. 112°34'30"W.

Issued in Washington, DC, on February 8, 1990.

Harold W. Becker,

Manager, Airspace—Rules and Aeronautical Information Division.

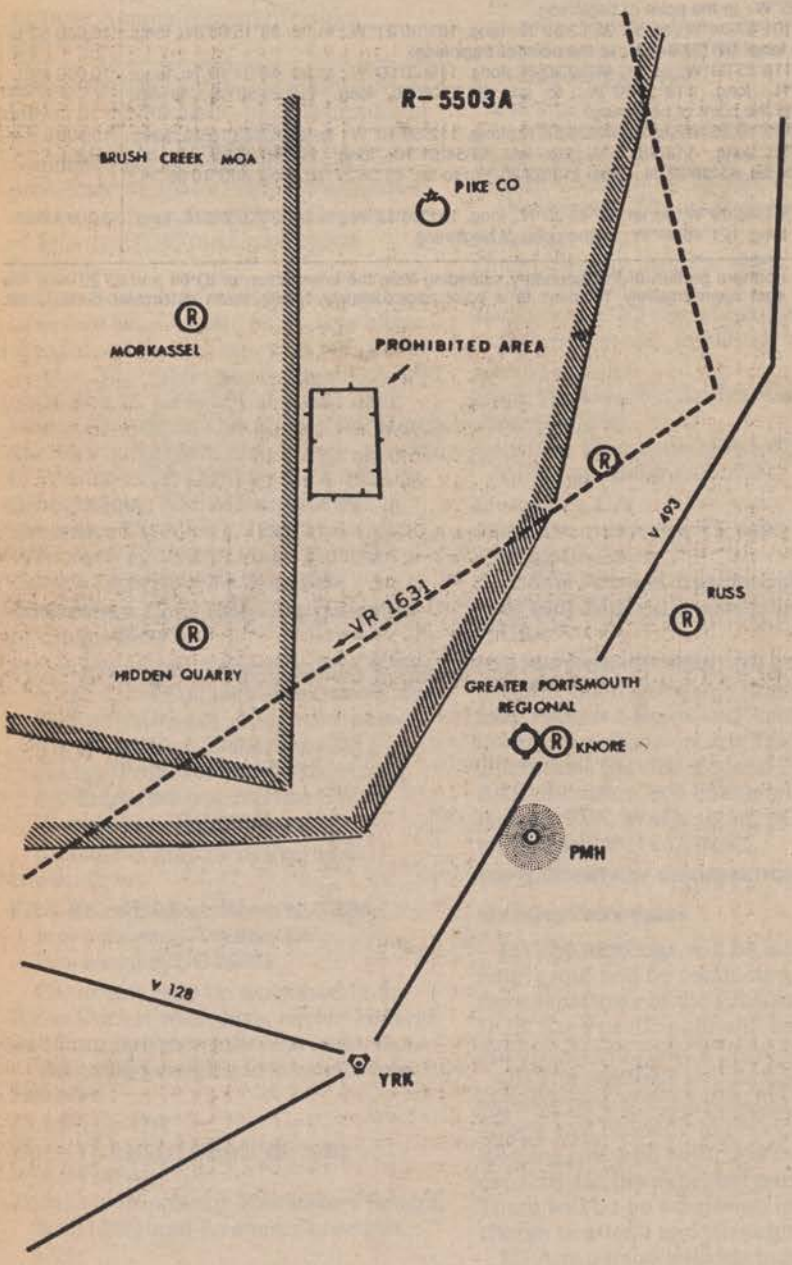
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PIKETON, OH.

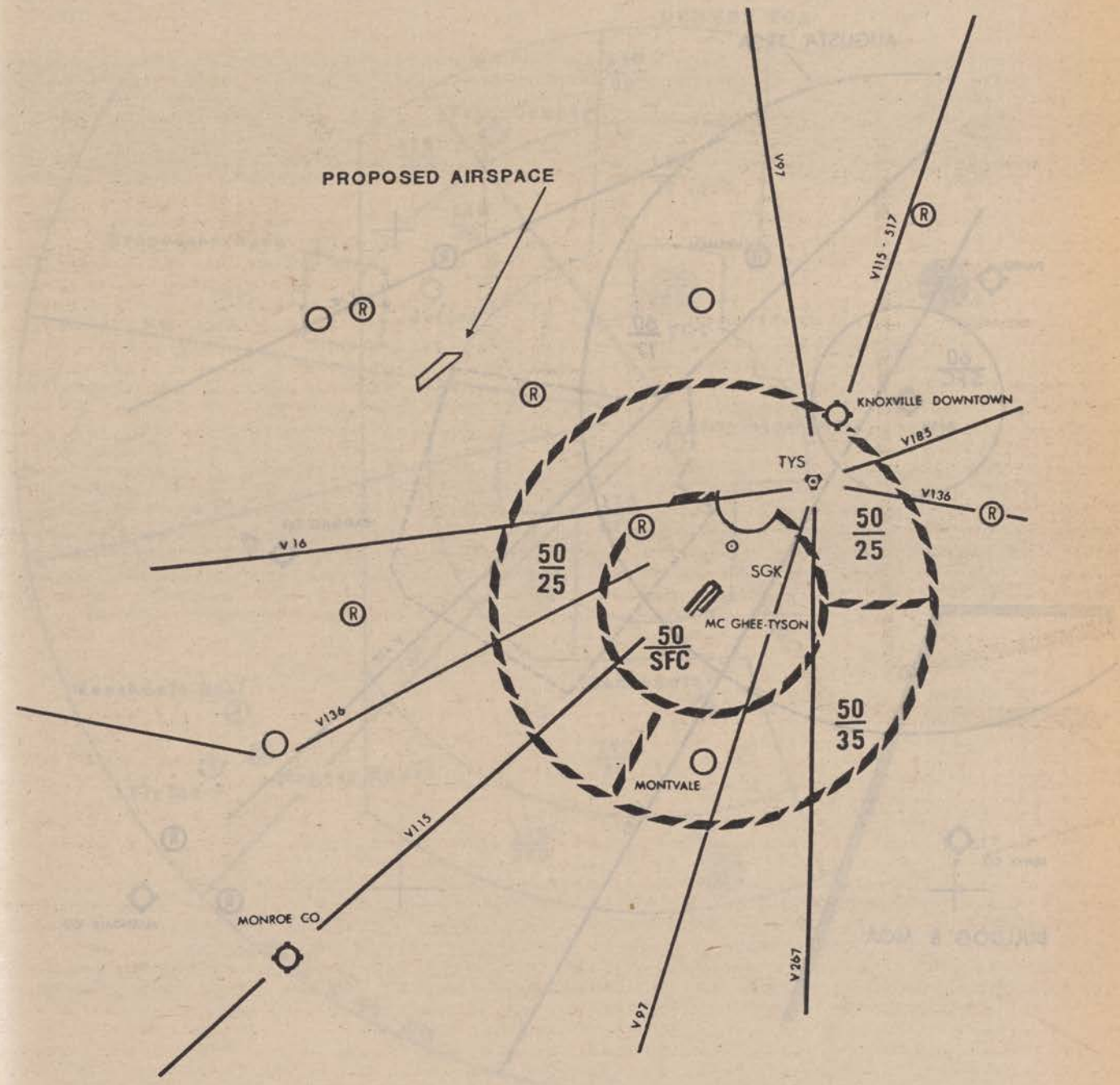
Proposed Prohibited Airspace

Designated Altitude
5,600 Ft.MSL



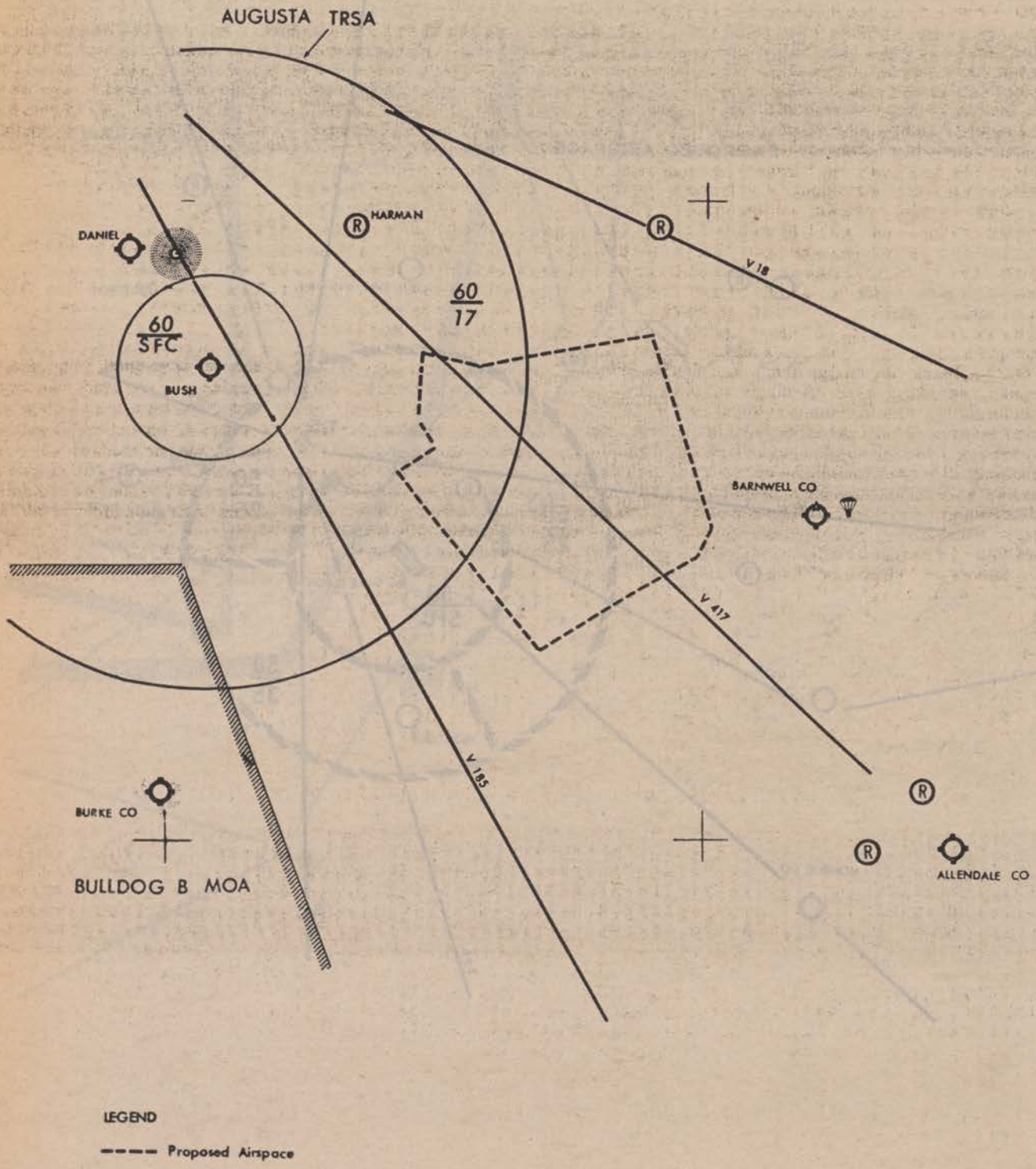
OAK RIDGE, TN.
Proposed Prohibited Airspace

Designated Altitude
4,000Ft. MSL



AIKEN, SC
Proposed Prohibited Airspace

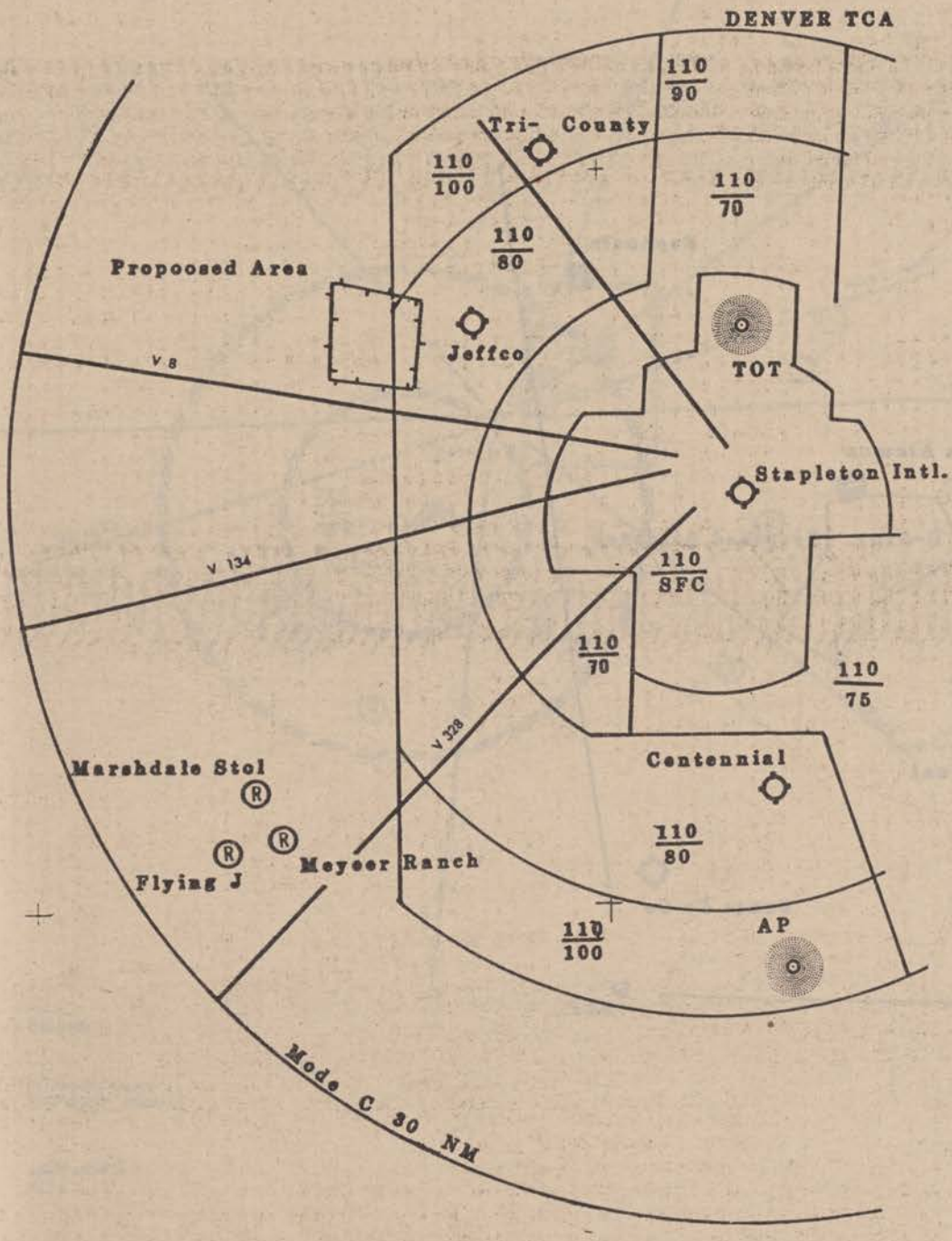
Designated Altitude
10,3000Ft. MSL



GOLDEN, CO.

