vada, Montana and Wyoming, for 180 days. SUPPORTING SHIPPERS: Slyter Chair, Inc., 3110 S. Cedar Street, Tacoma, Wash. 98409; The Northwood Corporation, P.O. Box 669, Bend, Oreg. 97701, Mt. Adams Furniture, Box 250, Wapato, Wash. 98951; Fashioncraft Furniture Co., 4600 SW. Macadam, Portland, Oreg. 97201; Monitor Cabinets, 3000 S. Alaska, Tacoma, Wash.; Design Group Incorporated, 5876 SW. Lakeview Blvd.; Lake Oswego, Oreg. 97034; and Inter Royal Corp., 970 E. 33rd Street, Salt Lake City, Utah 84105. SEND PROTESTS TO: L. D. Boone, Transportation Specialist, Interstate Commerce Commission, Bureau of Operations, 6049 Federal Office Bldg., Seattle, Wash. 98104.

No. MC 135797 (Sub-No. 15 TA), filed October 30, 1973. Applicant: J. B. HUNT TRANSPORT, INC., 833 Warner Street SW., Atlanta, Ga. 30310. Applicant's representative: Virgil H. Smith, Suite 12, 1587 Phoenix Blvd., Atlanta, Ga. 30349. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lawn mowers*, power (lawn mowers with engines or motors) and *tillers, rotary and parts thereof*, from the plantsite of Dynamark Sales, Inc. at Des Moines, Iowa, to points in Arkansas, Louisiana, Missouri, Oklahoma, Kansas, and Tennessee (Brownsville only), restricted to traffic originating at and destined to named points only, for 180 days. SUPPORTING SHIPPER: Wal-Mart Stores, Inc., P.O. Box 116, Bentonville, Ark. 72712. SEND PROTESTS TO: William L. Scroggs, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 1252 West Peachtree Street, NW., Room 309, Atlanta, Ga. 30309.

No. MC 135858 (Sub-No. 2 TA), filed November 9, 1973. Applicant: A. G. KNORR, ROBERT D. KNORR, AND GENE A. KNORR, doing business as KNORR TRUCKING, Sawyer, N. Dak. 58781. Applicant's representative: Harris P. Kenner, 615 South Broadway, P.O. Box 36, Minot, N. Dak. 58701. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (1) *Trailers, toe hitches, raw steel and component parts for feed lot equipment*, from the plantsite of Bocats, Inc., at Martin, N. Dak., to Garden City, Kans., and (2) *Prefabricated steel and component parts* for manufacturing trailers, from the plantsite of Bocats, Inc., Garden City, Kans., to Martin, N. Dak., restricted to transportation for the account of Bocats, Inc., for 150 days. SUPPORTING SHIPPER: Bocats, Inc., Martin, N. Dak. 58758. SEND PROTESTS TO: J. H. Ambs, District Supervisor, Interstate Commerce Commission, Bureau of Operations, P.O. Box 2340, Fargo, N. Dak. 58102.

No. MC 136208 (Sub-No. 1 TA), filed November 7, 1973. Applicant: CREAGER TRUCKING CO., INC., 710 N. Columbia Blvd., Portland, Oreg. 97217. Applicant's representative: George R. LaBissoniere, Suite 101, 130 Andover Park East, Seattle, Wash. 98188. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Frozen fruits, berries, vegetables, and potatoes*, from Arlington and Othello, Wash., and Ontario, Oreg., to El Paso and Dallas, Tex., for 180 days. SUPPORTING SHIPPER: Twin City Foods, Inc., P.O. Box 587, Stanwood, Wash. 98792. SEND PROTESTS TO: District Supervisor Huetig, Interstate Commerce Commission, Bureau of Operations, 450 Multnomah Bldg., 319 Southwest Pine Street, Portland, Oreg. 97204.

No. MC 136315 (Sub-No. 2 TA), filed November 7, 1973. Applicant: OLEN BURRAGE TRUCKING, INC., Route 9, Box 22-A, Philadelphia, Miss. 39350. Applicant's representative: Fred W. Johnson, Jr., P.O. Box 22628, Jackson, Miss. 39205. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lumber*, treated or untreated, and *forestry products*, from points in Neshoba, Calhoun, and Lamar Counties, Miss., to points in Massachusetts, Maine, New Jersey, Connecticut, Rhode Island, New York, Vermont, New Hampshire, Delaware, Maryland, Virginia, West Virginia, and the District of Columbia, for 180 days. SUPPORTING SHIPPER: Weyerhaeuser Company, Philadelphia, Miss. SEND PROTESTS TO: Alan C. Tarrant, District Supervisor, Interstate Commerce Commission, Bureau of Operations, Room 212, 145 East Amite Bldg., Jackson, Miss. 39201.

By the Commission.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.73-24997 Filed 11-23-73;8:45 am]

CUMULATIVE LISTS OF PARTS AFFECTED—NOVEMBER

The following numerical guide is a list of parts of each title of the Code of Federal Regulations affected by documents published to date during November.

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PART II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

CACAO PRODUCTS AND CONFECTIONERY

Proposed establishment of good manufacturing practice regulations

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 128c]

CACAO PRODUCTS AND CONFECTIONERY

Proposal To Establish Good Manufacturing Practice Regulation

The Food and Drug Administration has evaluated the conditions under which cacao products and confectionery are manufactured and packaged for human consumption. Some of these products are manufactured or packaged under inadequate sanitary conditions. The Food and Drug Administration and industry associations are seeking to improve the sanitary practices of the industry to ensure that all of these products are manufactured under adequate sanitary conditions and are safe, pure, and wholesome.

In 1971, at the request of the General Accounting Office, the Food and Drug Administration inspected 97 food manufacturing plants of all types. These were selected at random from about 4,550 food manufacturing plants in six Food and Drug Administration districts covering 21 states. Included in this survey were four cacao product and confectionery manufacturing plants. Three of these plants were not operating in compliance with good manufacturing practices.

In 1971 and 1972, the Food and Drug Administration surveyed 213 cacao product and confectionery manufacturing plants to evaluate compliance of the industry. The number surveyed represented about 20 percent of the U.S. firms manufacturing primarily cacao products and confectionery. Of the 213 firms inspected, 97 were not operating in compliance with good manufacturing practices.

The Food and Drug Administration has reviewed the administrative files and over 220 establishment inspection reports for cacao product and confectionery manufacturing plants and has visited six representative plants to identify critical control points in the manufacture, processing, handling, and packaging of these products. Based upon observations of problem areas in some plants, several critical control points have been identified as being important in the production of wholesome cacao products and confectionery and are included in the proposed current good manufacturing practice regulations for these products.

Food and Drug Administration consumer inquiry files for the six-month period from August 1972 through January 1973, contained 23 letters concerning cacao products and confectionery.

From December 1971 through February 1973, 6 legal actions against adulterated cacao products and confectionery or against the manufacturers of these products were approved by the Food and Drug Administration.

The data and information referred to above have been placed on display at the Office of the Hearing Clerk, Food and Drug Administration, Rm. 6-86, 5600 Fishers Lane, Rockville, MD 20852, for public review.

