DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 103, 129, 165, and 184

[Docket No. 88P–0030]

RIN 0910–AA11

Beverages: Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing a standard of identity for bottled water. At the same time, the agency is recodifying the standard of quality for bottled water. FDA is revising the definition for bottled water in the quality standard to include mineral water and ingredient uses of this product. In addition, FDA is defining ''artesian water,'' ''ground water,'' ''mineral water,'' ''purified water,'' ''sparkling bottled water,'' ''spring water,'' ''sterile water,'' and ''well water.'' FDA is exempting mineral water from certain physical and chemical allowable levels. FDA is taking these actions, in part, in response to a petition submitted by the International Bottled Water Association (IBWA). FDA finds that the regulations will promote honesty and fair dealing in the interest of consumers as well as the interests of the regulated industry.

EFFECTIVE DATE: May 13, 1996. The Director of the Office of the Federal Register approves the incorporations by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications at 21 CFR 129.35(a)(3)(ii), 129.80(g), and 184.1563(c), effective May 13, 1996.

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 5, 1993 (58 FR 393), FDA published a proposal to establish a standard of identity in § 165.110(a) for bottled water (hereinafter referred to as the January 1993 proposal). At the same time, the agency proposed to recodify in § 165.110 (b), (c), and (d), the standard of quality for bottled water currently found in § 103.35. FDA proposed to revise the definition for bottled water in the quality standard to include mineral water and ingredient uses of this product. In addition, FDA proposed to define ''artesian water,'' ''distilled water,'' ''mineral water,'' ''purified water,'' ''spring water,'' and ''well water.'' FDA proposed to exempt mineral water from certain physical and chemical allowable levels if the mineral water contained total dissolved solids (TDS) in excess of 500 parts per million (ppm). Interested persons were given until March 8, 1993, to submit comments.

In the Federal Register of March 9, 1993 (58 FR 13041), FDA extended the comment period to April 7, 1993. In addition, the agency reopened the comment period for comments concerning two spring water surveys that FDA received in response to the proposal (58 FR 34010, June 23, 1993). Interested persons were given until July 23, 1993, to submit comments concerning the two spring water surveys.

FDA received approximately 430 responses, each of which contained one or more comments, from trade and retail associations, government organizations, manufacturers, consumers, health care professionals, retailers, consumer groups, State groups, private organizations, the U.S. Congress, professional societies, and universities. The comments generally supported the proposal. Several comments addressed issues outside the scope of the proposal (e.g., microbiological quality standards, definitions for multicomponent bottled water beverages) that will not be discussed here. A number of comments suggested modifications and revisions in various provisions of the proposal. A summary of the suggested changes and the agency's responses follow.

Elsewhere in this issue of the Federal Register, FDA is proposing to update the methods referenced in § 165.110(b)(3) and to exempt mineral water from the allowable level for aluminum in the quality standard. FDA is responding to the comments on the January 1993 proposal that addressed those issues in that proposal.

II. The Standard of Identity

A. Coverage

The agency proposed in the January 1993 proposal, to move the definition for bottled water from the quality standard to the standard of identity and to revise the definition to include mineral water and ingredient uses of bottled water. Specifically, FDA proposed that bottled water be defined as water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients, except that it may contain safe and suitable antimicrobial agents. The agency also proposed that bottled water may be used as an ingredient in beverages (e.g., diluted juices, flavored bottled water) but stated that the term did not cover those food ingredients that are declared in ingredient labeling as ''water,'' ''carbonated water,'' ''disinfected water,'' ''filtered water,'' ''seltzer water,'' ''soda water,'' and ''tonic water.'' Finally, FDA proposed that the processing and bottling of bottled water must comply with applicable regulations in part 129 (21 CFR part 129).

1. One comment asked why bottled water is singled out for a source identification requirement (e.g., water from a municipal source), and why soft drinks, beers, reconstituted juices, salad dressings, and other products that contain water as an ingredient are not also subject to this requirement.