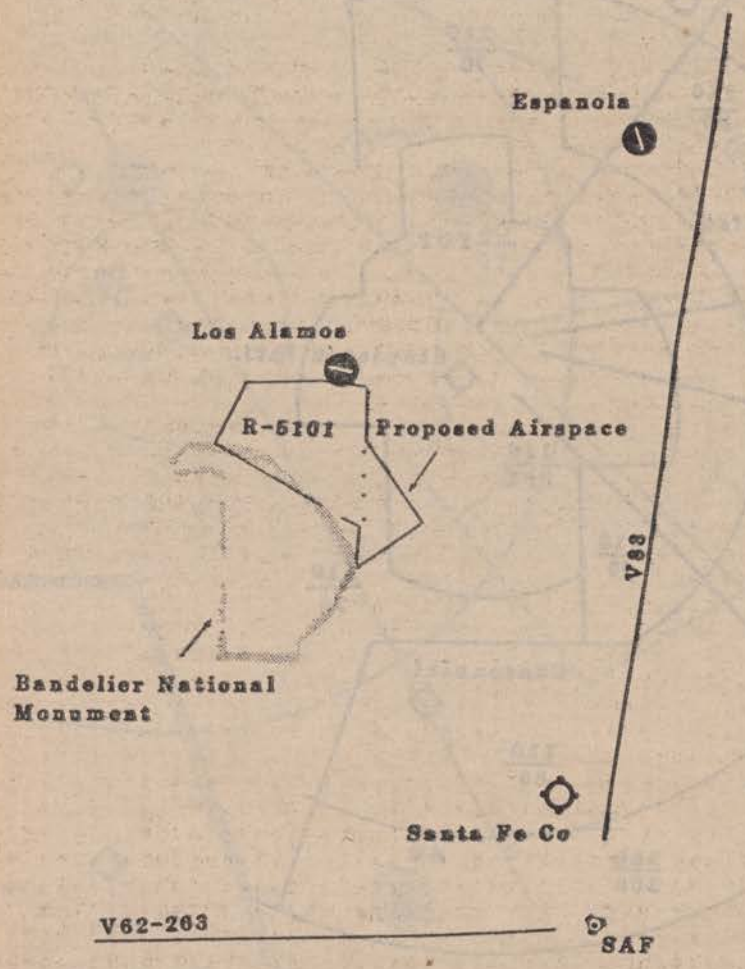
Proposed Prohibited Airspace

Designated Altitude
10,500 Ft. MSL



LOS ALAMOS, NM.
Proposed Prohibited Airspace

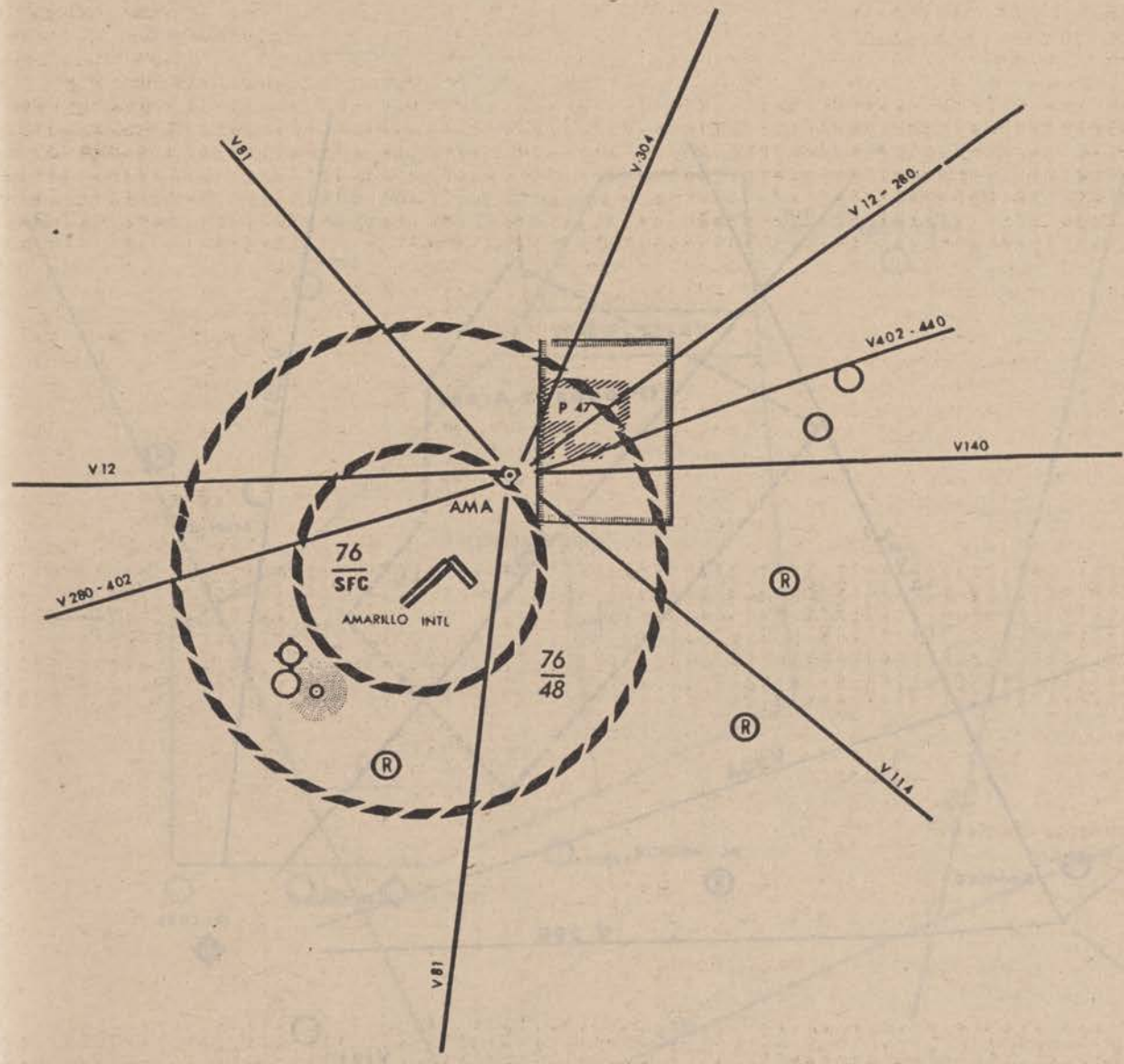
Designated Altitude
14,500Ft. MSL



AMARILLO, TX.

Proposed Prohibited Airspace

(Designated Altitude)
10,000FT. MSL



LEGEND

PROPOSED AIRSPACE

ARSA

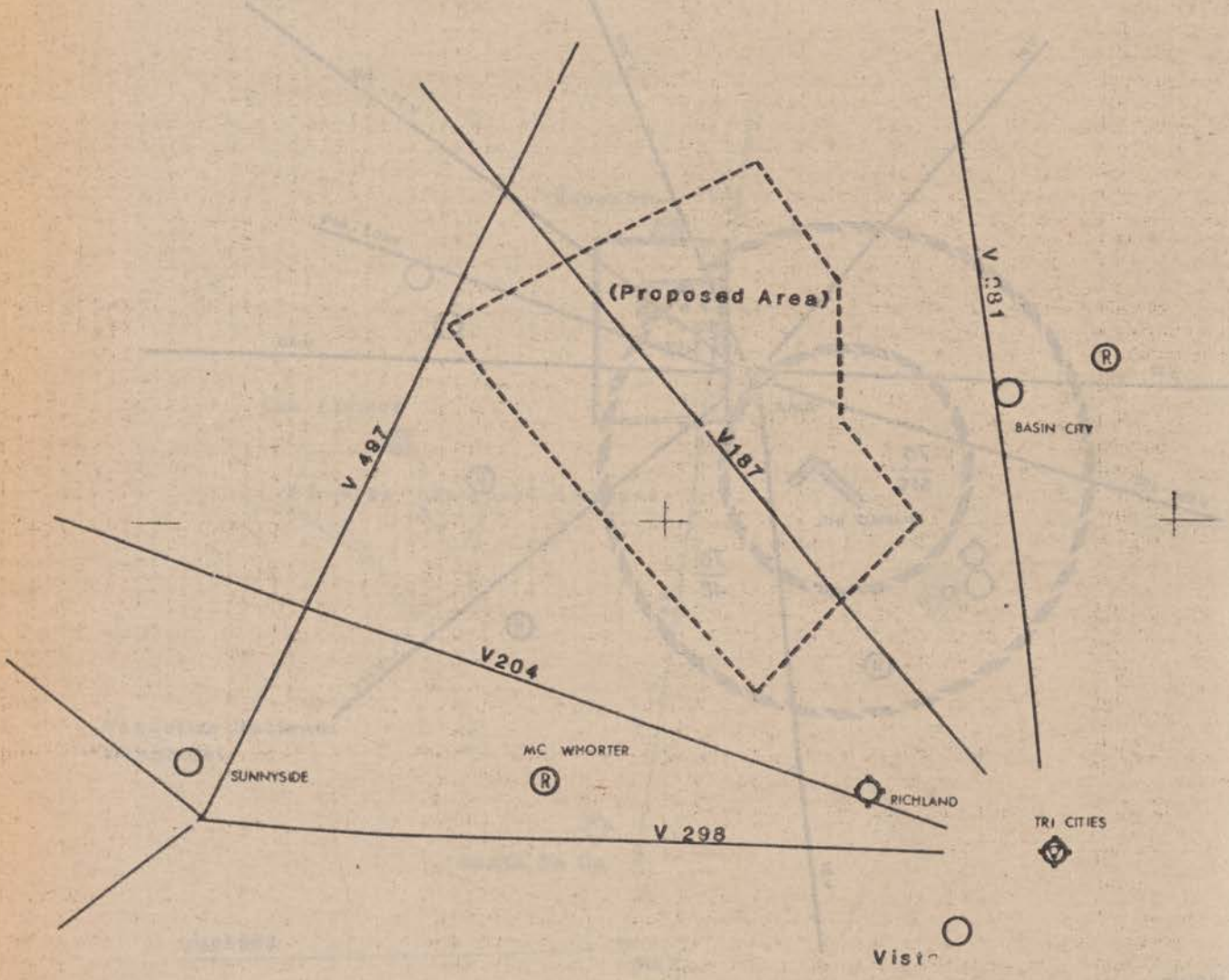
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RICHLAND, WA.

Proposed Prohibited Airspace

Designated Altitude

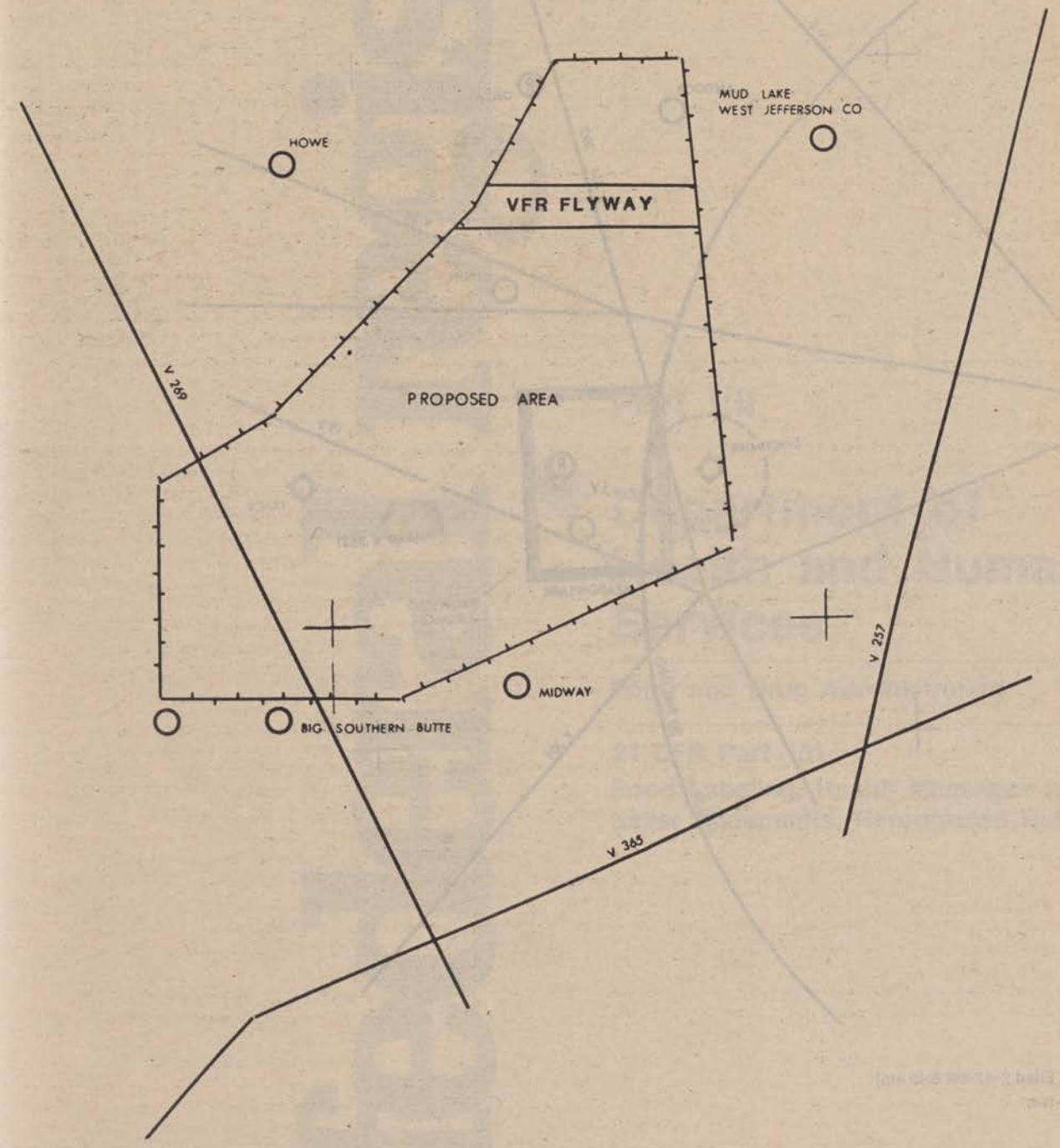
10,000 Ft. MSL



IDAHO FALLS, ID.