The National Confectioners Association of the United States, Inc., and the Chocolate Manufacturers Association of the United States of America have initiated and submitted discussion drafts of proposed good manufacturing practice regulations for their respective industries to the Food and Drug Administration. After reviewing these drafts and other relevant information, the Food and Drug Administration has prepared a single, proposed good manufacturing practice regulation for cacao products and confectionery. The unique characteristics of cacao products and confectionery, including low moisture, high solids, and often high sugar content, require that special consideration be given to processing methods and sanitary controls used in the processing of these products. It is important that a regulation incorporating these considerations be established for the manufacture of cacao products and confectionery. The proposed regulation does not supersede 21 CFR Part 128. Instead, the proposed current good manufacturing practice regulation for cacao products and confectionery supplements 21 CFR Part 128 by setting forth additional standards to be applied in evaluating the methods and procedures used in the manufacture, processing, packaging, or holding of cacao products and confectionery. The Commissioner of Food and Drugs intends to propose specific current good manufacturing practice regulations for individual segments of the food industry, and also intends to propose amendments to 21 CFR Part 128 to provide more current guidance to the entire food industry on plant sanitation practices.

Accordingly, the Commissioner of Food and Drugs proposes to establish a current good manufacturing practice regulation for the manufacture and processing of cacao products and confectionery.

Therefore, pursuant to provisions of the Food, Drug, and Cosmetic Act (secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 3422(a)(4), 371(a)) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that Chapter I of Title 21 be amended by adding a new Part 128c to read as follows:

PART 128c—CACAO PRODUCTS AND CONFECTIONERY

Sec.

AUTHORITY: Secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(4)).

§ 128c.1 Definitions.

For the purposes of this part, the following definitions apply:

(a) "Cacao products" mean any form of chocolate, chocolate product, cocoa, or cocoa product.

(b) "Confectionery" means candy and other food products made basically from sweeteners, frequently prepared with colorings, flavorings, milk products, cacao products, nuts, fruits, starches, and other materials, and often fashioned into attractive shapes or forms.

(c) "Lot" means a collection of primary containers or units of the same size, type, and style, produced under conditions as nearly uniform as possible, designated by a common container code or marking, and, in any event no more than a day's production.

(d) "Return" means clean, wholesome product(s) returned to the manufacturer for reprocessing for reasons other than insanitary conditions and which is suitable for use as food.

(e) "Rework" means clean, wholesome product(s) removed from processing for reasons other than insanitary conditions and which is suitable for reprocessing and for use as food.

(f) "Shall" refers to mandatory requirements and "should" refers to recommended or advisory procedures or equipment.

(g) "Waste" means product rejected due to filth or other contamination and not suitable for use as human food.

§ 128c.2 Current good manufacturing practice.

(a) The criteria and definitions in Part 128 of this chapter shall apply in determining whether the facilities, methods, practices, and controls used for the manufacture, processing, packing, or holding of cacao products and confectionery are in conformance with and are operated or administered in conformity with good manufacturing practices to produce, under sanitary conditions, food for human consumption.

(b) The criteria in §§ 128c.3 through 128c.8 set forth additional standards to be applied in evaluating the methods and procedures used in the manufacture, processing, packaging, packing, or holding of cacao products and confectionery.

(c) Pertinent criteria from Part 128 of this chapter have been incorporated into §§ 128c.3 through 128c.8 to emphasize critical control points in the manufacture, processing, packaging, packing, or holding of cacao products and confectionery.

§ 128c.3 Plants and grounds.

Wherever necessary to prevent contamination of products, raw materials, or packaging materials with micro-organisms, chemicals, filth, or other extraneous material, the following operations shall be separated by partition, location, air flow, enclosed systems, or other effective means:

(a) Receiving.

(b) Raw material storage.

(c) Cacao bean cleaning, roasting, cooling, cracking, and fanning.

(d) Cacao product milling, pressing, mixing, refining, conching, tempering, and molding.

(e) Pulverizing or separating of cocoa, and other dusty operations.

(f) Cacao product and confectionery processing.

(g) Portable equipment and utensil cleaning and sanitizing.

(h) Packaging and packing.

(i) Finished product storage and shipping.

§ 128c.4 Equipment and utensils.

(a) Food-contact surfaces shall be made of corrosion-resistant, nonabsorbant, nontoxic, smooth material which will not readily crack or disintegrate, and which will withstand the environment of its intended use and the action of food ingredients, cleaning compounds, and sanitizing agents.

(b) Seams on food-contact surfaces shall be smoothly bonded so that no inaccessible spaces exist in which dirt or organic material might accumulate.

(c) Non-food-contact surfaces of equipment shall be so constructed that they can be kept in a clean, sanitary condition.

(d) Equipment in which dusty ingredients are processed or which generate dusty materials should be equipped with dust-control devices which collect and remove particulate matter from the processing area.

(e) Regulating and/or recording controls, thermometers, other temperature measuring devices, and temperature recording devices on equipment used to pasteurize raw materials or products shall be accurate and effective for their designated uses. The accuracy of temperature controlling, measuring, and recording devices on equipment used to control or prevent undesirable microbial growth in raw materials or finished products shall be within ±2° F.

(f) Each freezer and cold storage compartment used for storing or holding raw materials or products capable of supporting growth of micro-organisms shall be fitted with an indicating thermometer, temperature measuring device, or temperature recording device so installed as to show accurately the temperature within the compartment, and should be fitted with an automatic control for regulating temperature or an automatic alarm system to indicate a significant temperature change in a manual operation. Cooling tunnels on processing lines shall have access doors or other provisions to permit cleaning of the interior.

§ 128c.5 Personnel sanitation facilities.

(a) Adequate and readily accessible hand washing and sanitizing facilities shall be provided in the plant for employees who may handle unprotected food, unprotected packaging materials, and food-contact surfaces. Such facilities shall be furnished with running water at a suitable temperature for hand washing, effective hand cleaning and sanitizing preparations, sanitary towel service or suitable drying devices, and, where appropriate, waste receptacles, and should be equipped with water control valves so designed and constructed as to prevent recontamination of clean, sanitized hands.

(b) Readily understandable signs directing employees handling unprotected food, unprotected packaging materials, or food-contact surfaces, to wash and sanitize their hands before starting work, after each absence from post of duty, and when their hands may have become soiled or contaminated shall be conspicuously posted in the processing room(s) and in all other areas where employees may handle such materials and surfaces.

(c) Supervisors shall maintain sufficient control to ensure that employees handling unprotected food, unprotected packaging materials, or food-contact surfaces wash and sanitize their hands before starting work, after each absence from post of duty, and when their hands may have become soiled or contaminated.

§ 128c.6 Equipment and utensil cleaning and sanitizing.

(a) Cleaning and sanitizing of utensils and equipment shall be carried out in such a manner as to prevent raw material, packaging material, or product contamination.

(b) Food-contact surfaces of equipment used for processing or holding low moisture raw materials or products such as chocolate, fats and oils, corn sirup, peanut butter, and similar materials which are not conducive to microbial growth shall be maintained in a sanitary condition. When wet cleaning of such equipment may cause conditions conducive to microbial growth, other appropriate cleaning methods shall be utilized to prevent product contamination.

(c) Poisonous or dangerous cleaning compounds, sanitizing agents, and pesticide chemicals shall be applied, stored, and held in such a manner as to prevent food or packaging material contamination. These materials shall be identified and used only in such manner and under such conditions as will be safe for their intended use. Any applicable regulations promulgated by the Environmental Protection Agency for the application, use, or holding of such materials shall be followed.

§ 128c.7 Processes and controls.