The agency considered the scope of the bottled water standard, particularly its application to water used as an ingredient in multicomponent foods such as flavored waters and diluted juices, in the proposal to this final rule (58 FR 393 at 395). FDA stated that highlighting the water component of these products is effectively a claim that the water ingredient in the beverage has particular value, and that consumers are likely to purchase these products in large measure because of the claim concerning the water ingredient. For example, in a significant number of situations, the labeling of products stated or implied that the water originated from a source such as a spring or a well. In contrast, in products such as soft drinks or reconstituted juices in which water is simply used as an ingredient, no claim is made about the water. The intent of the proposal was not to require source labeling of all water ingredients from a municipal source, but to require it in the former type of situation, where the finished product is bottled water or the labeling makes an explicit or implied claim concerning the water ingredient.

Under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(a)), a product is misbranded if its labeling is false or misleading in any particular. To determine whether the absence of information on food labels constitutes misbranding the agency must take into account the extent to which the labeling fails to reveal facts material in light of representations made or suggested with respect to consequences that may result from the use of the article under customary or usual conditions of use (section 201(n) of the act (21 U.S.C. 321(n))). The agency does not deem

source labeling of ingredient water from a municipal source as a material fact unless labeling representations are made or suggested that the water possesses particular properties.

Thus, the agency finds no reason to include water that is not a highlighted ingredient in the bottled water standards, and the comment has not provided a basis to do so. Therefore, § 165.110 applies only to bottled water and ingredient uses of water where the water ingredient is highlighted in the labeling.

2. Two comments expressed concern about sparkling water being regulated under the bottled water standards. They stated that sparkling water has long been understood by consumers and recognized by FDA as a common or usual name for unsweetened and unflavored water containing compressed carbon dioxide. The comments contended that consumers clearly understand ''sparkling water'' to be in the same category as ''carbonated water,'' ''seltzer water,'' ''soda water,'' and ''tonic water,'' substances that historically have been regulated by FDA as ''soft drinks.'' They stated that as such, ''sparkling water'' is more appropriately classified as a ''soft drink'' that is not subject to the proposed bottled water standard.

Some comments stated that it was unclear whether ''sparkling water'' was included under the exemption for ''carbonated water'' and asked for clarification. One comment stated that if the standard does not encompass the term, FDA should include ''sparkling water'' in the definition of bottled water.

FDA stated in the preamble to the proposed rule that when a beverage is labeled as containing ''water,'' ''carbonated water,'' ''disinfected water,'' ''filtered water,'' ''seltzer water,'' ''soda water,'' and ''tonic water,'' there is no claim that the water ingredient has particular value, and that, thus, these ingredients were not included in the definition of bottled water (58 FR 393 at 395). This proposed exclusion did not extend to the term ''sparkling water'' or to any other term not specifically excluded by the standard. In the proposal, the agency used the example of the term ''sparkling'' as indicating that the water ingredient possessed a specific characteristic or had received a specific treatment (*id.*). FDA tentatively concluded at that time that use of such highlighted terms concerning the water component was effectively a claim that the water ingredient in the beverage had particular value, and that consumers were likely to purchase these beverages in large measure because of the claim.

The agency notes, however, that sparkling water was included in the former soda water standard. In the Federal Register of February 16, 1967 (32 FR 2940), the agency amended the soda water standard to add the term ''sparkling water'' to the standard as an example of a type of soda water generally designated by a particular common name. FDA proposed this change to permit the designation of nonsweetened and nonflavored soda water by names other than those prescribed in the standard (31 FR 11109, August 20, 1966). However, FDA repealed the standard of identity for soda water in the Federal Register of January 6, 1989 (54 FR 398) because some provisions of the standard were being adequately dealt with by other regulations, while other provisions were no longer necessary.

Given the traditional use of this term, as evidenced by the repealed standard, the agency agrees that the term ''sparkling water'' describes a nonsweetened and nonflavored carbonated water, and that it thus, is a term that is synonymous with the term ''carbonated water.'' The fact is that the agency had separate standards at one time for bottled water and for soda water, and that it included sparkling water in the soda water, and not the bottled water standard. Therefore, the comments have persuaded the agency that some types of sparkling water are in the same category as ''carbonated water,'' ''seltzer water,'' ''soda water,'' and ''tonic water,'' and should be regulated as a soft drink instead of as a bottled water. Accordingly, the bottled water standard in § 165.110 does not include those food ingredients that are declared in ingredient labeling as ''water,'' ''carbonated water,'' ''disinfected water,'' ''filtered water,'' ''seltzer water,'' ''soda water,'' ''sparkling water'' (except as explained in this response) and ''tonic water.''