Proposed Prohibited Airspace

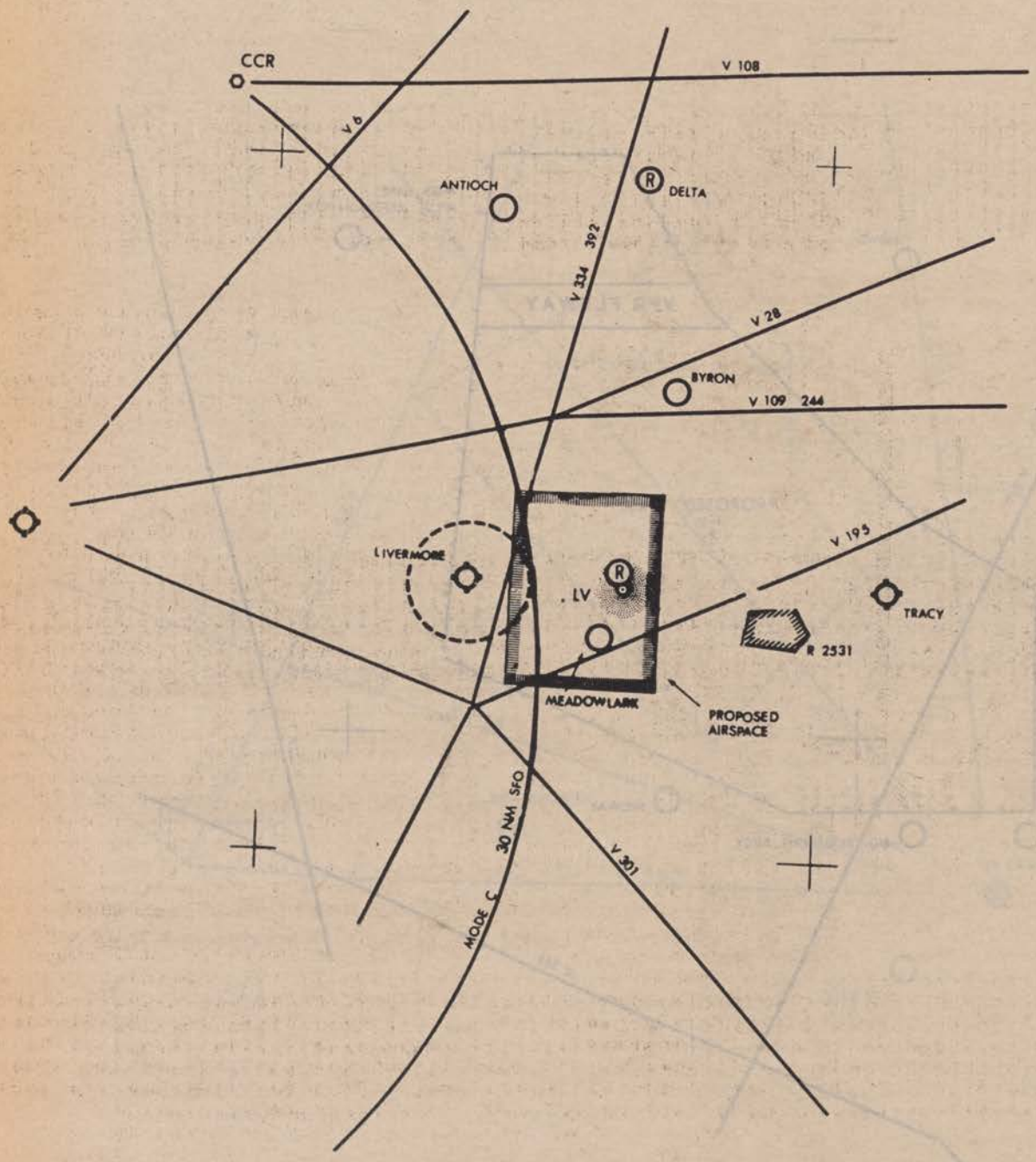
Designated Altitude
10,000 Ft. MSL



LIVERMORE, CA.

Proposed Prohibited Airspace

Designated Altitude
3,000 Ft. MSL



Doc. 90-3377 Filed 2-12-90; 8:45 am]
NG CODE 4910-13-C

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federal register

Tuesday
February 13, 1990

Part VII

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101

Food Labeling; Health Messages and Label Statements; Reproposed Rule

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 85N-0061]

RIN 0905-AB67

Food Labeling; Health Messages and Label Statements; Reproposed Rule

AGENCY: Food and Drug Administration HHS.

ACTION: Reproposed rule.

SUMMARY: The Food and Drug Administration (FDA) is reproposing to amend the food labeling regulations to provide for the use of health messages on food labeling. The purpose of this reproposal would be to establish procedures for permitting valid and reliable consumer information on food labels about the value that ingestion (or reduced ingestion) of a dietary component, as part of a total dietary pattern, may have in either lowering the risk, or forestalling the premature onset, of a particular chronic disease condition. In light of this reproposal, the agency is withdrawing the August 4, 1987 (52 FR 28843), proposal on health messages on food labels. FDA is also outlining how it is likely to enforce its regulations that bear on health messages during the period that it is receiving and considering comments on this reproposal. Finally, FDA is providing information on the proposed functions and responsibilities of the Public Health Service (PHS) Committee on Health Messages; on the agency's proposed plan to utilize health messages as a consumer education tool; and on the agency's proposed plan to prepare a consumer guide to food labeling.

DATES: Written comments by April 16, 1990. The agency is proposing that any final rule based on the reproposal become effective 1 year after date of publication of the final rule in the Federal Register.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

FOR FURTHER INFORMATION CONTACT: V. P. Frattali, Center for Food Safety and Applied Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1064.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of August 4, 1987 (52 FR 28843), FDA published a proposal to amend the food labeling regulations to "codify and clarify" the agency's policy on the appropriate use of health messages on food labeling. "Health messages" refer to statements concerning reducing the risk, or forestalling the premature onset, of certain chronic serious disease conditions (e.g., coronary heart disease, high blood pressure, cancer, osteoporosis) through changes in the diet. In the proposal the agency discussed its rationale for initiating a change in traditional agency policy by permitting well-supported health messages to appear on food labels. The proposal also summarized four relevant citizen petitions (filed by the Center for Science in the Public Interest, the Council for Responsible Nutrition, the National Food Processors Association, and the Kellogg Co.) and invited comments on them. The agency also announced that the Assistant Secretary for Health (ASH) would establish an interagency Committee on Health Messages (the PHS Committee) chartered by the Public Health Service as an advisory body to FDA in the development of health messages appropriate for food labeling. Finally, the agency posed a series of questions and called for comments on all aspects of the document.

FDA requested written comments on the proposed rule and related issues by November 2, 1987. Based on several requests, the agency extended the comment period until January 4, 1988 (November 2, 1987 (52 FR 42003), corrected November 16, 1987 (52 FR 43772)). FDA received approximately 575 comments in response to the proposal, including comments from consumers and consumer advocacy groups, health care professionals and biomedical professional organizations, industry and trade associations, academicians and their societies, and Federal, State, and local government agencies.

During the comment period the Commissioner held a series of informal meetings with representatives of (1) the food industry and related trade associations, (2) consumer advocacy groups, (3) biomedical professional organizations, and (4) representatives of the food supplement industry (Refs. 1 through 4). The purpose of these meetings was to establish a dialogue with each of the groups on the many issues involved in establishing a new policy on health messages on food labels. In addition, the Human Resources and Intergovernmental Subcommittee of the House Committee on Government Operations (the Subcommittee) held a hearing on this subject in December 1987 (Refs. 5 and 6).[1] Views expressed at the meetings and at the congressional hearing were taken into consideration in the development of this reproposal.

II. Comments on Appropriateness of 1987 Proposal

Many of the comments concerning the agency's initial proposal expressed general support for the concept of providing information to consumers about the diet and its impact on human health. Some of those who commented expressed support for the use of the food label as a proper vehicle for conveying health-related dietary information, thus enhancing consumer awareness of the relationship between diet and health.

However, there were strongly expressed views that safeguards must be in place to limit the nature and scope of health statements that may be used on the food label or labeling and thus reduce the potential for false or misleading statements. Numerous comments, for example, suggested that food label statements have the potential to be misleading if they do not provide complete and balanced information that would enable the consumer to understand the important ramifications of a specific diet/chronic disease relationship. Other comments were concerned about how all the information needed by consumers can be provided in the very limited space available on the food label and in sufficient detail to be of value to consumers in assessing a particular food and how it fits into the context of a total diet.

Many comments contended that the initial proposal was vague and unenforceable and expressed concern about potential proliferation of deceptive labeling under the new policy. Numerous comments called for clarification of what constituted valid, reliable scientific evidence to support any health message. Many comments also pointed out that strict enforcement by the agency was important and expressed the belief that the agency did not have the resources to do the job adequately, particularly if government preclearance was not in place.

The majority of comments on the initial proposal from the medical profession, academicians and their societies, dietitians and their societies, and consumer advocacy groups, while endorsing the concept of health

[1] In October 1989, the Subcommittee held a second hearing on health messages. The views expressed at this hearing were also considered by the agency in the development of this reproposal (see Ref. 9).

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messages on food labels, opposed the proposal. Approximately half of the comments from individual consumers, State and local government representatives, and foreign respondents also expressed opposition to the August 1987 proposal. Many of these comments contended that health messages on food labels are not in the consumer's best interest, and that FDA's current policies and standards have served the agency and the public very well and, therefore, should be maintained.

Some comments expressed the view that it is not possible to devise label statements that are pertinent for the general population. A few comments noted that label statements appropriate for adults may be inappropriate or harmful for infants, preschoolers, senior citizens, or other specific groups.

Other comments suggested that the dietary needs of individuals are so diverse that it is inappropriate to provide dietary information on food labels.

A large number of comments asserted that the initial proposal was not in the public interest because it could substantially increase the use of misleading claims on food labels. Some comments noted that the food label is currently viewed as a credible source of information, and that a proliferation of health claims would undermine this credibility and confuse consumers.

III. 1989 Food Labeling Advance Notice of Proposed Rulemaking

On August 8, 1989 (54 FR 32610), FDA published an advance notice of proposed rulemaking (ANPRM) concerning food labeling. The agency requested public comments on five areas: (1) Whether to revise the requirements for nutrition labeling; (2) whether to change the nutrition label format on food packages; (3) whether to revise the requirements for ingredient labeling; (4) whether to formally define commonly used food descriptions and reconsider the use of standards of identity for foods; and (5) how to reasonably permit the use of messages on food labels that link food components to reducing the risk of chronic disease.

The ANPRM noted the extreme divergence of opinions on the legal, scientific, and practical aspects of the 1987 health messages proposal (52 FR 28843) and stated that this divergence had impeded the agency's progress toward a resolution (54 FR 32610 at 32615). Thus, FDA considered it appropriate to request further comments from interested persons. Specifically, the agency requested comments on the approach or process that it should utilize to assure resolution of the health messages issue.

The ANPRM also noted that, to maximize the public's responsiveness to the many important food labeling issues, FDA planned to hold public hearings in different areas of the country (54 FR 32610). A notice announcing the dates, location, and focus topics of a series of four public hearings on food labeling and an extension of the comment period on the ANPRM until January 5, 1990, was published in the **Federal Register** on September 20, 1989 (54 FR 38806). On December 7, 1989, FDA held a food labeling hearing in Seattle at which health messages were the prime focus. The comments received at this hearing, and the other hearings held under the ANPRM, that relate to health messages will be considered as part of this rulemaking on health messages.

FDA recognizes that there are descriptors that are used on food labels that describe only the characteristics of the food, although they may have some health implications (e.g., "low in saturated fat"). FDA advises that it intends to address these descriptors separately under the ANPRM and not through this rulemaking.

IV. Deficiencies in, and Withdrawal of, the 1987 Proposal

Based in part on the adverse comments and the extreme divergence of opinion about the August 1987 proposal, the agency has concluded that the proposal was too broadly written. Some manufacturers have taken advantage of the uncertainties created by the August 1987 proposal by making drug claims on health fraud products and then, when challenged by FDA, asserting that these claims are consistent with how food can be labeled under the proposal. The August 1987 proposal was not intended to provide a means by which fraudulent or misleading claims could be made to the American public. Thus, while FDA continues to believe that some form of health message could be an appropriate part of the food label, the agency has become convinced that the health messages concept needs to be refined and narrowed in scope from that presented in the 1987 proposal.

In view of these factors, FDA has decided to withdraw the August 1987 proposal in its entirety and to replace it with this reproposal. This reproposal, which is based in large part on the agency's consideration of the comments on the August 1987 proposal, supersedes that proposal in all respects. Specifically, pursuant to 21 CFR 10.85(e), the advisory opinion contained in the August 1987 proposal is revoked. Accordingly, the agency is no longer bound in any way by the 1987 proposal or by the statements made in its preamble. This reproposal sets forth the agency's tentative views on health messages. Nothing contained in this reproposal should be considered to be an advisory opinion within the meaning of 21 CFR 10.85(d)(1).

FDA is taking this action even though the ANPRM contemplated that health messages would be included among the subjects considered as part of that proceeding (54 FR 32614 to 32615). The factors that have led FDA to withdraw the 1987 proposal have convinced the agency that more specific action with respect to health messages is necessary at this time.

Once the agency has concluded the hearings on the ANPRM and received comments on the ANPRM and on this reproposal, FDA will determine how to proceed in this rulemaking.

V. The Reproposal

A. The Role of Food

As discussed in the August 8, 1989 ANPRM, claims regarding the role of a food in the prevention, cure, mitigation, or treatment of a disease evidence an intent to offer the product as a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the act)(21 U.S.C. 321(g)(1)(B)). The ANPRM also recognized that, under section 201(g)(1)(C) of the act, claims regarding the effect of food on the body need not make that food a drug if the claims relate to how the food affects the structure and function of the body. Therefore, a discussion on the label of a food product of the role of calcium, for example, in building strong bones and teeth would generally not be a drug claim. Foods have effects like these by virtue of their nutritional value when consumed over time and not as the result of an immediate pharmacological response, as is the case with drugs. However, comments on the August 1987 proposal (as discussed in more detail later in this document) reveal that this distinction between food and drugs was not sufficiently drawn in the 1987 document, causing confusion in interpretations of the intent of the proposal. With the publication of this reproposal, FDA is providing guidance on what distinguishes a food claim from a drug claim.