The manufacturer shall employ appropriate quality control procedures and treatments to ensure that raw materials and finished products are wholesome and fit for food, that packaging materials are safe and suitable, and that all of the foregoing materials are otherwise in compliance with the Federal Food, Drug, and Cosmetic Act.

(a) *Handling of raw materials.* (1) Milk and milk products shall have been pasteurized before use, and egg products shall have been pasteurized or otherwise treated to destroy viable Salmonella microorganisms before use, or these materials shall be pasteurized or otherwise treated during processing operations to destroy pathogenic microorganisms. The manufacturer shall ensure that gelatin, dried coconut, nuts, and other raw materials susceptible to contamination by pathogenic microorganisms are free of such microorganisms before these materials are incorporated into finished products unless these materials are pasteurized or otherwise treated before or during processing operations to destroy pathogenic microorganisms. This may be accomplished by analyzing these materials for pathogenic microorganisms, by purchasing these materials under a supplier's guarantee or certification, or by other acceptable means.

(2) The manufacturer shall ensure that peanuts, Brazil nuts, pistachio nuts, filberts, walnuts, almonds, pecans, corn meal, and other raw materials susceptible to aflatoxin contamination comply with current Food and Drug Administration regulations, guidelines, and action levels for natural or unavoidable defects before these materials are incorporated into finished products. This may be accomplished by analyzing these materials for aflatoxins, by purchasing these materials under a supplier's guarantee or certification, or by other acceptable means.

(3) The manufacturer shall ensure that nuts, raisins, cacao beans, spices, rework, return, and other raw materials susceptible to infestation or contamination by animals, birds, vermin, microorganisms, or extraneous material comply with current Food and Drug Administration regulations, guidelines, and action levels for natural or unavoidable defects before these materials are incorporated into finished products. This may be accomplished by examining these materials for infestation and contamination, or by other acceptable means.

(b) *Storing and holding of raw materials.* Raw materials shall be held in their original containers or in containers so designed and constructed as to prevent raw material contamination. Raw materials and packaging materials shall be held at such temperature and relative humidity and in such a manner as to prevent their adulteration, contamination, or decomposition.

(1) Materials capable of supporting growth of pathogenic microorganisms shall be stored at a temperature below 40° F. or above 140° F., except for short periods of time as required to facilitate processing.

(2) Frozen materials shall be kept frozen and should be stored at a temperature of 0° F. or below.

(3) Liquid sugars shall be held in such a manner as to prevent microbial growth or any other direct or indirect contamination. Storage tanks for liquid sugars shall have filtered air-intake vents.

(4) Liquid mixtures containing egg products or other perishable materials and capable of supporting growth of pathogenic microorganisms shall be held in such a manner as to preclude the growth of these microorganisms or shall be processed in such a manner as to destroy these microorganisms. This may be accomplished by:

(i) Maintaining the mixtures at a temperature below 40° F. after removal from storage and disposing of the unused portion at least every 12 hours during operations and at the end of the day's operation; or

(ii) Maintaining the mixtures at a temperature below 50° F. after removal from storage and disposing of the unused portion at least every 4 hours during operations and at the end of the day's operation; or

(iii) Pasteurizing or otherwise treating the mixtures during processing operations to destroy pathogenic microorganisms.

(c) *Processing operations.* (1) Frozen egg products shall be defrosted in a sanitary manner and by such methods that their wholesomeness is not adversely affected. This may be accomplished by defrosting at a temperature of 40° F. or below, or by defrosting at a temperature above 40° F. for a period of time not exceeding 24 hours, provided that the temperature in any part of the defrosted liquid does not exceed 50° F.

(2) Processes intended to pasteurize or otherwise treat materials to destroy pathogenic microorganisms shall be scientifically determined to be adequate under the conditions of manufacture for a given product to ensure destruction of such microorganisms.

(3) Rework, when stored or held, and return shall be considered as raw materials. They shall be held in properly identified containers and examined before reprocessing.

(4) Waste shall not contribute to direct or indirect product contamination. This may be accomplished by holding the waste in properly identified containers and collecting it on a regular basis. Waste should be segregated and removed from the processing area daily.

(5) Effective measures shall be taken to prevent cross contamination between raw materials and finished products or between these materials and refuse. When any of these materials are unprotected they shall not be handled simultaneously in a receiving, loading, or shipping area. Raw materials and products transported by conveyor shall be protected against contamination from extraneous material.

(6) Equipment, containers, and utensils used to convey, process, hold or store raw materials or products shall be handled during processing or storage in such a manner as to prevent raw material or product contamination.

(7) Suitable equipment such as sieves, magnets, electronic metal detectors, or other effective devices shall be utilized where necessary to prevent the inclusion of metal or other extraneous material in the finished product.

(8) Molding starch shall be passed through a sieve and a metal trap or be otherwise treated before it is reused in molding operations whenever necessary to remove extranenous material that may contaminate products.

(9) The cooling and winnowing of roasted cacao beans and the processing and storage of cocoa nibs shall be carried out in such a manner as to prevent product contamination.

(10) Cacao bean shell, dust, and other residue particles resulting from cracking operations shall be handled and held in such a manner as to prevent product contamination.

(d) *Testing.* Raw materials, products-in-process, and finished products shall be sampled and examined for microbial, chemical, and other adulteration as necessary to ensure that processing steps and sanitary controls are adequate. Adulterated materials shall be disposed of in such a manner as to prevent raw material, rework, return, or finished product contamination, or shall be reconditioned, if feasible, and then re-examined and found to be wholesome before being incorporated into finished products.

(e) *Coding.* Permanently legible code marks shall be placed on the outer layer of each shipping container and should be placed on the outer layer of each finished product package. Such marks shall identify at least the plant where packed and the product lot.

(f) *Warehousing and distribution.* Finished products shall be handled in storage, during shipment, and while being held for sale in such a manner as to prevent product contamination. Transportation equipment, warehouses, and other facilities used for storing, holding, or transporting finished products shall be of such design and construction as to prevent contamination or adulteration of the products, and minimize deterioration of product quality. Such facilities and equipment shall be free of vermin or other objectionable conditions.

§ 128c.8 Records.

(a) Records shall be maintained of examinations of raw materials, packaging materials, and finished products and of supplier's guarantees or certifications that verify compliance with Food and Drug Administration regulations and guidelines.

(b) Processing and production records covering processes intended to pasteurize or otherwise treat materials to destroy pathogenic microorganisms shall be maintained, shall contain sufficient information to permit a public health evaluation of the processes, and shall be retained for a period of time that exceeds the shelf life of the finished product, except that they need not be retained more than two years.

(c) Records shall be maintained to identify the initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use.

Interested persons may, on or before January 25, 1974, file with the Hearing Clerk, Food and Drug Administration, Room 6-86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: November 9, 1973.

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

[FR Doc.73-24662 Filed 11-23-73;8:45 am]

federal register

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PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

BOTTLED WATER

Quality standards; addition of fluoride, and current good manufacturing practice regulations

Title 21—Food and Drugs

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

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 11—STANDARDS OF QUALITY FOR FOODS WHICH THERE ARE NO STANDARDS OF IDENTITY

Quality Standards for Bottled Water

In the matter of establishing quality standards for bottled water (21 CFR Part 11):

A notice of proposed rulemaking was published in the FEDERAL REGISTER of January 8, 1973 (38 FR 1019), to amend 21 CFR Part 11 by adding to Subpart B a new § 11.7 on bottled water. A correction of § 11.7(b)(1)(ii) of the proposal was published in the FEDERAL REGISTER of January 23, 1973 (38 FR 2219). Interested persons were invited to submit comments on the proposal within 60 days and the time for filing comments was extended an additional 30 days by notice published in the FEDERAL REGISTER on March 30, 1973 (38 FR 8273).