However, the term ''sparkling water'' may also refer to water that is naturally carbonated (i.e., contains carbon dioxide as it emerges from the source) and that is labeled as ''sparkling water.'' The bottled water standard has traditionally included this type of water because the water has not been carbonated in the same sense that a soda water is carbonated (i.e., with added carbon dioxide). Thus, water that contains carbon dioxide as extracted from the source is not a soda water and must continue to be regulated as a bottled water. Therefore, to differentiate between the two types of sparkling waters, the agency is defining ''sparkling bottled water'' in § 165.110(a)(2)(v) as bottled water that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide that it had at emergence from the source. This definition is in accordance with the definition in the European Regional Codex Standard (ERCS) for ''naturally carbonated natural mineral water'' (Ref. 1).

The agency concludes that defining the term ''sparkling bottled water'' is within the scope of this rulemaking because FDA proposed that sparkling water be included under the bottled water standard. As a consequence of proposing that course of action, FDA has been persuaded that some types of sparkling water should be excluded from the standard and that it should differentiate among the types of sparkling water in its bottled water regulations.

3. Two comments objected to the exclusion of carbonated bottled waters from the bottled water standards. They stated that any product that professes to be, or that has as an important ingredient that is one of the defined bottled water types (e.g., spring water, mineral water), whether noncarbonated or carbonated, should be considered to be bottled water. The comments contended that only those carbonated products with respect to which no reference is made to defined bottled water types should be excluded.

The agency agrees with the comment. Products or ingredients described by a term that is defined by the standard of identity (e.g., ''spring water'') or with a term that makes a claim about the water (e.g., ''natural water'') are standardized waters and must comply with § 165.110 whether carbonation has been added or not. Although terms to describe the water ingredient in a product may sometimes be used in combination with a term that is not included under the standards (e.g., ''carbonated spring water'' or ''filtered natural water''), the product or the water ingredient in the product must comply with the bottled water standards because a claim is being made concerning the value of the water. However, use of only a term specifically excluded from the bottled water standards (e.g., ''filtered water'' or ''carbonated water'') means that no claim is being made concerning the value of the water, and, thus, the water is not a standardized food.

4. Several comments stated that it is inconsistent for FDA to exempt carbonated waters from the bottled water standards. They held that carbonated water may be consumed at levels which constitute a major portion of an individual's daily water intake. One comment added that exempting

carbonated water from the bottled water category does not provide for consumer safety or confidence.

The agency does not agree with the comments, although it acknowledges that carbonated waters may constitute a major portion of some consumers' daily water intake. However, FDA points out that standards of identity and quality are not established because a product is consumed in large volumes or for consumer safety or confidence but are established to promote honesty and fair dealing in the interest of consumers.

''Carbonated water'' or ''soda water'' has traditionally not been covered by the provisions of the bottled water quality standard because it has been considered to be a soft drink. Bottled water and soda water, although similar, are two different foods as evidenced by the fact that the agency had quality standards for bottled water at the same time that it had a standard of identity for soda water that included ''carbonated water.''

FDA tentatively concluded in the proposal that it would not include ''carbonated water'' in the standards for bottled water because it has historically not been considered to be bottled water. In addition, the agency tentatively concluded that the standards for bottled water covered water ingredients that were highlighted because of a claim concerning the water ingredient itself.

Labels of foods that claim to contain as an ingredient, or to be, ''carbonated water'' do not claim or imply any particular properties or characteristics for the water ingredient. Any claims on such foods for the ingredient are simply that carbon dioxide has been added. Thus, ''carbonated water'' does not fit within the type of food that the bottled water standard is intended to address because no claim is being made about the water itself. The agency finds no reason to include ''carbonated water'' in the bottled water standard, and the comment has not provided any basis to do so. Therefore, the agency concludes that it has not been inconsistent in the regulation of ''carbonated water'' and ''bottled water.''