In providing this guidance, FDA is governed by the definitions in the act and guided by judicial opinions construing these definitions. In one such decision, the United States Court of Appeals for the Seventh Circuit

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concluded that "* * * the statutory definition of 'food' includes articles used by people in the ordinary way most people use food—primarily for taste, aroma, or nutritive value." (*Nutrilab, Inc.* v. *Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983)).

The concept of "nutritive value" in this decision is basic to the distinction between a food and a drug. Nutritive or nutritional value is the ability of food to supply nourishment, that is, that that is necessary for maintaining life. Nutritional value is realized, however, only as part of a total diet.

Nutritional value includes the usefulness of a food component in reducing the risk of a disease or condition that is caused solely as a consequence of a lack or insufficiency of that component in the diet. As a hypothetical example, were pellagra a major disease in the U.S., a discussion of the role of niacin in preventing pellagra could be considered a nutritional claim, and thus a food claim, because pellagra is a direct result of a niacin deficiency, and that deficiency can be corrected by consuming nicacin at levels that approximate the Recommended Dietary Allowance. (However, elsewhere in this document, FDA proposes that health messages be limited to chronic diseases of major importance. Moreover, a claim related to a disease that is virtually nonexistent in the U.S., such as pellagra, could be misleading because it could convey an impression to the consumer that the ordinary diet is not sufficient to prevent the disease.) On the other hand, a discussion of, or a claim relative to, the role of niacin in reducing serum cholesterol, and thus reducing the risk of coronary heart disease, would go beyond the concept of health messages and enter the realm of drug claims because the ability to reduce serum cholesterol is not related to niacin's role as a vitamin in the diet at levels approximating the Recommended Dietary Allowance. Such a claim is a therapeutic claim related to the effect of a level of the nutrient far beyond that provided by an ordinary, nutritious diet.

Nutritional value may also include the usefulness of a food component, consumed as part of the total diet, in reducing the risk, or forestalling the premature onset, of a chronic disease condition. It is now believed that diet can have some effect on a person's risk of developing chronic diseases. Assuming that there is appropriate scientific evidence to support the existence of such an effect, a discussion of that effect would not necessarily make a food a drug. For example, a dietary reduction of saturated fat has been associated with a reduction in blood cholesterol level, which is a known risk factor for cardiovascular disease. On the label of a food that is low in saturated fat, a discussion of this association, and of how the food could be used as part of a low fat diet, would arguably be a discussion of its nutritional value and not evidence that the intended use of the product is as a drug.

In sharp contrast is the discussion of the role of the "food component" in *Nutrilab, Inc.* v. *Schweiker, supra*. That case involved "starch blockers," tablets and capsules that consisted of a protein that was extracted from a certain type of raw kidney bean. This protein functioned to prevent an enzyme from acting in the gut. The manufacturer of this product claimed that the tablets and capsules would block the digestion of food and aid in weight loss. The court found, based on these claims, that these products were taken for their effect on the body, rather than for their taste, aroma, or nutritional value. Therefore, the court concluded that these products were drugs and not foods (id. at 338–339).

The purpose of this reproposal is to explore further whether and how useful, truthful, and nonmisleading health messages about the nutritional value of foods with respect to chronic diseases can be formulated.

B. The Surgeon General's Report and the National Academy of Sciences (NAS) Report

Two recent major reports that bear directly on this question are the Surgeon General's Report on Nutrition and Health by the Public Health Service of the Department of Health and Human Services (DHHS 1988) ("the Surgeon General's Report") and "Diet and Health: Implications for Reducing Chronic Disease Risk" by the National Research Council's Food and Nutrition Board (NAS 1989) ("the NAS Report"). These reports have provided comprehensive analyses of the current scientific evidence on the relationship between diet and health.

The Surgeon General's Report analyzed the scientific evidence relating dietary excesses and imbalances to chronic disease and, on the basis of this evidence, recommended dietary changes intended to improve the public health. Through extensive review chapters, the report examined in detail the current knowledge about the relationships between specific dietary practices and specific disease conditions and summarized the implications of this information for individual food choices, public health policy initiatives, and further research.

The NAS Report, which was issued a year later, also provided a comprehensive analysis of the scientific literature on diet and the spectrum of major chronic diseases. The report systematically evaluated the scientific evidence relating dietary components, foods, food groups, and dietary patterns to the maintenance of health and reduction of risk of chronic diseases; assessed the scientific evidence relating these same factors to health and reduction of chronic disease risk; proposed dietary guidelines for maintaining health and reducing chronic disease risk; and suggested directions for future research.

There is general agreement between these two reports in their conclusions about the current state of knowledge about diet and health and a convergence of dietary recommendations that apply to risk reduction with respect to several chronic diseases. Both reports, for example, identify the reduction of total fats as the primary priority for dietary change because of their relationship to the risk of several important chronic disease conditions. Together, the two reports represent the most generally agreed upon scientific basis for health messages and recognized the utility of food labeling as a vehicle for providing a consumer with information on the relationship between diet and health.

C. FDA's Objectives in This Reproposal on Health Messages

Historically, FDA has treated health messages relating to chronic disease conditions as indicating that a product was intended to be used for drug purposes. Under this historical view, a new drug application was required to substantiate the safety and the effectiveness of the product.

In recent years, however, FDA has come to the tentative judgment that it may be appropriate to allow expanded health information on products that are consumed primarily as foods. Such information, if based on sound scientific data and if properly presented, can be useful to consumers who desire to adopt a healthier dietary pattern.

FDA is concerned, however, that if health messages are to be permitted, they be authorized with appropriate restraints that will protect the public. The agency's first level of concern is related to protection of the public health. In particular, FDA wants to ensure that health messages are not presented in such a way that certain segments of the population will forgo needed medical treatment based on the

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information that they obtain from the label and labeling of the food products they consume. Likewise, the agency is concerned that consumers who are under a doctor's care for treatment of chronic disease conditions and who may be taking drugs for those conditions, not substitute commonly available foods for the prescribed treatment. To this end, FDA is reasserting in this document the traditional distinctions between foods and drugs which became blurred as a result of the August 1987 proposal.

Under the act, FDA is also responsible for assuring that consumers are not misled by the labeling of either foods or drugs. The agency's responsibility extends not only to prohibiting false statements but also half truths or other statements on labels or in labeling that may mislead the public. In this regard, section 201(n) of the act provides in essence that in determining whether a label or labeling is misleading, the agency must look not only at what is said but also to the relevant information that has been omitted.

In the context of health messages on food labels, FDA believes that statements relating to medical, scientific, or health information have a potential for misleading the public, which has come to expect very high standards in the quality and accuracy of this information. There are numerous ways in which such information can be misleading. For example:

1. The statement on the label may be inconsistent with the total scientific knowledge on the topic being addressed, or it could highlight certain findings without indicating that other data point to different conclusions.

2. The statement may reach a conclusion that goes beyond what available scientific data actually demonstrate.

3. The label of a particular product may suggest that the product will reduce the risk of developing a chronic disease condition when the available data reveal that only the total dietary pattern produces this effect.

4. Even if the information is truthful, the emphasis or other aspects of the presentation may cause the consumer to misperceive the truth (e.g., a health message tied to the low cholesterol content of a food that is high in saturated fat).

FDA is thus trying to formulate a health messages policy that avoids these or other possible ways of misleading the consumer. Indeed, the agency does not believe that it is in the public interest for the food label to lose its credibility. FDA also firmly believes that all responsible companies, as well as the community of public health professionals and consumers, support having expanded health information that minimizes the likelihood of consumers being misled.

Finally, FDA is concerned that there be equal treatment of all competitors who are selling similar products to the public. Those responsible companies who are attempting to label their products honestly and in accordance with the laws and applicable regulations should not have to face competition from labels that are intended to increase market share by causing consumers to draw unsupported conclusions about the health effects of products that are no better than competing products in the marketplace.

This reproposal is intended to help achieve these multiple objectives. The agency recognizes, however, that it may not have achieved the right balance. FDA, therefore, invites comments from all segments of the public on whether the balance should be different, or whether there are other improvements in the policy that should be considered.

D. Provisions of the Reproposed Amendment to § 101.9

The purpose of this reproposal is to establish procedures for permitting valid and reliable consumer information on food labels about the value that ingestion (or reduced ingestion) of particular food components, as part of a total dietary pattern, may have in lowering the risk, or delaying the premature onset, of a particular chronic disease condition. The reproposal lists the criteria that a health message on a food label would have to satisfy to meet that purpose and to avoid causing the food to be in violation of the act. In addition, these criteria would provide guidance to the PHS Committee, which FDA is proposing to establish, in its deliberations on the appropriateness and sufficiency of the science supporting a particular diet/chronic disease relationship being considered as a topic for a health message. The criteria also would provide guidance to other interested persons who might wish to propose a health message to the agency for its consideration.

The following is a description and brief explanation of the criteria for FDA to use in deciding whether a particular diet and chronic disease relationship is a candidate for a health message:

Proposed § 101.9(i)(1) retains the current rule that a food would be misbranded if its labeling claims that, because of the presence or absence of certain dietary properties, the food is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom. Such a food would also be subject to regulatory action based on the fact that it is a drug under the definition in 21 U.S.C. 321(g)(1)(B). However, given the Surgeon General's Report, the NAS Report, and other evidence of growing acceptance that diet has a role in reducing the risk, or forestalling the premature onset, of certain chronic disease conditions, FDA is proposing to allow foods to bear a health message about the association of diet and chronic diseases in certain limited conditions. As the agency discussed above, these health messages can be viewed as descriptions of the nutritional value of the food. The agency also recognizes that a claim that a product "may reduce the risk" or "may forestall the premature onset" of a particular chronic disease is arguably a claim that it will prevent or mitigate the disease and thus a drug claim. If these claims are drug claims, the agency is considering using its enforcement discretion in the limited circumstances outlined in this reproposal to not take actions against such products under the drug provisions of the act. FDA requests comments on the appropriateness of the aforementioned claims and on whether these claims should be viewed as claims about nutritional value or as drug claims.

FDA is proposing to allow health messages on foods based on its finding that all of the following criteria are met:

(1) The label statement is truthful and not misleading. This criterion would be crucial to the successful implementation of the reproposed health message policy. It is self-evident that the label statement would have to be truthful. The concept that the label statement must not be misleading is equally important. Section 201(n) of the act instructs the agency, when determining if a label is misleading, to consider what is omitted from, as well as what appears on, the label.

There are, as discussed previously, a number of ways for a label statement to be misleading. In addition to the ways listed above, a label statement would be misleading, first, if it omitted significant information that might be needed to properly interpret the label statement. Second, while specific statements might be true by themselves, when considered with other label statements, the overall impression conveyed might be misleading. Third, a labeled food might contain insignificant amounts of the dietary component referred to in the label statement. Fourth, the food, in addition to having a health benefit, may have other attributes that might make a health claim for the product misleading. These, and possibly other, conditions could lead FDA to conclude that a label

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statement caused the food to be in violation of any final rule based on this reproposal.

(2) The label statement is limited to describing the value that ingestion (or reduced ingestion) of a dietary component, as part of a total dietary pattern, may have in either lowering the risk, or forestalling the premature onset, of a chronic disease condition. Such a statement would have to be based on the totality of publicly available scientific evidence, including that evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles.

This criterion would require that the statement be supported by a sound body of scientific evidence upon which a significant agreement exists among qualified experts as to the relationship between a dietary component and the reduction of risk presented by a particular chronic disease condition (see discussion in section V. E. of this document, infra). FDA would not accept preliminary data or significantly contradictory findings as the basis of support for a label statement. While all relevant data on a topic would be considered, the quality of study from which data are derived would have an important bearing on how much weight is placed on the data. Finally, judgments concerning the quality of data, the appropriateness of the study design, and the conclusions derived from the total body of evidence would be based on those generally recognized scientific procedures and principles that are most appropriate to the issues being addressed.

(3) The label statement is consistent with generally recognized medical and nutritional principles for a sound total dietary pattern.

Each label statement would have to provide some basis for a consumer to decide whether (and how) the labeled food best fits into an individual's diet.

(4) The label statement is based on and consistent with the conclusions set forth in an applicable scientific summary and consumer health message summary (see discussion in section V. E. of this document, infra) accepted by FDA.

FDA is proposing to establish scientific summaries and consumer health message summaries to ensure that there is scientific and practical support for health messages, and that the scientific support is available in a comprehensive form to consumers. The health message contained in the label statement would be described in greater detail in these documents. The health message summary would be an extension of the label statement for purposes of providing full information and proper balance to the label statement itself. The existence of these documents would enable the consumer to better judge whether the label statement applies to him or her and, in certain instances, to what extent it applies.

(5) The label statement includes a reference to the applicable consumer health message summary (see discussion in section V. E. of this document, infra).

FDA is proposing to require that the health message include a reference to the applicable consumer health message summary. This reference would direct the interested consumer to more complete and balanced information on the food component/chronic disease interaction being referred to by the label statement. Under this proposed mechanism, the most complete expression of the health message would be contained in the consumer health message summary. It would be necessary for the label statement to contain a reference to this summary because, otherwise, the label would fail to reveal the existence of more complete information that would be required to complement and give balance to the label statement.

(6) The food is labeled in accordance with the requirements of § 101.9.

FDA believes that nutrition labeling is another mechanism to provide more complete information on the nutritional characteristics of the labeled food. Because virtually any food can be appropriate for certain individual diets and inappropriate for others, the information supplied by nutrition labeling would allow individuals to judge whether a given food will be compatible with their individual dietary goals. An important aspect of this reproposal is that the use of a health message would trigger full nutrition labeling in accordance with 21 CFR 101.9.

E. Scientific Summaries, Consumer Health Message Summaries, Model Label Statements, and Consumer Guide to Food Labeling

Under this reproposal, the agency is proposing to require the development of three items as a means of regulating the content of health messages: (1) Scientific summaries, (2) consumer health message summaries, and (3) model label statements. In addition, the agency is proposing to develop a consumer guide to food labeling. These four components together represent a possible vehicle by which the agency could communicate to the industry, the scientific community, and consumers what FDA considers to be appropriate information regarding diet and chronic disease interactions suitable for discussion on the food label. For each diet and chronic disease topic area, a scientific summary, a consumer health message summary, and model label statements would be developed concurrently. Although these three components are discussed separately below, they would be submitted as a unit to the PHS Committee for scientific and health-policy review.