Thirty-three comments were received from consumers, a Federal agency, State and local health agencies, industry, trade associations, testing and consulting services, and educational organizations.

1. Comments from several State health agencies stated that promulgation of the proposed standard would result in conflicts between State and Federal requirements for bottled water.

The Commissioner of Food and Drugs recognizes that State and local governments have traditionally exercised regulatory control of drinking water supplies, including bottled water, and that some States have laws and regulations establishing microbiological and chemical limits for bottled water. In some instances, the limits in State laws or regulations are more restrictive than those of the proposed Federal standard. The Federal standard represents the lowest acceptable quality for bottled water that does not require a label statement of substandard quality. Bottled water meeting the Federal standard may be lawfully marketed in interstate commerce. It is anticipated that this standard may serve as the basis for uniformity among State regulations for bottled water. Federal and State regulations may co-exist if compliance with the State regulation does not prevent compliance with the Federal regulation.

2. Several State health agencies considered the proposal inadequate to establish a standard of quality for bottled water and recommended that it not be promulgated. They suggested that it might be possible to establish a comprehensive regulatory program based on the Environmental Protection Agency's (EPA) revision of the drinking water standard. If the use of the revised EPA standard is not possible, it was suggested that a whole new system of microbiological and chemical monitoring of bottled water be developed which would include frequent inspection and sampling of bottled water, the water source, and the processing operations. The comments contained no specific plans or suggestions for a system of microbiological or chemical monitoring of bottled water.

The current Federal drinking water standard was developed by the U.S. Public Health Service in 1962. EPA now has the responsibility for establishing and updating the drinking water standard and an extensive revision of that standard is currently being undertaken. The Commissioner will periodically review and revise the bottled water standard in order to assure that it is kept compatible with the EPA drinking water standard.

The quality of bottled water is affected by such factors as the excellence of the water source and the degree of control present at the time of processing. It is not the purpose of this regulation directly to control such factors. These are elements of the manufacturing process which are properly included in good manufacturing practices (GMP) regulations, which are proposed elsewhere in this issue of the FEDERAL REGISTER. The GMP regulations will provide the broader type of regulation suggested by State agencies.

3. One comment suggested that all domestically produced bottled water be required to be from State certified plants and that the Food and Drug Administration certify all suppliers of imported bottled water.

The Commissioner recognizes that many States currently require some form of licensing of plants or certification of the water source. Nothing in this regulation prevents such State requirements. A State may certify and otherwise regulate bottled water processed within that State as long as such regulation does not conflict with Federal regulations. The Federal quality standard pertains only to the actual bottled water, while State approval usually covers additional items such as the suitability of the water source. The Commissioner concludes that State certification requirements are more appropriately considered in connection with the proposed GMP regulations. The Food and Drug Administration does not certify importers of other foods and does not believe that certification of importers of bottled water is warranted. Imported bottle water is currently examined for compliance with the act, and the new quality standard applies to imported as well as domestic bottled water.

4. One comment suggested that the limits and sampling procedures proposed in the standard are not applicable in all cases because the sources of water used by bottled water manufacturers are more diverse than the sources of water used for municipal water supply systems.

Since the proposal was patterned after the drinking water standard, any source of water that may be used under the drinking water standard may also be used to produce bottled water that will meet the requirements of the proposed bottled water standard. The Commissioner has concluded that the criteria of the drinking water standard, which was designed for public water supply systems, can be applied to bottled water except that the sampling plans for the repetitive examination of public water supplies for microbiological limits are not appropriate for bottled water, as discussed in the preamble to the proposal. No information was received that would indicate that the quality standard would preclude the use of any appropriate water source now being used for bottled water.

5. One comment suggested that more stringent limits than those included in the drinking water standard be applied to bottled water since many consumers assume that bottled water is of a higher quality than tap water.

Although some consumers may assume, and some promotion of bottled water may encourage, the assumption that bottled water is of a higher quality than tap water, there is no Federal requirement to this effect. The quality of both tap and bottled water can vary widely due to the source itself (underground wells or springs or surface waters such as rivers and lakes) as well as to treatments these waters may receive during processing (chemical precipitation and flocculation, adjustment of pH reaction, filtration, softening, chlorination and fluoridation, substitution of minerals, etc.). Because of these source and treatment variables there is no basis for assuming that bottled water is of a higher quality than municipal tap water. The standard of quality being promulgated does not represent an optimum level or even average level of quality, but only the minimum acceptable level of quality for bottled water. The Commissioner has concluded, based on the available data, that the criteria of the drinking water standard, with the exception noted above, are as appropriate for the quality of bottled water as for the quality of tap water.

6. One comment questioned whether the standard would be applicable to bottled water dispensed from a coin-operated dispenser into a container provided by the consumer.

The standard applies only to sealed containers of bottled water, as stated in § 11.7(a), and thus applies to sealed containers of bottled water for use in dispensers. Once a container of water used in a dispenser, coin operated or otherwise, is opended however, the standard will no longer be applicable because the water quality may be altered as a result of it being exposed to various environmental factors that are either an integral part of the dispenser or are associated with it.

7. Several comments suggested that the proposed standard should also apply to bottled mineral water. Two of these comments predicted confusion in the industry as a result of excluding bottled mineral water from the requirements.

The Commissioner has concluded that bottled mineral water is a product inherently different from bottled water. As a result of further study of bottled mineral water, it has been decided to develop a separate standard of quality for that product. The lack of such a standard

applicable to bottled mineral water is only a temporary situation.

8. One comment requested that the proposed standard consider quality factors for bottled water held for years for emergency use.

The Commissioner is aware that the quality of bottled water may change during long term storage. Nevertheless, the Commissioner finds no basis for excluding such bottled water from the standard. No other criteria were offered in the comments submitted. Thus, the standard is applicable to bottled water that is to be stored for a prolonged period of time. It is recommended that stocks of such bottled water be replaced periodically because of possible quality deterioration.

9. One comment stated that the term "lot" should be defined. Others stated that the collection of 10 containers is statistically unsound when the size of the containers in the lot are "very small." One comment also considered it unreasonable to collect 10 containers when the containers in the lot are "large."

The terms "lot," "sample" and "analytical unit" as used in the proposed standards were defined in § 11.2, published in the FEDERAL REGISTER of August 2, 1973 (38 FR 20726). For purposes of determining quality factors related to manufacture, processing or packing, a "lot" is defined as a collection of primary containers or units of the same size, type and style produced under conditions as nearly uniform as possible and usually designated by a common container code or marking, or in the absence of any common container code or marking, a day's production. For purposes of determining quality factors of bottled water related to distribution and storage, a "lot" is defined as a collection of primary containers or units transported, stored, or held under conditions as nearly uniform as possible. Examples of a "lot" are containers or units produced during the same shift or day, or transported or stored as a single item of trade. A "sample" is a composite of 10 subsamples (consumer units), taken one from each of 10 different, randomly chosen shipping cases, to be representative of a given lot. An "analytical unit" is defined as the portion of food (water) taken from a subsample of a sample for the purpose of analysis.