5. Two comments stated that the terms ''carbonated water,'' ''disinfected water,'' ''filtered water,'' ''seltzer water,'' ''soda water,'' and ''tonic water'' should be defined to avoid confusion by industry and consumers as to what types of water are covered by the bottled water standards and what types of water are not. One of the comments stated that these terms may have different meanings to the bottled water and beverage industries and consumers.

The agency does not agree with the comments. There is general understanding of the meanings of these terms, even though they are not defined in FDA's regulations. ''Carbonated water,'' ''disinfected water,'' ''filtered water,'' ''seltzer water,'' ''soda water,'' and ''tonic water'' are common or usual names that are in general use by both manufacturers and consumers. In the proposal to this final rule (58 FR 393 at 395), the agency noted that the terms ''carbonated water,'' ''seltzer water,'' ''soda water,'' and ''tonic water'' have historically been considered to be soft drinks, and that ''disinfected water'' and ''filtered water'' described water that has been subjected to a commonly used treatment.

The reason for not addressing these terms under the bottled water standard is that they make no claims about the water used in the ingredients that they denominate. The exclusion is not based on the specific source, composition, or processing of these types of waters. The comments did not provide any information to persuade the agency to conclude otherwise. Therefore, FDA is not defining these common terms at this time. However, persons interested in establishing definitions for ''carbonated water,'' ''disinfected water,'' ''filtered water,'' ''seltzer water,'' ''soda water,'' and ''tonic water'' may petition the agency to do so, providing recommended definitions and justification for the recommendations.

6. Several comments objected to any definition of bottled water that does not allow for the addition of ingredients such as minerals for flavor, flavors that comprise less than 1 percent by weight of the product, and carbon dioxide. They stated that changing the definition of bottled water to exclude established products would: (1) Be costly to the bottled water industry; (2) exempt excluded bottled water products from meeting FDA's proposed health, safety, and quality standards; and (3) confuse rather than unify regulatory authority. One comment declared that it is imperative that the final regulation include all established products of the bottled water industry.

One comment stated that some model codes and State regulations provide for the addition of ingredients to bottled water provided that these additives comprise less than 1 percent by weight of the final product. The comment noted that many consumers may supply a major portion of their daily water intake needs with these 1 percent bottled water products.

Another comment noted that § 129.80(a) states that carbonation, mineral addition, or any other process shall be done in a manner so as to be effective in accomplishing its intended purpose and in accordance with section 409 of the act. It stated that there is no reason to disallow any of these processes or their resultant products as bottled water.

FDA does not agree that it is changing the definition of bottled water. The agency acknowledges that some State regulations define bottled waters with added flavors, minerals, and carbon dioxide as described in the comments (Ref. 2). However, the Federal definition of ''bottled water'' has traditionally been ''water that is sealed in bottles or other containers and that is intended for human consumption'' (§§ 103.35(a)(1) and 129.3(b) (1994)). This definition is the basis of the definition that FDA is adopting in this final rule (§ 165.110(a)(1)). Although § 129.80(a) mentions treatment of product water with carbonation and mineral addition, among other processes, any bottled water product with added ingredients would be just that—bottled water with added ingredients. (However, see the discussion of fluoride in bottled water in comment 8 of this document.)

Firms may manufacture nonstandardized bottled water products with ingredients such as minerals for flavor, flavors that comprise less than 1 percent by weight of the product, and carbon dioxide added to bottled water. The common or usual name of the resultant product must reflect these additions. However, only the bottled water ingredient is subject to the standard in § 165.110. The other ingredients in the product are subject to regulation under the food additive or other food ingredient provisions of the act. Thus, it is not necessary to include added ingredients, such as minerals for flavor, flavors that comprise less than 1 percent by weight of the product, or carbon dioxide, in the standard for bottled water.

Therefore, for the reasons listed above the agency is not persuaded by the comments to include the addition of minerals, flavors, and carbon dioxide in the standard of identity for bottled water in § 165.110(a)(1).

7. One comment stated that all bottled waters imported into the United States should meet all of FDA's requirements for bottled waters including mineral water. It added that U.S. standards should not be lessened to meet European standards unless there are compelling public health reasons for doing so.

FDA agrees that both foreign and domestic bottled waters sold in interstate commerce in the United States must comply with the act and the regulations issued thereunder, including the specific regulations for bottled water

found in part 129 and § 165.110. Although the agency attempts, where possible, to harmonize its regulations with the regulations of other countries, there must be appropriate grounds for FDA to amend any of its bottled water regulations, whether or not such action would harmonize international standards.