The agency is outlining only one possible approach to regulating health messages. However, FDA may decide that an alternate mechanism is more appropriate. For example, FDA may be convinced that all claims that address a special dietary need that exists by reason of a chronic condition (e.g., the need to reduce blood cholesterol levels) should be regulated under section 403(j) of the act (21 U.S.C. 343(j)), as a claim related to a food for special dietary use. Another possibility would be the establishment of a petition process for health messages. Thus, FDA solicits comments on the appropriate mechanism for regulating the content of health messages.

1. Scientific summary

The purpose of the first component of the reproposed process would be to summarize the most relevant scientific information on the role of a particular food component (e.g., calcium) in reducing the risk of premature onset of a particular chronic condition (e.g., osteoporosis) and to permit FDA and the PHS Committee to decide whether there is adequate scientific evidence to develop a model label statement.

a. *Content of summary.* Each scientific summary would concentrate on the findings of appropriate review articles, National Institutes of Health consensus development conferences, and other appropriate resource materials, particularly the Surgeon General's Report and the NAS Report. Issues addressed in the scientific summary would include such questions as:

(1) Is there an optimum level of the particular food or food component to be consumed beyond which no benefit would be expected?

(2) Are there safety concerns about high levels of consumption?

(3) Are there certain populations that must receive special consideration?

(4) What are the foods that are significant sources of the component being considered, and what are the roles of these foods in the context of the total diet in affecting a particular condition? and

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(5) What other nutritional or health factors (both positive and negative) are important to consider when consuming such foods and food components?

b. *Scientific standard.* FDA seeks comment on the standard that would be used in deciding whether a particular dietary/chronic disease relationship actually exists, and whether, if it does, it is an appropriate basis for a health message. Possible standards include whether a consensus exists to support the relationship, as evidenced by authoritative reports such as the Surgeon General's Report and the NAS Report, or whether substantial evidence of the existence of the relationship would be adequate.

(1) A few comments on the initial proposal indicated that unpublished or proprietary studies, as well as published studies, should be accepted as appropriate for supporting health messages. Some comments suggested that proprietary studies should be kept confidential until after the health claim is made public, so that the manufacturer sponsoring the study could enjoy the competitive advantage afforded to the initial user of the label claim. On the other hand, one comment suggested that manufacturers should not be allowed to conduct their own studies to support health claims. A few comments requested that studies be peer-reviewed before they are accepted as adequate support for a health message.

Under the proposed process for developing a health message, FDA and the PHS Committee would consider any valid and reliable scientific evidence that is submitted, regardless of the source. The most important characteristic of study results is that they be obtained from well-designed and well-conducted studies, whether published or unpublished, proprietary of publicly available. It is nonetheless essential to the goals of the health messages policy that the data be open to public scrutiny. The open nature of the review process that FDA is proposing makes it impossible to treat a study as confidential once it has been submitted to the PHS Committee for review. Further, any topic area for which there is sufficient evidence to successfully support a label statement is likely to have been investigated in multiple studies from a number of different, publicly available sources. Thus, it is probable that data from government and academic laboratories will be available to compare with data from manufacturer-sponsored studies. Concerning peer-reviewed data, FDA regards the process set out in the proposal for developing health messages as an adequate peer review process. Scientific data would be subjected to expert scrutiny as it progresses through the various stages of the process.

(2) Several comments offered advice on whether clinical studies, animal studies, and epidemiological data should be required or viewed as sufficient scientific evidence to support a health message. A few comments noted that it is difficult to conduct adequate, well-controlled clinical studies related to foods, and that a requirement for such studies might hamper development of health messages. At least one comment noted that it is not possible to specifically prescribe the type of studies that will be needed to support health messages. On the other hand, some suggested that epidemiological data alone should be accepted as sufficient to support a health message.

FDA tentatively concludes that the agency will not prescribe a specific set of studies or types of studies as being sufficient to support a health message. The very nature of the various food components and the wide variability of possible studies make it difficult to outline precise requirements. The amount and type of evidence required may differ from case to case, depending on a number of variables. The ideal circumstances is to have data from well-designed and conducted studies to provide the scientific basis for any decision that might be made.

(3) A few comments indicated that corroboration of health messages should be based on the more stringent standard of a "consensus of scientific opinion," rather than the "weight of the scientific evidence" standard. On the other hand, some comments objected to requiring a consensus because it is impossible to achieve. A few comments contended that, if a consensus is required, consumers would be deprived of early access to valuable nutrition information.

FDA has carefully considered a number of different approaches regarding the appropriate standard of proof for health messages. As discussed elsewhere in this document, FDA believes that the nutrition and health issues raised by the health messages concept are vitually important to the American consumer. These considerations are far too important to the potential outcome of some of our most common chronic diseases to consider the scientific data in less than a very rational and serious manner. The main objective of the reproposed health messages concept is to provide useful nutrition information to consumers regarding the potential influence of their eating patterns on a number of chronic diseases. Thus, given the important nature of the relationships being discussed, the huge number of people that may be affected, and the lasting impressions that official pronouncements leave on the public consciousness, FDA tentatively concludes that the standard proposed will meet the objective. However, because the scheme laid out in this proposal has not previously been elucidated, the agency, as stated above, seeks further comment on what this standard should be.

(4) Several comments suggested that health messages based on preliminary studies or unconfirmed findings should be permitted. Some of these comments clarified that a statement indicating the preliminary or unconfirmed nature of the findings should be included in the health message.

FDA does not agree that health messages on food labeling should be made based only on preliminary or unconfirmed findings. Label statements contemplated by the proposal and this reproposal would convey dietary recommendations that are based on valid, reliable scientific evidence that is generally recognized and accepted by the scientific community. The agency considers that preliminary and unconfirmed findings would not be sufficient to ensure that the specific dietary recommendation implied or expressed in a health message is truthful and nonmisleading. The reproposal does not contemplate condoning health messages outside those developed through the process detailed earlier in this document or by whatever alternate process is ultimately adopted in the final rule.

(5) A few comments recommended that the requirements for substantiating health messages for foods should be the same as for drugs.

The criteria laid out in this reproposal pertain to substantiating a given health message and are not entirely dissimilar from the criteria that would be applied in substantiating the validity of a drug claim. The primary difference between the approaches lies in the agency's willingness to consider a broad array of data concerning the relationship between diet and chronic disease, including data that, over the years, have helped form generally recognized medical and nutritional principles concerning what constitutes a sound total dietary pattern.

2. Consumer health message summary

The second component of the reproposed process for developing a health message would entail the

development of a "consumer health message summary." The agency agrees with comments on the initial proposal that stressed that consumer education programs are vital to the successful communication of dietary advice and to the appropriate use of such advice. Consequently, the consumer health message summaries would provide the supporting scientific information on a specific diet/chronic disease relationship in lay language, would be available for distribution to the general public, and would be referred to in the label statements. A consumer health message summary would be developed for each diet and chronic disease relationship for which a health message would be appropriate. FDA seeks comments on how these messages would best be developed.

The summaries would provide further detail and balance to the brief summaries that may appear on food labels. They would include recommendations concerning the role of specific food components in the total dietary pattern and useful information on sources of the food component—including, when appropriate, quantitative dietary intake recommendations for the general population, and special considerations that may apply to selected subpopulations (such as infants and children). In conjunction with the food label, the consumer health message summary would serve two basic functions. First, it would foster public health by providing a more extensive source of information on a relationship between a given diet and a condition (compared to what is possible in the limited space on the food label), and second, it would help to alleviate the potential problem of information overload on the label. As described further below, the reproposal would require a cross-reference to the consumer health message summary to appear on the food label. The label statement would have to bear a reference to a consumer health message summary to ensure that a complete and balanced discussion about appropriate use and limitations of the nutritional component is provided.

3. Model label statement

The third component of the reproposed process for developing a health message would be the formulation of model label statements that may be used on food labels to convey appropriate information regarding a diet/chronic disease interaction or topic area. The nature and extent of the label statement would be based directly on, and supported by the conclusions of, the scientific summary. Model label statements would be developed for each of the topic areas in which the agency would have determined, based on the advice of the PHS Committee, that the state of scientific opinion supports dietary recommendations, as related by the contents of the scientific summary. The model label statement would define the minimum material facts that must be included in a label statement to ensure that it is not misleading. The model label statements would include:

(1) A brief capsulized statement (e.g., 50 words in length) of the relevant conclusions of the appropriate scientific summary;

(2) A statement of the extent to which the food product contains or does not contain the key food component, and how this food product helps the consumer to attain a total dietary pattern or goal associated with reduction in the risk of the relevant chronic disease;

(3) A reference indicating that more complete nutrition/chronic disease information is available from the appropriate consumer health message summary, and how that summary may be obtained; and

(4) A statement directing the consumer's attention to the nutrition label for further nutrition information.

Although manufacturers would be urged to use approved model label statements, they would be free to devise their own statements, provided those statements are consistent with the conclusions of the approved scientific summaries and consumer health message summaries and meet the criteria identified in the reproposal.

A few comments on the August 1987 proposal opposed the initial proposal for FDA to develop model label statements. Some comments contended that the process for developing model label statements would be too slow and would, therefore, hamper industry's creativity and flexibility for providing consumers with health-related information.

FDA recognizes that the process for developing health messages would require a commitment of time, and that any delay caused by the time needed for their development may be considered by some to be an impediment to industry's ability to provide consumers with chronic disease-related information. However, the agency's belief that it needs to develop model label statements has been reinforced by the comments that expressed concern that without proper guidance there is a real potential for proliferation of false and misleading health claims. As stated earlier, the agency believes that the process for developing health messages would not be inordinately slow. Therefore, FDA has tentatively concluded that the agency should prepare the model label statements.

4. Consumer guide to food labeling

The reproposed process for developing a health message would also entail the development of a consumer guide to food labeling (consumer guide) that would discuss in general terms how the various types of consumer-oriented information found on the food label are to be used.

The consumer guide would address questions such as: (1) What is a consumer health message summary and who is it for? (2) What is nutrition labeling and how is it used in dietary planning? (3) What is the importance of the total diet in maintaining good health? (4) What is the process used to develop label statements and consumer health message summaries? (5) Are label statements and consumer health message summaries applicable to specific groups (e.g., certain statements or messages may not be appropriate for infants or children)? and (6) How can consumers use ingredient statements, common or usual names of foods, and descriptors (e.g., "low sodium") to assist them in sound dietary practices?

There would be one "umbrella" consumer guide prepared that would be broadly applicable to all health message subject areas.

F. The PHS Committee on Health Messages

FDA is proposing to have all components of the reproposed health message process, described above, reviewed by the PHS Committee established by the ASH. The PHS Committee would be chaired by the ASH or the ASH's designee and be composed of individuals within Government who are knowledgeable in the sciences relating to diet, nutrition, and health. FDA is proposing that in addition to itself, the PHS Committee would include representatives from other components of the PHS (Office of the Assistant Secretary for Health, National Institutes of Health, Centers for Disease Control) and from the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA). The Federal Trade Commission (FTC) would appoint a liaison member.

The PHS Committee would serve as an advisory body to FDA on issues related to the use of food labels to

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communicate information on the relationship between diet and health. The specific functions of the PHS Committee would be to review and make recommendations on the documents described above (section V. E. infra).

PHS Committee members would coordinate review of these documents with appropriate scientific personnel within the represented agencies. The PHS Committee would solicit the views and comments of other recognized experts in specific areas. These other experts could be from government agencies not represented on the PHS Committee, academia, consumer groups, industry, or the biomedical professions. Expert opinion could be either submitted in writing or presented orally to the PHS Committee. The PHS Committee could recommend consumer testing of model label statements and consumer health message summaries to ensure that they would be correctly interpreted by consumers.

If the PHS Committee concluded that truthful, nonmisleading chronic disease-related label statements could be developed in a specific area, the PHS Committee would request that FDA announce in the Federal Register the availability for public comment of draft scientific summaries, consumer health message summaries, and model label statements.

After appropriate deliberations, the PHS Committee could recommend that FDA adopt, by publication in the Federal Register, approved model label statements. The PHS Committee could also recommend that a particular topic area covered by a draft scientific summary is not adquately supported by scientific evidence and is not suitable for label statements. In addition, the PHS Committee could recommend that additional diet and chronic disease relationships be considered for development of scientific summaries, consumer health message summaries, and model label statements.

1. Many comments on the initial proposal supported the role of the PHS Committee in developing model label statements. However, a few comments objected to the formation of the PHS Committee, contending that it is premature, unnecessary, and potentially counterproductive. Some comments argued that the PHS Committee would be unnecessary because it would have no legal or procedural status for issuing binding advice.

FDA disagrees with the position that the formation of the PHS Committee, under the process outlined in this document, would be unnecessary or counterproductive. Although the PHS Committee would have no legal or procedural status for issuing binding advice, this fact would not render the PHS Committee unnecessary. The PHS Committee would serve the important function of reviewing and making recommendations on scientific summaries, consumer health message summaries, and model label statements. Having the recommendations of the PHS Committee would assist FDA in taking the procedural actions needed to implement these recommendations, as appropriate.

2. Several comments objected to the composition of the PHS Committee. Some comments suggested that the PHS Committee should include industry and consumer representatives and pediatricians. Some comments indicated that the PHS Committee should also include representatives from FTC and the National Marine Fisheries Service (NMFS) of the National Oceanic and Atmospheric Administration (NOAA). One comment suggested establishing an industry advisory panel to the PHS Committee to assure that industry could participate in the information of guidelines and suggestions for health messages.

It is important for the various agencies of the Federal government that have relevant expertise to have a forum that would permit the agencies to coordinate their expertise in developing meaningful health messages. The ASH would determine the exact makeup of the PHS Committee if FDA determines that it is appropriate to establish such a committee. However, if the PHS Committee is established, it should include both PHS components and other Federal agencies. Thus structured, the PHS Committee would be able to operate efficiently and would ensure that the views of qualified experts, as well as the views of all interested persons, receive full consideration. Because the PHS Committee would be charged with ensuring that interested persons have an opportunity to make their views known to the PHS Committee, there would be no need for each interested group to have a representative on the PHS Committee or for separate advisory panels to be created.

3. One comment indicated that, for each model label statement approved by the PHS Committee, FDA should provide a comprehensive explanation of the basis for the claim and the reasons for the PHS Committee's approval of the statement. A few comments also suggested that the PHS Committee publish draft health messages for public comments.