The sampling plan specified in the proposal is to indicate the procedures that will be used by the Food and Drug Administration to determine whether a lot is in compliance with the standard. The proposal does not require manufacturers or others to use the sampling or testing plans contained in the standard. The Commissioner advises that manufacturers and others may use any type of sampling and testing plans they choose. However, it should be determined that any plan used to check compliance with the standard will produce results compatible with those contained in the regulation.

Complete assurance that every container or unit of a lot is in compliance with the proposed standard would, of course, require destructive analysis of the entire lot. Therefore, a statistical approach involving analysis of a representative sample from the lot is appropriate. The Commissioner concludes that the sampling and testing procedures contained in the regulation, which have been evaluated statistically and judged to be satisfactory, are reasonable and appropriate for compliance purposes.

10. One comment indicated that a sample could not be tested before the sample lot of bottled water would be consumed. The comment also mentioned that the sampling and analysis provided for in the proposal would give no indication of the quality of the whole or continuous production of a bottled water manufacturer.

The Commissioner is aware that instances may occur where a lot could be consumed before a sample analysis is completed. This problem is no different for any other food that is presently manufactured under a quality standard. Experience indicates that only on rare occasions is the time interval between production and retail sale too short to permit sampling and analysis. No information was submitted establishing that the time between production and retail sale of bottled water is routinely too short to make such sampling impractical. Bottled water manufacturers, as opposed to municipal water supplies, operate on a production line/lot basis. The nature of the operation necessitates that the standard of quality for bottled water be applied on an individual lot basis. Firms producing substandard quality bottled water not properly labeled as such, will be subject to regulatory action under the act even if none of the substandard lots sampled is available for seizure.

11. One comment suggested that the standard should specify periodic testing of bottled water by independent laboratories operated by graduate biochemists and located near the plant where the water is bottled.

The Commissioner rejects this suggestion as being unnecessarily restrictive. Sampling and testing performed by the manufacturer that is compatible with the requirements of the regulation will be sufficient.

12. Several comments objected to the sale of substandard quality bottled water, even though the regulation requires this fact to be declared on the label. One comment stated that consumers would not notice the substandard quality declaration and another requested that the substandard quality declaration be required to be placed prominently on the principal display panel. One comment suggested that, in lieu of the substandard quality statement in the proposal, either of the following statements be used: "Not for Human Consumption" or "This Product Does Not Meet the Standards of the FDA."

Section 403(h)(1) of the act specifically provides for the use of a label statement of substandard quality when the quality of a food falls below the standard of quality established for the food. The regulation requires the label statement of substandard quality to be placed prominently on the principal display panel(s) of the label immediately and conspicuously preceding or following the name of the food in letters not less in height than those required for the net quantity of contents statement. The Commissioner therefore concludes that the statements of substandard quality are appropriate and should not be changed.

13. Comments from several State health agencies objected to the proposal because it does not provide for the safety of bottled water. One comment suggested that the regulation contain a statement to the effect that, because the standard does not mention certain harmful substances, such silence should not be taken to imply that such substances are allowed in bottled water.

Pathogenic bacteria, heavy metals, and radioactivity ordinarily are not the subject of a quality standard, but rather are factors related to adulteration. In this instance, heavy metals and radioactivity are included as quality factors because of their traditional handling under the drinking water standards and the desirability for consistency in this respect. Limits for adulteration may be promulgated elsewhere in Food and Drug Administration regulations, but they are not properly within the scope of Part 11, which is limited to quality factors. If bottled water contains any substance at a level considered injurious to health, it will be deemed to be adulterated and appropriate regulatory action will be taken, whether or not it meets the standard of quality. The Commissioner concludes that the statement in § 11.7(g) is adequately explicit on this subject and that additional statements are unnecessary.

14. Several comments objected to the standard plate count (SPC) criterion of 500 microorganisms per milliliter. Some comments objected on the basis that the proposed SPC criterion was unduly restrictive, while others would impose an even more stringent SPC. Those objecting that the SPC was too restrictive stated that the SPC limit has no relationship to the quality or safety of bottled water, the SPC limit is equivalent to requiring a sterile product, the SPC limit is unduly restrictive when compared to the microbiological levels permitted or commonly found in other foods, and often a lot of bottled water meeting the proposed SPC limit at the time of filling will exceed this limit after storage under adequate conditions. Some comments suggested that the SPC limit should apply only at the time of bottling or within 24 hours of bottling. Those feeling that the proposed SPC was too lenient proposed that the regulation require that bottled water be commercially sterile since microorganisms multiply in bottled water and often are pathogenic to the very young, the very old, and debilitated medical patients, and it is feasible to produce commercially sterile bottled water and other beverages, such as soft

drinks, fruit juices, and malt beverages. One comment suggested an SPC limit of 100 microorganisms per milliliter.

All water contains microorganisms. The number and types of bacteria present in untreated water from underground or surface sources are dependent upon the quality of the sources. For example, surface waters such as rivers or streams used as sources for municipal water supplies that are also outlets for treated or untreated sewage effluents of communities upstream may be expected to contain greater numbers and more types of microorganisms than a surface water located in an uninhabited area which is protected from such contamination. Treated water (water which has been processed through a municipal water treatment plant or a bottled water plant) also contains microorganisms. In the case of treated water, however, the total number of microorganisms has been greatly reduced and pathogenic organisms have been destroyed or removed. In this instance, the number and types of microorganisms are dependent not only on the original quality of the source but also upon the types and degree of treatment the water receives during processing (e.g., flocculation, filtration, chemical disinfection, etc.). Unless a treated water contains a residual concentration of a disinfectant such as chlorine, the few microorganisms that remain in a water after treatment are capable of multiplying and usually do so upon storage of the water. Treated water that is sealed in a bottle and which does not contain a residual concentration of a chemical disinfectant can be expected to contain a few bacteria that are natural to the water, and these few bacteria can be expected to multiply in the bottled water during storage. This is a natural phenomenon that may occur in water that is processed and bottled under the best of current sanitary and processing conditions. This multiplication is usually of a cyclic nature in that, during storage in a sealed bottle, the bacteria at first multiply and then die off. The few surviving cells may once again give rise to increased numbers that in turn die off. This cycle may occur several times. No microbial spoilage or contamination occurs.

The good manufacturing practices (GMP) regulations proposed elsewhere in this issue of the FEDERAL REGISTER are intended to assure that bottled water is manufactured under good sanitary conditions that protect it from contamination with filth or harmful or deleterious substances. Monitoring for pathogenic organisms will be required. One of the factors of bottled water that is deemed desirable by the consumer is the freedom from chemical disinfectants. Because bottled water will be required to be processed in accordance with good manufacturing practices, the Commissioner concludes that an SPC standard for bottled water is not warranted.

The fact that some other foods are commercially sterile or have very low microbial levels does not directly bear on the issue of an appropriate microbial level for bottled water. A requirement that bottled water, which is not subject to microbial spoilage and which has been processed in accordance with good manufacturing practices, be sterile is not justified at this time.