B. Fluoridated Water

The agency did not propose a definition for ''fluoridated water,'' although it did request comments on the need to define types of bottled water other than those for which it proposed definitions. Some comments addressed issues on fluoridated water that fall within the scope of this rulemaking. Therefore, the agency is addressing these issues in this final rule.

8. Several comments stated that the addition of fluoride to bottled water should be allowed. One comment noted that many people specifically request and use fluoridated water because of its benefits to dental health. The comment stated that these products have long been established and should not be discontinued. One comment noted an inconsistency between the definition of bottled water and the provisions of proposed § 165.110(b)(4)(ii) that discuss the addition of fluoride.

FDA agrees that there is an inconsistency between the proposed standard of identity and the standard of quality for bottled water with respect to the addition of fluoride. The agency proposed in § 165.110(a)(1) that bottled water contain no added ingredients other than safe and suitable antimicrobial agents. This provision would preclude the addition of fluoride (58 FR 393 at 407). The quality standard, however, provides maximum levels for bottled water to which fluoride is added (§ 165.110(b)(4)(ii)).

The agency recognizes that water with fluoride added may provide a benefit to consumers. The Surgeon General's Report on Nutrition and Health (the Surgeon General's report) recommends that community water systems contain fluoride at optimal levels for prevention of tooth decay, and that, if such water is not available, other appropriate sources of fluoride should be used (Ref. 3). Bottled water may be used by some consumers as an alternative to community drinking water. Therefore, because of the unique circumstances presented by fluoride, the agency is providing for the optional addition of fluoride to bottled water in § 165.110(a)(1) within the limitations established in the quality standard (§ 165.110(b)(4)(ii)).

Because the agency is providing for the optional addition of fluoride to bottled water, the standardized product may be a multiingredient food, and, as such, its label must bear ingredient labeling. According to § 101.4(a)(1) (21 CFR 101.4(a)(1)), all food ingredients are required to be declared on the label. Therefore, bottled water containing added fluoride must list the names of the water ingredient and the fluoride.

Therefore, because FDA is providing for the optional addition of fluoride to bottled water, and thus, bottled water may be a multicomponent food, the agency is adding § 165.110(a)(4) to require that each of the ingredients used in the food be declared on the label as required by the applicable sections of 21 CFR parts 101 and 130.

9. Several comments requested that FDA define ''fluoridated water.'' Some of these comments recommended that ''fluoridated water'' be defined as bottled water containing naturally occurring or added fluoride, and that the label specify whether fluoride is naturally occurring or added. One comment stated that the regulation only discusses maximum limits on fluoride addition without setting a minimum, thus opening a loophole that would allow manufacturers to add insignificant amounts of fluoride to their products and call them ''fluoridated water.'' One comment stated that any water that is called ''fluoridated water'' should contain not less than 0.8 milligram per liter (mg/L) fluoride ion. Another comment stated that any water that is defined as ''fluoridated water'' should contain not less than 1.0 mg/L fluoride. One comment requested that ''fluoridated water'' be defined only as water containing added fluoride.

FDA has provided for the use of the terms ''fluoridated,'' ''fluoride added,'' and ''with added fluoride'' on the label or in labeling of bottled water that contains added fluoride in § 101.13(q)(8). The agency adopted this regulation in the Federal Register of January 6, 1993 (58 FR 2302 at 2314) and stated that the presence of fluoride in bottled water is of interest to consumers, and its declaration should not be prohibited. However, the agency also stated that it did not wish to encourage unnecessary addition of fluoride to bottled water, and that it was concerned that if it permitted the use of terms like ''good source of fluoride'' or ''high in fluoride,'' they might encourage such additions. Therefore, the agency has not defined a nutrient content claim for fluoride. Instead, it has provided that a statement indicating the presence of added fluoride could be used, but that the claim cannot include a description of the level of fluoride present.