The scientific support for model label statements recommended by the PHS Committee for FDA approval would be contained in the scientific summary. The draft scientific summaries as well as the draft consumer health message summaries and model label statements would be made available for public comment after the PHS Committee recommends to FDA that they be published.

4. A few comments suggested that meetings held by the Committee should be open to the public.

If the Committee is established, its meetings will be open to the public, if appropriate.

5. One comment suggested that health messages should be developed by a process similar to the process used for developing Recommended Dietary Allowances. Another comment suggested that health messages should be based on the dietary guidelines published by DHHS and USDA.

FDA agrees that a proccess must be developed that benefits from expert interpretation of the best scientific data available. The process outlined in this reproposal is similar to the process used by the Committee on Dietary Allowances of the Food and Nutrition Board for establishing the Recommended Dietary Allowances. FDA believes that the recommendations made in the dietary guidelines and the scientific data used to develop those guidelines would be carefully considered in the process used to develop health messages.

G. Effect of Use of Summaries

If FDA adopts the mechanism outlined in this reproposal, it would function in the following way: The use of approved label statements and health message summaries would be viewed by the agency as an appropriate, worthwhile effort to inform the American consumer about the relationship between diet and certain chronic diseases. Accordingly, food products bearing model label statements or similar label statements derived from or adequately supported by one of the scientific and consumer health message summaries and consistent with the characteristics of the respective food products would not be the subject of enforcement action under either the food or the drug misbranding provisions or the new drug provisions of the act solely because of the presence of such statements. Manufacturers, however, who deviate inappropriately from model label statements and consumer health message summaries would subject their products to substantial risk of regulatory action

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under the food and drug misbranding provisions as well as the new drug provisions of the act.

H. Implementation

Comments on the initial proposal suggested that FDA, when formulating health messages, follow a more limited, manageable approach than that laid out in the 1987 initial proposal. These comments requested that FDA focus on the role of diet in reducing the risks presented by those diseases that are of major significance to the American population. The comments asserted that such an approach would be consistent with the agency's desire to use the food label to communicate meaningful health-related information.

The agency carefully evaluated these comments. Part of that evaluation included a consideration of the major interactions between diet and chronic diseases for which there exist sufficient evidence and scientific acceptance that would support a health message appearing on food labeling. Consistent with the comments mentioned above, the recent Surgeon General's Report supports restricting the agency's attention to a limited number of topic areas. The agency has tentatively identified six topic areas as appropriate subjects for initial consideration: (1) Calcium and osteoporosis; (2) sodium and hypertension; (3) lipids and cardiovascular disease; (4) lipids and cancer; (5) dietary fiber and cancer; and (6) dietary fiber and cardiovascular disease. FDA believes that these topic areas relate to problems of major health significance and are areas that have been the subject of sufficient scientific study to establish a science base adequate for review by FDA. By concentrating its efforts on developing scientifically supportable label statements regarding these areas; the agency believes it has the most realistic chance of providing the public with useful, desirable health-related information. Moreover, an initiative limited to these six areas would be most manageable in light of the effort and resources needed to thoroughly and responsibly develop chronic disease-related messages.

The agency acknowledges that, as knowledge about diet and health interaction continues to grow, health messages may be approrpiate in other areas. Thus, the regulatory process set out in this reproposal would permit the development of other scientific summaries, consumer health message summaries, and model label statements, as advances in scientific knowledge warrant.

VI. Interim Enforcement Policy

Several comments on the 1987 proposal suggested that FDA implement a moratorium on the use of label statements contemplated by the proposal until a more definitive enforceable regulation could be developed. FDA agrees that under its current regulations, health messages, as defined in this document, would be misleading and thus would be barred. While FDA recognizes its obligation to follow its regulations, the agency also recognizes that it does not have the resources to take action against all products that bear health messages. Therefore, FDA believes it is appropriate to set forth in a general way how the agency is likely to exercise its enforcement discretion with respect to health messages.

In conjunction with this reproposal, manufacturers may continue to include health messages on their products. Such messages will be carefully scrutinized, however, on a case-by-case basis. The agency will exercise its enforcement discretion and bring regulatory actions against label claims in appropriate circumstances. For example, if a message states or implies that the product is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom, FDA may bring an action against the product as a drug as well as a misbranded food. In addition, the agency may bring an action against a product as a misbranded food if it bears a health message that is false or is misleading in any respect.

FDA does not believe that it is appropriate to define the claims that can be made without concern that FDA will bring regulatory action against products so labeled. One of the difficulties with the August 1987 proposal was that it attempted to define a "safe harbor" through a notice of proposed rulemaking. Under *Community Nutrition Institute* v. *Young*, 818 F.2d 943 (D.C. Cir. 1987), the agency simply cannot bind itself in this way in a proposed (or in this case, a reproposed) rulemaking. Thus, it is not possible to define a "safe harbor" at this time.

Accordingly, FDA provides the following guidance on how it is likely to exercise its enforcement discretion.[2]

1. As stated above, FDA recognizes that a claim that a product "may reduce the risk" or "may forestall the premature onset" of a particular chronic disease is arguably a claim that it will prevent or mitigate that disease and thus a drug claim. While FDA requests comment on this issue, the agency advises that the use of either of the phrases "may reduce the risk" or "may forestall the premature onset" in a claim in one of the six topic areas about which significant and general scientific agreement exists, in and of itself, is less likely to result in regulatory action than will a claim that more firmly asserts the relationship between the food component and the disease.

2. In the absence of a final rule that defines a "safe harbor," the use of any health message on a food label may result in a regulatory action. However, the health messages that are, for the present, least likely to run the risk of regulatory action are those regarding topic areas about which significant evidence and general scientific agreement exists. The two recent authoritative reports on the relationship between diet and health cited above, the Surgeon General's Report and the NAS Report, have identified six topic areas about which such evidence may exist: (1) Calcium and osteoporosis, (2) dietary fiber and cancer, (3) lipids and cardiovascular disease, (4) lipids and cancer, and (5) sodium and hypertension, and (6) dietary fiber and cardiovascular disease.

In deciding how it will exercise its enforcement discretion with respect to claims that come within these six areas, the agency will consider such factors as whether the claim is adequately supported by the scientific evidence; whether the claim is exaggerated; whether the food component that is the subject of the claim is present in sufficient quantities (or reduced sufficiently) to justify the claim; and whether the benefits from the component (or reduction of the component) are outweighed by the negative attributes of another component of the food with respect to the same chronic disease (e.g., a heart disease claim on a low sodium food with a high saturated fat content).

3. A claim outside the six topic areas for which supporting scientific evidence is rapidly accumulating is at greater regulatory risk than those in the six areas, but the agency is still likely to consider the nature of the claim and the extent of support for the claim before taking regulatory action.

4. A claim outside the six areas with no developing scientific support is likely to be misleading and thus will be at greatest risk of regulatory action.

FDA recognizes that the absence of a defined "safe harbor" at this time may restrict the development of health

[2] Obviously, a food product must not be adulterated in any way, e.g., it must not contain an unapproved food additive.

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messages on food labels. The agency believes that the food label has an important role as part of a broader public education initiative about nutrition and health, and that this initiative is in the best interest of consumers. The agency also recognizes, however, that the food label alone cannot reasonably be expected to convey a complete and balanced summary of any particular diet/chronic disease relationship. The concept of health messages on food labels is relatively new, the practical implementation and scope of which is still being defined. Therefore, there is a need to move systematically and cautiously to establish a process to ensure that truthful, useful, and nonmisleading health messages that consumers can understand and rely upon can be developed.

The agency also cautions that this document is only a proposal. No final decision has been made regarding the types of claims that may be made on food, even with respect to the six topic areas identified on the basis of the Surgeon General's Report and the NAS Report. Therefore, the agency reiterates that it will evaluate health messages on a case-by-case basis at least until there is a final rule in this proceeding.

VII. Other Comments on the Initial Proposal

A. Introduction

FDA recognizes that the interchangeable and inconsistent use in the initial proposal of various phrases such as "health messages" and "health-related messages," "health claims," and "health-related claims or information" was confusing. The agency considers that the phrase "health messages" more appropriately describes the type of information that was contemplated in the initial proposal and that best reflects the total concept of health information reflected in this reproposal.

Therefore, the agency has clarified and refined the terminology, as reflected in the definitions of "scientific summary," "consumer health message summary," "consumer guide to food labeling," and "model label statements" discussed earlier in this preamble. The agency's responses in the reproposal to comments received on the initial proposal have been made consistent, to the extent possible, with the defined terms.

Several comments on the initial proposal addressed issues raised by one or more of the citizen petitions referred to above. However, most of the comments did not generally refer to, or specifically identify, the citizen petitions as a basis for their comments. FDA, however, is treating the citizen petitions as comments on the initial proposal and is consolidating the issues raised in the citizen petitions with those raised in other comments.

B. Scope

1. One comment on the initial proposal recommended that the final rule clarify that the regulation applies to food labeling, as well as labels.

The agency advises that any final rule based on this reproposal would apply to food labeling. Section 201(m) of the act defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

2. Some comments suggested that label statements related to previously prevalent nutrition deficiency diseases should be permitted; e.g., scurvy or pellagra.

The purpose of this reproposal is to set forth procedures that could be established to permit food labels to bear valid and reliable consumer information about the relationship between several food components in the diet and chronic diseases. The focus of this rulemaking is on reduction of risk of serious chronic conditions that are of major importance in the United States. Hence, label statements concerning specific nutrient deficiency diseases, which are virtually nonexistent in the United States, could be misleading because they convey the false impression that the ordinary diet is not sufficient to prevent these diseases.

C. Legal Issues

3. A number of comments on the initial proposal pertained to FDA's regulatory authority over food labeling. Some comments contended that permitting health messages on foods without first subjecting the products to the rigors of the new drug approval process for such claims would be a violation of statutory requirements. Similarly, several comments argued that permitting such claims would be a reversal of the agency's long-standing policy prohibiting health messages and would be contrary to established legal precedent. On the other hand, some comments contended for various reasons that FDA has no legal basis to regulate foods as drugs on the basis of labeling claims.

FDA has broad regulatory authority over food labeling. The preamble to the August 4, 1987, proposal discussed the history of FDA's regulation of health-related information on food labeling. As discussed in that proposal, and as reflected in this document, the inclusion of health-related information on food labeling may affect the regulatory status of the food and may cause the food not only to be misbranded within the meaning of the act but also to be deemed a drug within the meaning of the act and therefore subject to the drug misbranding and new drug approval provisions of the act.

4. Several comments asserted that the First Amendment to the U.S. Constitution provides manufacturers and distributors of foods with the right to label their products with truthful and nonmisleading health messages. One comment noted that this right has been upheld in recent Supreme Court decisions defining the permissible scope of commercial speech. Other comments disagreed, stating that the agency has authority to restrict such claims when FDA determines that these restrictions are necessary to protect the public health.

The doctrine of commercial free speech was first recognized in 1975. See *Bigelow* v. *Virginia*, 421 U.S. 809 (1975). The fact that many of the cases that FDA and the courts have relied upon for its authority to control health-related claims for foods precede 1975 has led to questions about whether FDA's enforcement of the act in certain circumstances unduly infringes upon commercial free speech.

In general, the applicability of the First Amendment to commercial free speech is based on the "informational function" of advertising. See *Central Hudson Gas & Electric* v. *Public Service Commission*, 447 U.S. 557 (1980). The First Amendment does not protect commercial speech concerning illegal activity or speech that is false or misleading. In addition, even if the commercial speech is not misleading and is otherwise lawful, it nevertheless may be regulated if: (1) the governmental interest in regulating the speech is substantial; (2) if the regulation directly advances the governmental interest; or (3) if the restrictions are not more excessive than is necessary to serve the governmental interest (id. at 564). See also *Board of Trustees of the State University of New York* v. *Fox*, _____ U.S. _____ 109 S. Ct. 3028 (1989).

Congress has given FDA the authority to prohibit inappropriate health messages on food products. Preventing consumer deception is clearly a substantial governmental interest. Agency action to establish criteria for permitting nonmisleading and truthful label statements helps prevent consumer deception, protects the public health, directly serves the public and

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governmental interests, and, accordingly, does not infringe upon a manufacturer's commercial speech.

5. Some comments recommended that FDA work closely with other Federal agencies such as USDA and FTC to ensure that Federal agencies adopt a uniform policy on health messages. A few comments also advocated that FDA adopt FTC's "substantiation policy" that allows health-related claims in advertising as long as the claims are not deceptive.

In this reproposal, FDA reaffirms its intention, as stated in the initial proposal and suggested by the comments, to work closely with other Federal agencies to maximize consistency in approaches to providing dietary guidance. The intragovernmental committee structure proposed for adoption would provide for a degree of coordination among the agencies represented. The ASH may expand the PHS Committee, if it is established, beyond PHS to include other Federal agencies. Two key agencies with related responsibilities, FTC and USDA, would likely be involved in the deliberation of any committee, and other agencies would be consulted as appropriate.

Congress, however, explicitly granted different agencies different regulatory authority regarding food advertising and labeling. For example, FTC regulates food advertising under sections 5 and 12 of the Federal Trade Commission Act. These sections prohibit unfair or deceptive advertising.

Consistent with its efforts to be sensitive to the needs of advertisers and to avoid unduly burdening advertisers with regulations, FTC, in the late 1980's, issued three policy statements concerning how it interprets its law enforcement mandate under the Federal Trade Commission Act. One of the policy statements deals with the "substantiation" of claims made in advertising. The statement provides that firms are responsible for the level of substantiation that their advertisement conveys to the consumer. FTC determines the amount of evidence needed for "reasonable basis" for support of the advertisement. This "reasonable basis" can be one study recognized by some but not the majority of the experts in a given area of expertise. A "reasonable basis" can also be the results of one study even if they conflict with those of another similar study.

FDA is not convinced that this standard is adequate for determining the appropriateness of claims on the food label. As several comments pointed out, it is important that consumers maintain confidence in the food label. Consumers view food labeling as more reliable and trustworthy than food advertising. The existence of this dichotomy in consumer preception of the information from these two sources is supported by the results of several surveys and confirmed by a number of experts in the area of advertising and communication (Ref. 8).

Food labeling has a high degree of acceptance among the general public. For example, when asked in a 1984 Roper Survey what sources of information about the nutritional content of food they thought most useful, labels on food packages were the most widely used source, mentioned by 57 percent of the public. Advertisements were considered the most useful source by only 4 percent. These results are essentially unchanged from a 1976 survey. Similarly, a 1980 FDA survey indicated that the perceived honesty/integrity/truthfulness of the food label is very high. Only 1 percent of respondents reported ever having bought a food product that was falsely labeled. In a 1981 survey about what FDA activities were most worthwhile, the two highest rated activities (tied for first) were "making sure food is safe to eat" and "making sure food labeling is honest" (Ref. 8).