The primary purpose of a standard of quality is to establish the minimum acceptable quality criteria for a product when it is offered to the consumer. It is in the interest of consumers that all of the criteria of the standard shall be applicable at the point of retail sale and use of the sealed containers of bottled water, instead of being applicable only within a 24 hour period of bottling. However, the Commissioner also recognizes that wide fluctuation in the microbial level of bottled water does occur after the product is sealed in containers and that this fluctuation is not necessarily indicative of product quality. Review of the comments and further consideration of available microbiological data on bottled water reveals that sufficient grounds exist for the objections to the proposed SPC limit. Therefore, the Commissioner has deleted § 11.7(b)(2) of the proposal containing an SPC limit for bottled water.

15. One comment recommended that the size of the analytical unit taken for bacteriological analysis by the multiple-tube fermentation and membrane filter methods should be specified and related to the microbiological limits.

The Commissioner concludes that the analytical unit size is immaterial if the analytical units are of equal volume. In the multiple tube fermentation method, 50 milliliters (ml) (5–10 ml portions) are examined. In the membrane filter method, 100 ml of water are examined. To eliminate the possibility of confusion on this point, § 11.7(b) has been revised to state that the sample is to consist of analytical units of equal volume.

16. One comment requested clarification of the coliform criterion in § 11.7(b)(1). The comment assumed that the intention of § 11.7(b)(1) was to establish a limit of 2.2 coliform organisms/100 ml based upon the average value determined from the 10 analytical units that comprise the 50-ml sample. The comment apparently further assumed that no more than one sample (rather than one analytical unit of the 10-unit sample) can exceed a most probable number (MPN) of 9.2 coliform organisms/100 ml. Another comment stated that this section establishes a more restrictive coliform criterion than that contained in the drinking water standard. One comment recommended that bottled water be required to be free of coliforms.

The coliform criteria in the proposal and in § 11.7(b)(1) of the final regulation are essentially the same as those of the drinking water standard. These criteria are based upon the laboratory testing of a representative sample of water from the lot. The sample is composed of 10 containers from a lot, from each of which is removed a 5-ml portion for analysis. Not more than one of the 5-ml portions may contain an MPN of 2.2 or more coliform organisms/100 ml, and none of the 5-ml portions may contain an MPN of 9.2 or more coliform organisms/100 ml. Thus, this coliform requirement is not based upon an average value of the ten 5-ml portions, and the regulation specifically prohibits any sample containing an MPN of 9.2 or more coliform organisms/100 ml. Because these limits are essentially the same as those in the drinking water standard, the Commissioner concluded that a lower coliform limit for bottled water is not warranted.

17. One comment suggested a complete revision of § 11.7(b)(1)(ii) (membrane filter method) to make it comparable to § 11.7(b)(1)(i) (multiple-tube fermentation method).

The multiple-tube fermentation test and the membrane filter test are based upon two different principles. The former employs the MPN technique, which provides an estimate of the upper limit of the number of coliform organisms present in the water. The latter test provides a direct enumeration of the number of coliform organisms in the water. Although these test procedures are different, the quality of the water is assured by either test when the results obtained demonstrate that the water meets the criteria of the standard.

18. Comments were received that the minerals for which U.S. Recommended Daily Allowances (U.S. RDA) have been established (copper, iron, and zinc) should not be limited by the proposed regulation. It was stated that the limits on these nutritional minerals were established primarily on esthetic factors, such as taste and rust deposition on plumbing fixtures and laundered clothing.

The amount of copper, iron, and zinc present in bottled water might be nutritionally significant only if the daily consumption of water were one liter or more. The consumption pattern of water in the population is extremely variable, and depends to a large extent on the average ambient temperature of the geographic area. The Commissioner concludes that bottled water should not be relied on as a primary source of nutritional minerals. The limits for these minerals in bottled water are therefore intended to control such quality attributes as taste and rust deposition and should be the same as the limits set forth in the drinking water standard.

19. One comment recommended that the sodium content of bottled water be declared since the sodium content of the diet is important to a significant segment of the population.

If bottled water purports to be or is represented as a mean of regulating the intake of sodium or salt the label is required to bear a statement of the sodium content as specified in § 125.9. Bottled water not represented specifically for use in sodium-restricted diets need not bear a statement of sodium content. The drinking water standard does not contain a limit for sodium content, but sodium content is indirectly limited by the 500 milligram per liter limit for total dissolved solids.

20. One comment indicated that if the source of water is from the manufacturer's premises the limits for cadmium, copper, lead, and zinc could be lowered since the limits were established in the

drinking water standard with allowances made for the fact that the level of these chemicals in tap water is partly the result of the metal plumbing and distribution system of municipal water supplies.

Bottled water is not necessarily manufactured from a well or spring located on the manufacturer's premises. In some instances, the source of the waters used may be a spring or well located many miles from the processing plant. In other instances, the source may be tap water from municipal water supplies. Regardless of the location of the water source, in most cases the water will contact pipes, tanks, or other metal equipment surfaces, which will contribute some amounts of these minerals to the water. The Commissioner therefore concludes that it is unnecessary and unwarranted to establish lower limits for cadmium, copper, lead, and zinc in bottled water than those established for these minerals in the drinking water standard.

21. Several comments were received concerning the fluoride limit in the proposed standard. Two comments objected to the fluoride level being based on the air temperature at the point of bottling and recommended that the fluoride level be based on the air temperature where the bottled water is sold. One comment stated that the 2.4 milligrams (mg.) per liter fluoride limit is too high and could cause significant mottling of teeth. A fluoride limit of 1.5 mg./liter or 1.0 mg./liter was recommended. One comment recommended that bottled water containing more than 0.7 mg./liter fluoride be labeled "fluoridated water" and the fluoride content declared. Another comment recommended specific fluoride labeling for bottled water.

The proposed limits on fluoride in bottled water were taken directly from the drinking water standards. Fluoride levels in the drinking water standards are based on air temperatures because the amount of water (and consequently the amount of fluoride) ingested is influenced primarily by air temperature. The range of fluoride levels permitted by the drinking water standards is 1.4 to 2.4 mg./liter for naturally present fluoride and 0.8 to 1.17 mg./liter for added fluoride. The Commissioner recognizes the merit of the comments that, in many instances, bottled water is sold in areas having significantly different temperatures than the area where the water was bottled and consequently that fluoride limits based on the air temperature at the bottling location could have the effect that bottled water would meet the drinking water standard fluoride limit at the bottling location, but would exceed the drinking water standard fluoride limit if it was distributed to an area having a significantly higher air temperature.

Therefore, the Commissioner has revised the fluoride requirement of the proposal, in the case of bottled water packaged in the United States, so that the standard is based on the air temperature at the location where the bottled water is sold at retail, instead of the air temperature at the bottling location. This approach will require the bottler to have full knowledge of the retail distribution pattern of his product and the annual average maximum daily air temperatures of each retail sales area in order to determine if his product complies with the fluoride limit of the standard. However, should a bottler wish to eliminate the need for his being continuously informed regarding air temperature data for all retail sales areas, he may limit the naturally present fluoride content in bottled water containing no added fluorides to a maximum of 1.4 mg./liter and in bottled water containing added fluorides he may limit the fluoride content to a maximum of 0.8 mg./liter. In that case the fluoride limits of the drinking water standards will be met in all retail sales areas.

Since the bottlers of imported bottled water do not usually have direct control of the retail sale of their product, the Commissioner has established 1.4 mg./liter as the maximum fluoride limit for imported bottled water containind naturally present fluoride and 0.8 mg./liter as the maximum fluoride limit for imported bottled water containing added fluoride. At this level, imported bottled water may be sold in any location and not exceed the fluoride level of the drinking water standards.