Implementation of a health messages policy must proceed in a way that maintains and enhances consumer confidence in the reliability and integrity of the food label. The agency believes that the implementing mechanisms set forth in this reproposal will safeguard against false and misleading label statements. FDA also plans to continue to consult with other agencies, including USDA and FTC, whenever appropriate to promote consistent policies.

6. One comment contended that any prohibition of "health claims" would contravene expressed Congressional intent for information to be disseminated to the public regarding the relationship between diet and health.

FDA believes that its efforts in this rulemaking are consistent with the congressional intent. Although Congress intended that truthful and nonmisleading information regarding the relationship between diet and health be disseminated to the public, Congress also charged FDA with enforcement of the misbranding and new drug provisions of the act. By this reproposal, FDA intends not to interfere with the dissemination of accurate information but to establish a process by which truthful and nonmisleading information about the relationships between diet and health may be provided to the public in food labeling.

7. One comment recommended deleting the word "solely" from proposed § 101.9(j). The comment argued that if a label statement complies with the requirements of proposed § 101.9(i), the labeling should not be a factor in determining whether the food is a "drug" within the meaning of the act.

FDA has removed proposed § 101.9(j) from the reproposal. Given the changes that FDA has made in the proposal, the agency felt that removal of this provision was appropriate.

D. Dietary Supplements

8. A number of comments stated that section 411 of the act (21 U.S.C. 350) (the Vitamin and Mineral Amendments of 1976) precludes FDA from restricting the use of truthful health- and disease-related information in labeling of dietary supplements.

FDA's legal authority for regulating health claims on dietary supplements and its fundamental approach to such regulation did not drastically change as a result of the 1976 amendments. Although the 1976 amendments unquestionably limited FDA's regulatory authority over vitamins and minerals, the scope of the limitations is not broad. As the conference report (Ref. 7) on the amendments makes clear, the purpose of the amendments was to impose three restrictions on the agency. Each restriction deals with the potency of vitamin products (including foods for special dietary use).

First, FDA was prohibited from using its authority under section 201(n), 401, or 403 of the act (21 U.S.C. 321(n), 341, and 343) to impose maximum limits on the potency of safe vitamins and minerals intended for ingestion in tablet, capsule, or liquid form or intended as foods for special dietary use as defined by the amendments. Second, the amendments prohibited FDA from classifying as a drug any natural or synthetic vitamin or mineral, offered by itself or in combination, solely because it exceeded the level of potency that FDA determined to be nutritionally rational or useful. The third limitation imposed by the amendments was to prohibit FDA from using its authority concerning misbranding and standards of identity to limit the combination or number of any safe vitamin or mineral products identified in the amendments.

Excluded from these limitations is any vitamin, mineral, or other ingredient or special dietary food which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or pregnant or lactating women. See

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section 411(a)(2) of the act (21 U.S.C. 350(a)(2)).

The conference report on the bill discussed the extent and the purpose of section 411(a)(2) of the act as follows:

> The provision with respect to foods intended for use in the treatment or management of specific diseases or disorders was adopted in conference in order to make clear that the proposed new section 411(a) of the Act does not override the Secretary's authority under section 401, 403, or 201(n) of the Act to limit the potency and combination of vitamins, minerals, other ingredients in foods, or foods, represented *for use in the dietary treatment or management of individuals with specific diseases or disorders*, or of post-operative or convalescing medical patients.
>
> Since each of these foods must be precisely formulated to meet the needs of individuals with specific diseases and disorders, the conference substitute clearly preserves the authority of the Secretary to regulate as foods the nutritional formulation, composition, and potency of each product represented for such uses * * *. (Emphasis added)
>
> Dietary management with these products is not only of major clinical value to the individual, but can be lifesaving in many instances. In the case of phenylketonuria and maple syrup disease, these foods provide the only means for *prevention* of mental retardation particularly in infants and young children, or for the partial restoration of mental capacity in older children. Special formula feedings are essential to long-term maintenance of severely debilitated individuals. Low sodium foods are useful in dietary management of individuals with severe forms of hypertension, acute heart failure, acute nephritis, toxemia of pregnancy and similar disorders when the degree of sodium restriction must be greater than that achievable with conventional foods * * * (Ref. 7, p. 27).

In sum, even the limitations in section 411 of the act on regulations concerning vitamin/mineral potency are limited.

Moreover, although the 1976 amendments expressly refer to special dietary use products as foods, the conference report goes on to make quite clear the agency may regulate any vitamin and mineral product as a drug: "If a product containing vitamins, minerals or other ingredients is a drug within the meaning of section 201(g) of the act, the [FDA] may, with respect to such product, exercise [its] authority" under the drug provision of the act (Ref. 7, p. 28). In so stating, Congress recognized a distinction between a representation that a vitamin or mineral product will prevent disease (which is a drug type claim) and a representation that a vitamin or mineral product supplies "a special dietary need that exists by reason of * * * disease," (which is a food type claim) (section 411(c)(3)(a) of the act). This is consistent with FDA's history of regulation of foods for special dietary use.

It is for all the above-stated reasons that the agency has concluded that section 411 of the act does not mandate that certain health and even disease-related information be permitted on the label of dietary supplements of vitamins and minerals. Section 411 of the act affirmatively limits FDA only to the extent FDA seeks to use the drug and misbranding provisions of the act to regulate the potency of foods for special dietary use which may contain vitamins and minerals.

9. One comment requested clarification of whether the initial proposal would affect the labeling of foods for special dietary use that simply identify the presence or absence of nutritionally recognized constituents.

The agency advises that the labeling of foods for special dietary use in the manner described in the comment would not be affected by any final rule based on this reproposal as long as the labeling did not include a health message.

10. A few of the comments on the initial proposal objected to FDA's statement in the proposal that, for dietary supplements, "the extent to which the criteria for evaluating health-related claims can be met may be limited." The comments contended that the statement reflects an alleged bias against dietary supplements and presumes that lable statements are inappropriate for dietary supplements. Several comments noted that dietary supplements are foods and suggested that they should not be treated any differently than other foods. In addition, the comments maintained that FDA should be evenhanded in its enforcement activities for dietary supplements.

Under the reproposal, FDA would apply the same criteria to all foods, including dietary supplements. Therefore, the agency does not agree that its discussion about the propriety of label statements on dietary supplements represents an agency bias against supplements. FDA's discussion of dietary supplements was, however, a reflection of agency support for the joint DHHS/USDA "Dietary Guidelines for Americans" statement, "There are no known advantages and some potential harm in consuming excessive amounts of any nutrient. Large dose supplements of any nutrient should be avoided." These guideline statements are directed at a normally healthy population and do not address specific subpopulations that may have medical reasons for specific nutrient needs. FDA's reproposed health message concept is based on a presumption that an appropriate, nonmisleading label statement will encourage consumers to develop a well-balanced dietary pattern and will not over-emphasize the role of a single food, including a dietary supplement, in enhancing good health.

11. Some comments contended that available literature already recognizes that individual nutrients are not only helpful, but necessary for the prevention of degenerative illness. Some comments alleged that, in some circumstances, a dietary supplement may be preferable to a food that provides the nutrient. Comments also argued that, for most nutrients, there is such a large margin of safety that it is unlikely that harmful quantities of nutrients will be consumed. Other comments objected to the use of health messages on dietary supplements. These comments noted that there is no evidence to support the view that dietary supplements are beneficial and cautioned that over ingestion of dietary supplements can cause a nutrient imbalance or toxicity. Several comments noted that healthy adults and children can obtain adequate nutrients from dietary sources, and that therefore, supplementation generally is not needed.

FDA recognizes the validity of the concern about over ingestion of dietary supplements and also recognizes the fact that dietary supplements can be beneficial for some consumers with special nutrient requirements. During the process of developing scientific summaries, consumer health message summaries, and model label statements, if it decides to adopt that mechanism, FDA will proceed cautiously on each identified diet/chronic disease issue to determine whether appropriate label statements can be devised for dietary supplements.

12. One comment noted that even truthful statements such as "vitamin C keeps gums healthy," "B-vitamins release energy," and "vitamin A is essential for good vision," on a dietary supplement are inherently deceptive. The comment contended that such statements imply that the referenced metabolic processes would not take place in individuals who fail to consume that particular supplement.

Whether such claims are misleading will have to be evaluated on a case-by-case basis. For example, a claim could be considered misleading if it implies that ingestion of a nutrient will prevent a condition (e.g., lack of energy) that, among most Americans who suffer from it, is caused by other than nutrient deficiency. The agency does not encourage such statements for there is

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little to be gained from implications that a sound dietary pattern will not supply the nutrient needs for most individuals.

13. One comment noted that 21 CFR 101.9(i)(6) currently prohibits claims implying that a natural supplement is superior to a synethetic supplement. The comment contended that it is contradictory to propose limiting claims to natural nutrient sources or to imply that they may not be appropriate for synthetic sources, i.e., food supplements.

FDA does not agree that making a distinction between dietary supplements and traditional food when evaluating the appropriateness of label statements contradicts 21 CFR 101.9(i)(6). This cited regulation provides that a food shall be deemed misbranded if its label represents, suggests, or implies that a natural vitamin in the food is superior to an added or synthetic vitamin or differentiates in any way between vitamins naturally present and those that are added. Label statements developed under this reproposal would not distinguish between natural and synthetic vitamins. Foods traditionally fortified with synthetic nutrients may be appropriate candidates for label statements related to the added nutrient. Thus, FDA's concern about the appropriateness of label statements would not be based on consideration of whether a nutrient is naturally occurring or added from a natural or synthetic source.

14. One comment recommended that a health claim promoting a nutrient should be permitted only on a food that provides at least 20 percent of the U.S. Recommended Daily Allowance for the nutrient.

FDA believes that a single percent content level above which health messages are appropriate cannot be predetermined. The distribution of nutrients in the food supply varies significantly, with some concentrated in a few food sources and others ubiquitous throughout the food supply. FDA reiterates a statement made in the initial proposal that: "The dietary characteristics of the food must be consistent with the message being used." Part of this consistency concerns the relative contribution to the total diet of the food component by the food source. Therefore, part of the development of each scientific summary would be consideration of which foods constitute a significant source of the food component of sufficient dietary impact to merit a health-related label statement.

E. Food versus Drug Distinction

15. One comment objected to product names that convey or imply a health claim, such as "Brain Power," "Immune Booster," and "Stress Guard."

FDA does not condone the use of product names that imply that the particular product may be used as a drug-like treatment for specific physiological disorders. These products will be subject to action under the drug provisions of the act. Moreover, they may be subject to regulatory action on the grounds that they are misbranded.

16. Some comments contended that current scientific data on the role of nutrition in disease prevention and treatment are insufficient to support establishment of truthful and nonmisleading health messages on food labeling.

FDA has carefully considered these comments. FDA agrees that it is premature to develop scientific summaries for the majority of potential diet/chronic disease areas that are the subject of ongoing research. However, FDA tentatively finds that for a small number of topics it may be appropriate to allow health messages on food labels. While this is the first time that the agency has considered allowing the food package label to be used as a means of providing the consumer with information on nutrition's influence on chronic diseases, there are other authoritative nongovernmental health organizations, as well as PHS agencies and the qualitative dietary guidelines published by DHHS and USDA, that have provided dietary recommendations to consumers for a number of years. FDA believes that it may be possible, by carefully selecting and reviewing a limited number of diet and chronic disease topic areas, for the agency to provide valuable guidance to consumers while maintaining order in the use of this new labeling concept in the marketplace.

17. One comment recommended that health messages, based on verifiable, traditional uses should be permitted on "traditional medicinal foods," such as herbal remedies.

FDA believes that this comment misses a fundamental point of this labeling initiative. The agency's initial proposal provided that label statements should not imply that a particular food could be used as part of a drug-like treatment or therapy-oriented approach to health care. Herbal remedies are generally drugs within the meaning of section 201(g) of the act and will be regulated in FDA's traditional manner.

F. Implementation

18. Several comments recommended that, to ensure the protection of the public from false and misleading health messages, the agency should require premarket approval of all food labels or labeling that bear such messages. On the other hand, a number of comments asserted that FDA has no statutory authority to require preclearance of truthful, adequately substantiated health messages on food labeling. Several comments suggested that the agency require prior notification of the use of proposed health messages on food labeling. One of the comments recommended that FDA require that it be notified 90 days prior to use of such claims, retain authority to request additional information on or substantiation for such claims, and provide public notice of the proposed use of such claims to assure that it has received all relevant information. Another of the comments opposing preapproval for health messages suggested that FDA offer advisory opinions regarding the propriety of product specific health messages.

FDA has not felt it necessary to explore in-depth its authority to establish a premarket clearance system. The agency has tentatively concluded that truthful, useful, and non-misleading messages will be produced by the proposed system, and that it has the authority to establish such a system. FDA could adequately enforce this system through postmarketing action. The agency, however, has consistently stated that it would welcome discussions with manufacturers and distributors wishing to place health messages on food products before the marketing of foods bearing such statements to help ensure that the information to be communicated is consistent with agency policy. However, the mechanism of offering official advisory opinions regarding specific health messages would be inconsistent with applicable agency regulations which provide that official advisory opinions may not be given regarding a particular product or label but rather must involve an issue of broad applicability (21 CFR 10.85(a)(2)(iv)). The scientific summaries and model label statements detailed in this reproposal would serve the function of providing official advice to those interested in such information of broad applicability. The citizen petition process procedure in § 10.30 (21 CFR 10.30) would be available to persons interested in proposing the wording of scientific summaries and model label statements for classes of products. With respect to the labels of specific products, more informal advice can be provided on a case-by-case basis.

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19. One comment questioned whether more than one label statement could be permitted on a food label.

The agency has not proposed to establish a limit on the number of label statements that could be placed on a food label. Thus, it is conceivable that labeling for a specific food could include more than one label statement developed under any final rule based on the reproposal, provided that the combined effect would not be misleading, and that collectively the statements met the requirements of the act and of any final rule based on this reproposal.

20. Several comments on the initial proposal indicated that it would be difficult to distinguish misleading health messages from nonmisleading label statements because it would be possible to develop a claim that is literally accurate but nevertheless misleading because it fails to provide complete or balanced information about the food. For example, as a number of comments pointed out, a health message on a food label may distort the consumer's impression of the relative nutritional value of the food so that he or she may be encouraged to purchase a food bearing the health message in lieu of another food that provides more essential nutrients or that otherwise is more appropriate for a well-balanced diet. In addition, several comments emphasized that both positive and negative aspects of a food's contribution to the total diet should be presented.