The Commissioner concludes that the addition of fluorine compounds to bottled water should be permitted to be consistent with the policy of allowing the fluoridation of municipal water supplies. Accordingly, the Commissioner is proposing an appropriate regulation elsewhere in this issue of the FEDERAL REGISTER to provide for bottled water fluoridation.

Bottled water obtained from municipal water sources and some wells and springs may contain significant amounts of fluoride. The Commissioner concludes that it would be misleading to require bottled water to which fluoride has been added to be labeled differently from bottled water containing fluoride naturally or from municipal water supplies to which fluoride has been added. It is widely assumed by consumers that water contains fluoride. If any distributor of bottled water wishes to promote his product as containing a specific amount of fluoride, or no fluoride, he may properly do so as long as such claims are accurate and truthful.

22. Two comments suggested that the use of labeling terms describing the type of bottled water, such as spring water, well water, and distilled water, be regulated.

The Commissioner concludes that there is no need for a requirement that the source or treatment of the water be declared on the label of bottled drinking water. Bottled drinking water can be produced from various sources of water and various types of treatment of the water can be used in manufacturing bottled water of an acceptable quality. If the manufacturer decides to provide information in the labeling of or in advertising relating to bottled water, stating or implying it is the product of a specific source of water or that the water has been treated in a specific manner, such information must be truthful, factual, and not misleading in any respect. Section 403(a) of the act provides that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. The Commissioner concludes that this statutory authority is sufficient to provide for regulatory action in instances where false or misleading statements concerning the source or treatment of bottled water are made and that specific statements to this effect in the standard are not necessary.

23. Several comments requested that limits be established for some chemicals and substances in addition to those listed in the proposed standard. One comment indicated the limit proposed for nitrate was excessive. Some suggested that lower levels be set than those proposed.

The Commissioner is aware that chemicals other than those listed in the proposed standard could be found in drinking water at levels that adversely affect the quality of drinking water. Much new knowledge has been accumulated on chemical levels in drinking water since the drinking water standard was established in 1962. When revised by the Environmental Protection Agency, the drinking water standard undoubtedly will establish limits for additional chemicals and revise the limits for the chemicals listed in the 1962 standard, to reflect the latest knowledge and expert scientific judgment. Until the revised drinking water standard is published, the limits contained in the 1962 drinking water standard will be applicable. The compatibility of the bottled water standard with the drinking water standard will be maintained by revising the bottled water standard when the drinking water standard is revised.

A food additive regulation regarding added sodium nitrate has been promulgated by the Commissioner to limit unnecessary additions in specific foods (§ 121.1063). Addition to bottled water is not permitted, but nitrates may be naturally present in the water used. The nitrate level in the drinking water standard is under review along with other chemicals for which levels are set in this standard. Any modification in these levels as a result of this review will be reflected in the bottled water standard.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 403(h), 701, 52 Stat. 1046, 1047, and 1055–1056, as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 341, 343(h), 371) and under authority delegated to the Commissioner (21 CFR 2.120), Chapter I of Title 21 of the Code of Federal Regulations is amended in Part 11 by adding a new section to Subpart B, as follows:

§ 11.7 Bottled water.

(a) "Bottled water" is defined as water that is sealed in bottles or other containers and intended for human consumption. Bottled water does not include mineral water or any food defined in § 31.1 of this chapter.

(b) *Microbiological quality.* Bottled water shall, when a sample consisting of analytical units of equal volume is examined by the methods described in Part 400, of "Standard Methods for the Examination of Water and Wastewater," 13th Ed., 1971, American Public Health Association,[1] meet standards of microbiological quality as follows:

(1) *Multiple-tube fermentation method.* Not more than one of the analytical units in the sample shall have a most probable number (MPN) of 2.2 or more coliform organisms per 100 milliliters and no analytical unit shall have a MPN of 9.2 or more coliform organisms per 100 milliliters, or:

(2) *Membrane filter method.* Not more than one of the analytical units in the sample shall have 4.0 or more coliform organisms per 100 milliliters and the arithmetic mean of the coliform density of the sample shall not exceed one coliform organism per 100 milliliters.

(c) *Physical quality.* Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the method described in Part 100 of the 13th Ed., 1971, of "Standard Methods for the Examination of Water and Wastewater," American Public Health Association,[1] meet standards of physical quality as follows:

(1) The turbidity shall not exceed 5 units.

(2) The color shall not exceed 15 units.

(3) The odor shall not exceed threshold odor No. 3.

(d)(1) *Chemical quality.* Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in Part 100 of the 13th Ed., 1971, of "Standard Methods of Examination of Water and Wastewater," American Public Health Association,[1] meet standards of chemical quality and shall not contain chemical substances in excess of the following concentrations:

Substance	*Concentration in milligrams per liter*
Arsenic	0.05
Barium	1.0
Cadmium	0.01
Chloride	250.0
Chromium (Hexavalent)	0.05
Copper	1.0
Cyanide	0.2
Iron	0.3
Lead	0.05
Manganese	0.05
Nitrate	45.0
Phenols	0.001
Selenium	0.01
Silver	0.05
Sulfate	250.0
Total Dissolved Solids	500.0
Zinc	5.0

(2)(i) Bottled water packaged in the United States to which no fluoride is added shall not contain fluoride in excess of the levels in Table 1 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 1

Annual average of maximum daily air temperatures:	*Fluoride concentration in milligrams per liter*
50.0–53.7	2.4
53.8–58.3	2.2
58.4–63.8	2.0
63.9–70.6	1.8
70.7–79.2	1.6
79.3–90.5	1.4

(ii) Imported bottled water to which no fluoride is added shall not contain fluoride in excess of 1.4 milligrams per liter.

(iii) Bottled water packaged in the United States to which fluoride is added shall not contain fluoride in excess of levels in Table 2 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 2

Annual average of maximum daily air temperatures:	*Fluoride concentration in milligrams per liter*
50.0–53.7	1.7
53.8–58.3	1.5
58.4–63.8	1.3
63.9–70.6	1.2
70.7–79.2	1.0
79.3–90.5	0.8

(iv) Imported bottled water to which fluoride is added shall not contain fluoride in excess of 0.8 milligram per liter.

(e) *Radiological quality.* Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in Part 300 of the 13th Ed., 1971, of "Standard Methods for the Examination of Water and Wastepaper," American Public Health Association,[1] meet standards of radiological quality as follows:

(1) The bottled water shall not contain radioactivity in excess of the following concentrations:

Substance	*Concentration in micro-microcuries per liter*
Radium-226	3
Strontium-90	10

(2) When it is known that the strontium-90 and alpha emitters are absent, the composite shall not contain a gross beta concentration in excess of 1,000 micromicrocuries per liter.

(f) *Label statements.* Bottled water, the quality of which is below that prescribed by this section, shall be labeled with a statement of substandard quality as follows:

(1) When the microbiological quality of bottled water is below that prescribed by paragraph (b) of this section, the label shall bear the statement of substandard quality specified in § 11.1(b).

(2) When the physical, chemical, and/or radiological quality of bottled water is below that prescribed by paragraphs (c) through (e) respectively of this section, the label shall bear the statement of substandard quality specified in § 11.1(b) except that, as appropriate, instead of or in addition to the words "Contains Excessive Bacteria" the following statement(s) shall be used:

(i) "Excessively Turbid", "Abnormal Color", and/or "Abnormal Odor" if the bottled water fails to meet the requirements of paragraph (c) (1), (2), and/or (3), respectively, of this section.