FDA is also concerned that consumers may be misled by statements that appear on food labels. In an effort to minimize this occurrence, the agency has proposed to adopt a mechanism that it believes would limit the potentially misleading aspects of health messages. FDA has tentatively determined that by concentrating its initial efforts on those food components for which there appears to be some significant degree of general scientific agreement regarding their importance in reducing the risk of chronic health conditions or in delaying their onset, it can provide a degree of guidance to industry that would effectively minimize the misuse or abuse of the health message concept.

In addition, the development and publication of scientific summaries and consumer health message summaries discussing any beneficial or adverse properties, sensitive subpopulations, significant food sources of each food component, and how this component interacts with other components in the total diet, would provide balanced guidance to consumers and enable them to make more informed choices in food purchasing and diet. FDA's tentative view is that scientific summaries and consumer health message summaries, along with nutrition labeling, would serve to minimize the potential that a health message about a single food component would communicate a misleading message to consumers.

21. Some comments suggested that promulgation of a regulation to permit health messages on food would lead to possible overfortification of the food supply.

It is difficult to predict what immediate influence any final rule based on this reproposal would have on the food industry with respect to additional efforts to fortify foods. FDA shares the concerns of this comment that indiscriminate addition of vitamins and minerals to foods, especially to unexpected or unusual food sources of those nutrients, could have unpredictable adverse consequences on selected individuals within the general population. Therefore, FDA reminds manufacturers of the agency's food fortification policy (21 CFR 104.20) and expects the food industry to follow this policy when fortifying foods. This practice should avoid the potential problem cited by this comment.

22. Several comments underscored the need for ensuring that health messages convey information about the relationship between the total diet and chronic diseases. Comments cautioned against overemphasizing the role of specific foods in controlling disease. Comments also indicated that claims suggesting a competitive advantage of one food over another should not be permitted. Comments indicated that food- or brand-specific health messages should not be permitted.

FDA agrees that misleading claims comparing one food with another should not be allowed. One reason that FDA has proposed to establish the scientific summaries and consumer health message summaries is that it believes that they would help to ensure that consumers will be provided accurate and balanced information regarding the intake of a given food component, its relationship to the total diet, and its influence on health. The agency tentatively believes that the overall health message concept set out in this reproposal will help to reduce the possibility that the role of specific foods in reducing the risk of chronic disease conditions will be overemphasized. While it is difficult to predict all possible types of health messages that may be made in the future, FDA does not currently envision a health message that would be unique to a single type or brand of food.

23. A few comments suggested that health messages may indirectly harm consumers who follow the advice presented in them in lieu of seeking conventional medical care.

FDA tentatively believes that the system by which health messages would be developed under this reproposal will be unlikely to produce messages that would dissuade consumers from seeking conventional medical attention. The proposed scientific summaries would define the state of scientific knowledge regarding the role of a food component and a sound total diet in reducing the risk of certain chronic disease conditions. They, together with the proposed consumer health message summaries, would discuss labeling and the importance of total diet, thus providing balanced information for all health messages. Simply stated, the scientific summaries, consumer health message summaries, and model label statements are in no way intended to provide a substitute to seeking conventional medical care.

24. One comment suggested that the initial proposal would result in untrue or misleading health claims relating to hypoallergenicity of certain foods. The comment feared that such claims might encourage the allergic individual to ingest foods with allergic reaction potential.

FDA tentatively believes that the procedures described in this reproposal would provide an adequate means of assessing the scientific validity of suggested label statements and would minimize the possibility of untrue or misleading health messages appearing on food labeling. Ingredient disclosure requirements, which are useful to allergic individuals, are unaffected by this reproposal.

Hypoallergenic foods must comply with 21 CFR 105.62. FDA assumes that allergic patients will continue to follow the dietary recommendations of their physicians and will not be influenced by label statements concerning unrelated food component/chronic disease interactions to consume foods to which they know they will adversely react.

25. Some comments on the initial proposal suggested that other sources of accurate and truthful health-related information were more appropriate and reliable methods of communication than food labels. A few comments suggested that FDA concentrate its efforts and resources on utilizing and expanding educational programs that currently exist. Pamphlets and videos were suggested as appropriate mechanisms for disseminating nutrition information.

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FDA agrees that consumer education programs are vital to the successful communication of dietary advice and to the appropriate use of such advice. Accordingly, the health message concept in this reproposal emphasizes consumer education aspects in at least two important ways. First, the consumer health message summaries would be an integral part of FDA's health message program and contribute directly to consumer education. Second, FDA's Consumer Guide to Food Labeling would be a particularly important consumer education tool which is intended to have wide distribution.

26. Some comments contended that the relationship between nutrition and chronic disease is too complex to adequately explain on labeling. They contended that there is not enough space on the label to adequately and accurately provide a balanced presentation of the scientific evidence.

FDA is also concerned about the adequacy of the limited space available on most food labels for conveying sufficient information about the complex relationship between diet and chronic disease. The health message concept in this reproposal represents an effort to resolve the problem of providing a balanced presentation of scientific evidence. The consumer health message summary, which would be referred to in the model label statements, would be an extended source of information that the limited space on the label could not provide.

27. One comment requested clarification of the following statement which appeared in the preamble to the proposed rule: "The dietary characteristics of the food must be consistent with the message being used."

Under the reproposal, label statements would have to be pertinent to the product to which they apply. Label statements that discuss the positive aspects of certain nutrients could be made only on products containing significant amounts of that nutrient. Further, the valued nutrient or other substance would have to be shown to have equal benefit to that demonstrated in products used in scientific studies to support the claim (e.g., equal bioavailability and metabolic/physiological effect. FDA would be interested in comments on other ways in which this showing could be made). Moreover, the food, when considered as a whole, could not contain ingredients that would have attributes inconsistent with the claims being made in the label statement.

G. Nutrition Labeling

28. A few comments expressed concern that health messages may be misleading by virtue of their potential prominence on the label as compared to the lesser prominence of the nutrition label or of "negative" information about that food.

FDA agrees that it is desirable for food labels bearing a health message to provide a balanced picture of the food to the greatest extent possible. Therefore, a key aspect of this reproposal is that the use of a health message would trigger full nutrition labeling in accordance with 21 CFR 101.9. Balance would be achieved also through the proposed scientific summaries, consumer health message summaries, and consumer guide to food labeling. These educational tools would aid consumers in making appropriate food selections in the context of their own dietary needs. If a balanced message could not be devised for a given food, the presence of any message would be inappropriate and could result in regulatory action.

FDA also is concerned that "overprominence" of a label statement may lead consumers to choose less than optimal foods. For this reason FDA seeks comment on the appropriateness of requiring manufacturers who choose to use a health message on a package panel to include a reference to the nutrition label in the statement (e.g., "see nutrition label for further information"). The reference to the nutrition label would need to be of essentially the same degree of prominence as the label statement.

29. A number of comments pointed out that 21 CFR 101.9(h) (2) and (10) exempt dietary supplements and fresh fruits and vegetables from the requirement to bear complete nutrition labeling. Such comments requested clarification on whether this exemption would apply to such foods if they are labeled with health messages.

In initially proposing the requirement that a food label contain a health message also contain nutrition labeling required by 21 CFR 101.9, the agency did not address those product categories that are exempt from nutrition labeling under 21 CFR 101.9(h). Distributors of fresh fruits and vegetables that bear labels or labeling would be encouraged to provide full nutrition labeling if they ultimately elect to use a health message in conformity with any final rule based on this reproprosal. They would not, however, be required to do so. Currently, there is not a significant portion of the fresh fruit and vegetable market sold in labeled packages. If this marketing system changes, FDA would consider additional rulemaking to alter the exemption for these commodities.

In the case of dietary supplements not in food form, FDA would also encourage manufacturers to include nutrition labeling on the label if they provided a health message in conformity with any final rule based on this reproposal. However, virtually all dietary supplements not in food form do list the percentage of the U.S. Recommended Daily Allowance for the various vitamins and minerals provided in the product or are single vitamin or mineral products that provide the dosage strength of the product (e.g., calcium, 250 milligrams per tablet). FDA tentatively believes that such information, combined with the reference to the appropriate consumer health message summary, would provide the balanced information needed by consumers to make informed decisions about specific dietary supplements bearing health messages in conformity with this reproposal. If FDA should determine for any reason that additional rulemaking is necessary, it would act accordingly. Segments of the dietary supplement industry, in commenting on the proposal, asked that FDA provide an abbreviated format for nutrition labeling to be used for dietary supplements. The agency does not see a need for such action at this time.

30. A few comments expressed concern that some very nutritious foods, such as fresh fruits and vegetables, probably would not bear label statements because they generally are not labeled. Therefore, such products would be at a competitive disadvantage.

FDA regulations do not prohibit the labeling of fresh fruits and vegetable, nor would this reproposal preclude health messages on these products. Although these products frequently lack labels, labeling in the form of posters and other point of purchase information may become increasingly common. To ensure that consumers have sufficient information about the nutritional characteristics of the fresh fruits and vegetables bearing such label statements, the agency recommends that full nutrition information be provided whenever a health message is used.

31. One comment pointed out that the quantity of a component such as fiber is not required to be listed in the nutrition label. The comment suggested that, if a health message is made with respect to such a component, quantification of that component needs to be required in the nutrition label.

FDA recognizes that a situation could arise in which health messages might be appropriate for food components that

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are not currently provided for in the nutrition labeling format of 21 CFR 101.9. How FDA deals with a particular situation will depend, in large part, on the mechanism for developing health messages that it ultimately establishes. In addition, as part of the ANPRM published on August 8, 1989 (54 FR 32610), FDA is considering whether any additional food components should be included in the nutrition label. FDA requests comment on this issue as part of the broader proceeding that was initiated by publication of the ANPRM.

H. State Laws

32. A few comments were concerned that the proposed requirements may conflict with current State laws and regulations. The comments contended that adoption of the proposal would lead to different enforcement strategies among the States that could result in confusion and decreased consumer confidence in the quality of foods.

None of the comments cited specific examples where a conflict between State and Federal regulation would result because of the proposed regulations. Many States have food and drug laws that follow the Federal law, and regulations at the Federal level are also adopted at the State level.

In this area of law, FDA does not have express preemption authority over State law. Moreover, no information was presented in the comments that would justify FDA exercising its general Federal preemption prerogative.

I. Miscellaneous

33. Several comments were submitted that, although interesting and informative, were not directly relevant to the proposal. For example, some of those commenting provided ideas on additional information that should be provided on the food label. Such comments are outside the scope of the present proceedings, and responses to them are not provided in this document.

34. FDA received several comments on an earlier version of this reproposal that was inappropriately disclosed to the public. FDA will consider and respond to these comments as part of its review of all comments on this reproposal.

VIII. Economic Impact

35. A few comments suggested that the initial proposal would have an adverse economic impact on small businesses because they do not have the resources to conduct the studies necessary for developing supportable health claims and nutrition labeling.

FDA does not agree that this reproposal would cause a substantial economic burden for small business. The reproposal would not require any business, large or small, to use health messages or to conduct research to develop or support a label statement. Health messages developed under any final rule based on this reproposal are likely to be generic rather than brand specific and would be available for any manufacturer to voluntarily use on appropriate products. FDA recognizes that manufacturers who decided to use a label statement on a product that did not already provide nutrition labeling would have to bear the expense of developing nutrition labeling. These manufacturers would have to evaluate whether the advantages of providing a label statement outweighed the costs of developing nutrition labeling.

In accordance with the Regulatory Flexibility Act and Executive Order 12291, the agency previously considered the potential economic effects of the initial proposal. This reproposal has not effected a change that would alter the initial economic determination. Therefore, in accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action.

Furthermore, in accordance with Executive Order 12291, FDA has determined that the reproposal is not a major rule as defined by the Order. The agency has not received any new information or comments concerning the initial proposal that would alter its previous determination.

IX. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum of Meeting, FDA Commissioner with Food Industry and Related Trade Associations, November 30, 1987.

2. Memorandum of Meeting, FDA Commissioner with Consumer Advocacy Groups, December 2, 1987.

3. Memorandum of Meeting, FDA Commissioner with Biomedical Professional Organizations, December 3, 1987.

4. Memorandum of Meeting, FDA Commissioner with Dietary Supplement Manufacturers and Related Trade Associations, November 30, 1987.

5. FDA Proposals to Permit the Use of Disease-Specific Health Claims on Food Labels, Hearing Before a Subcommittee of the Committee on Government Operations House of Representatives, One Hunrdreth Congress, First Session, December 10, 1987, U.S. Government Printing Office, Washington, DC 1988.

6. Disease-specific Health Claims on Food Labels: An Unhealthy Idea, Forty-third Report by the Committee on Government Operations together with Dissenting Views, U.S. Government Printing Office, Washington, DC 1988.

7. House of Representatives Report No. 94-1005, Health Research and Health Services Amendments of 1976, Conference Report, April 2, 1976.

8. Memorandum by A.L. Levy, Ph.D., to Office of Nutrition, and Food Services, Center for Food Safety and Applied Nutrition FDA, April 17, 1987.

9. Testimony of FDA at a Hearing on Health Messages before the Human Resources and Intergovernmental Subcommittee of the House Committee on Government Operations, October 31, 1989.

List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

2. Section 101.9 is amended by revising paragraph (i)(1) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(i) * * *

(1) That the food, because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom. However, a food that is labeled in accordance with the requirements of this section may bear a health message about the association between diet and certain serious chronic disease conditions if all of the following conditions are met:

(i) The label statement is truthful and not misleading.

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(ii) The label statement is limited to describing the value that ingestion (or reduced ingestion) of a dietary component, as part of a total dietary pattern, may have in either lowering the risk, or forestalling the premature onset, of a particular chronic disease condition. Such a statement must be based on the totality of publicly available scientific evidence, including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles. A significant agreement must exist among qualified experts that the statement is supported by such evidence.

(iii) The label statement is consistent with generally recognized medical and nutritional principles for a sound total dietary pattern.

(iv) The label statement is based on and consistent with the conclusions set forth in an applicable scientific summary and consumer health message summary accepted by the Food and Drug Administration.

(v) The label statement includes a reference to the applicable consumer health message summary.

(vi) The food is labeled in accordance with the requirements of this section.

* * * * *

Dated: January 2, 1990.

James S. Benson,

Acting Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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