(ii) "Contains Excessive Chemical Substances", if the bottled water fails to meet any of the requirements of paragraph (d) of this section. The specific chemical(s) may be declared in lieu of the words "Chemical Substances" in the statement "Contains Excessive Chemical Substances". When a specific chemical is declared, that name by which the chemical(s) is designated in paragraph (d) of this section shall be used. Example: "Contains Excessive Copper".

(iii) "Excessively Radioactive" if the bottled water fails to meet the requirements of paragraph (e) of this section.

(g) Bottled water containing a substance at a level considered injurious to health under section 402(a)(1) of the act is deemed to be adulterated, regardless of whether or not the bottled water bears a label statement of substandard quality prescribed by paragraph (f) of this section.

Any person who will be adversely affected by the foregoing order may at any time on or before December 24, 1973 file with the Hearing Clerk, Food and Drug Administration, Rm. 6-86, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Objections may be accompanied by a memorandum or brief in support thereof. Six copies of all documents shall be filed. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date. This order shall be effective May 22, 1974.

(Secs. 401, 403(h), 701, 52 Stat. 1046, 1047, and 1055–1056, as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 341, 343(h), 371.)

Dated: November 9, 1973.

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

NOTE: Incorporation by reference provisions approved by the Director of the Federal Register December 12, 1972.

[FR Doc.73-24660 Filed 11-23-73;8:45 am]

[1] "Standard Methods for the Examination of Water and Wastewater," 13th Ed. 1971, can be obtained from the American Public Health Association, 1015 18th Street NW., Washington, DC 20036.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 121]

FOOD ADDITIVES

Proposed Addition of Fluoride to Bottled Water

Elsewhere in this issue of the FEDERAL REGISTER, the Commissioner of Food and Drugs is promulgating a standard of quality for bottled water. This standard sets permissible limits for fluoride content of bottled water.

Section 3.27 and 121.10 (21 CFR 3.27 and 121.10) permit the fluoridation of drinking water and the use of such fluoridated water in the manufacture and processing of food. Thus, fluoridated water may properly be used as bottled water.

The Commissioner has concluded that, for the same reasons that fluoridation of drinking water is a sound public health measure, fluoridation of bottled water within the limits established in the new quality standard should also be permitted. The Commissioner is therefore proposing to revise 21 CFR 121.10, explicitly, to recognize this practice.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 402, 409, 701(a), 52 Stat. 1046 as amended, 72 Stat. 1785, 52 Stat. 1055; 21 U.S.C. 342, 348, 371(a)), and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend Part 121 by revising § 121.10 to read as follows:

§ 121.10 Flourine-containing compounds; statement of policy.

The Commissioner of Food and Drugs has concluded that it is in the interest of the public health to limit the addition of fluorine compounds to foods (a) to that resulting from the fluoridation of public water supplies as stated in § 3.27 of this chapter, (b) to that resulting from the fluoridation of bottled water within the limitation established in § 11.7(d) of this chapter, and (c) to that authorized by regulations under section 408 of the act (40 CFR Part 180). It is further concluded that with the exception of certain dentifrices which have been excluded from prescription-dispensing requirements, preparations containing added fluorine compounds should be limited to sale on the prescription of practitioners licensed by law to administer drugs and in accordance with sections 503 and 505 of the Federal Food, Drug, and Cosmetic Act.

Interested persons may, on or before January 25, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 6-86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: November 9, 1973.

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

[FR Doc.73-24659 Filed 11-23-73;8:45 am]

[21 CFR Part 128d]

PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

Proposed Current Good Manufacturing Practice Regulations

The Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) have evaluated the conditions under which water is processed and bottled for human consumption, as well as the quality of bottled drinking water. Findings relative to bottled drinking water were included in the preamble to the proposed quality standards for bottled water published in the FEDERAL REGISTER of January 8, 1973 (38 FR 1019), and relevant background material has been filed with the Hearing Clerk.

EPA surveyed 25 bottling establishments during 1971 and 1972, which were selected to provide geographic distribution. This number represented about 5 percent of U.S. firms bottling water. Some of the findings of the survey, in addition to those noted in the above-referenced FEDERAL REGISTER notice, are as follows:

1. Only 11 of 25 plants collected four or more samples per month for bacterial analysis. Three bottlers collected no samples and eight bottlers collected only one sample per month.

2. Of the 25 plants surveyed, only two were reported as having adequate chemical analysis of their water products. The rest were reported as needing to increase the frequency and scope of chemical analysis.

3. In many cases, bottling was not performed under sanitary conditions.

4. There is considerable lack of uniformity among state regulations covering water-bottling plants and water products.

Based on the information obtained through its survey, EPA concluded that bottling plants, should in many instances adopt better quality control procedures and effect better disinfection and sanitation in the collection, processing, and bottling of water. EPA made the following recommendations:

1. Uniform regulations for plants should be developed, including minimum quality control procedures.

2. Bottling plants and their products should be subjected to regular surveillance to assure compliance with the regulations.

3. A minimum standard of quality should be established for water bottled and sold for human consumption.

A review of FDA field investigations of water-bottling plants showed a need for the same types of improvement as those indicated during the EPA survey. The major necessary improvements were as follows:

1. Better protection of the water source from contamination.

2. Better quality control procedures to assure the bacteriological and chemical safety of the water used for bottling.

3. More frequent checks on the condition of processing equipment and quality control procedures to determine the effectiveness of the various processing operations.

4. Adequate sanitization and protection of containers and closures prior to filling and capping.

5. Better coding of individual units of product so as to identify the date of production of a batch or segment of a continuous production run.

6. More frequent sampling and testing of bottled-water products to assure compliance with applicable standards and laws.

In October 1972, FDA received a discussion draft of a proposed good manufacturing practice (GMP) regulation from the American Bottled Water Association (ABWA) and a request that FDA promulgate such a regulation covering the bottled drinking water industry. This draft, the bottled drinking water regulations of ten States, the EPA bottled-water survey, FDA inspection reports, and the FDA analytical survey of bottled-water products were reviewed. FDA also reviewed other available information and made additional inspections of water bottling plants to obtain the most current information available.

The ABWA represents a large portion of the bottled drinking water industry. The ABWA and the FDA agree that it is essential that good manufacturing practices be established for the processing and bottling of all drinking water, as an adjunct to the standard of quality for bottled water, published elsewhere in this issue of the FEDERAL REGISTER.

With respect to sanitation of product containers, the experience of the U.S. Public Health Service has shown that examination of single-use containers is sufficient without rinsing each before use. Such a procedure is therefore incorporated in this proposal. Additional microbiological examination on a periodic basis is also recommended but not required.

Perhaps the most important aspect of the proposal deals with the requirement of bacteriological, chemical, physical, and radiological analyses. The following rules will apply. First, the source water must be sampled and analyzed semi-annually. Second, the product water, after processing but prior to packaging, must be sampled and analyzed as often as necessary to assure that the processing is effective. Third, the final bottled drinking water must be sampled and analyzed at least weekly for bacteriological purposes and at least semi-annually for chemical, physical and radiological purposes. Thus the safety and sanitary quality of the product will be assured.

On the basis of all this information, the proposed regulations set forth below have been prepared for the processing and bottling of drinking water, which includes all water processed and bottled