As stated in another final rule in the Federal Register of January 6, 1993 (58 FR 2079 at 2149), the agency has considered the identity statement ''fluoridated water'' to be misleading if the product is derived from a source naturally containing fluoride. Because the term ''fluoridated'' represents that fluoride has been added to the water, FDA concluded that the term ''fluoridated water'' should be used to describe only products to which fluoride has been added in the manufacturing process, and that such products would be required to bear nutrition labeling that complies with the simplified format (*id.*). FDA also points out that fluoride may not be present in amounts that exceed the limits in § 165.110(b)(4)(ii).

Although labeling could be used to describe whether fluoride was added or naturally present in bottled water, the term ''fluoridated'' continues to mean that fluoride has been added. FDA is not establishing a minimum level for fluoride addition because the terms ''fluoridated,'' ''fluoride added,'' or ''with added fluoride'' have been defined in § 101.13(q)(8) and amending that provision falls outside the scope of this final rule. However, if the addition of fluoride to water is so minimal that it would be considered dietarily insignificant, a product that bears a claim about such addition would be misbranded under section 403(a) of the act in that its labeling would be misleading because the use of the term ''fluoridated'' or any of its synonyms implies that fluoride has been added in a meaningful amount. Thus, FDA concludes that it has not created a loophole that would allow manufacturers to add insignificant amounts of fluoride to their products and call them ''fluoridated water.''

The Surgeon General's Report states that the optimal fluoride concentration of approximately 1 ppm fluoride has been shown to reduce the prevalence of dental caries by more than 50 percent (Ref. 3). In addition, the Surgeon General's Report states that current recommendations for optimum fluoride concentrations vary from 0.7 to 1.2 ppm (*id.*). Therefore, the comments' suggested values of 0.8 mg/L and 1.0 mg/L fluoride are meaningful amounts of this mineral in bottled water.

10. One comment stated that infant bottled waters may contain fluoride, and that the presence of this mineral may be a problem if parents are not aware that too much fluoride is undesirable, or that an infant should not receive both a physician's prescription of fluoride

drops and drink water containing fluoride. For this reason, the comment stated that the label of a bottled water containing 0.3 ppm or more fluoride should include a statement advising parents not to use the product before consulting with their baby's physician if the baby is receiving a fluoride supplement. The comment added that bottled water for general use is also used for infants, so such a label statement should be required on any bottled water containing 0.3 ppm or more fluoride. It stated that this level of fluoride is taken from the current recommendation of pediatricians and pediatric dentists relating to administration of fluoride supplements. It suggested that the statement could read as follows: ''Note: If you are giving your baby a fluoride supplement, do not use water with fluoride without consulting your doctor.''

The agency agrees that an advisory statement such as that suggested by the comment may be appropriate to prevent unwanted aesthetic effects from excessive doses of fluoride, and it encourages manufacturers to provide such information to consumers, especially on products labeled for infant use. However, FDA does not agree that this statement should be mandatory on all bottled waters containing 0.3 ppm or more fluoride. There are allowable levels for fluoride in the quality standard, and bottled water exceeding these levels must be labeled as substandard. The allowable levels are related to secondary levels established by the Environmental Protection Agency (EPA) for public drinking water in 40 CFR parts 141 and 143 and take into consideration excessive infant fluoride intake. In addition, as discussed in the previous comment, the Surgeon General's Report recommends an optimal level of 1.0 ppm fluoride in drinking water.

Fluoride supplements are generally prescribed for breast-fed infants because those infants frequently consume little or no water. Human milk contains little fluoride, even in areas with fluoridated water supplies. Physicians may also prescribe fluoride supplements for infants not receiving adequate dietary fluoride. Health care professionals must take into consideration the patient's weight and the exposure to fluoride from dietary and other sources to establish the proper dose (Ref. 4).

Therefore, the agency finds no basis to require an advisory statement concerning infant fluoride consumption on bottled waters containing 0.3 ppm or more fluoride.

C. Nomenclature

FDA proposed that the name of the standardized food meeting the definition of bottled water in § 165.110(a)(1) is ''bottled water'' or one of the following defined terms: ''Artesian water,'' ''distilled water,'' ''mineral water,'' ''purified water,'' ''spring water,'' and ''well water.'' The agency requested comments from interested persons on the definitions for these terms and on other terms that need to be defined.

11. A number of comments requested that FDA define the term ''drinking water'' because: (1) It is the most commonly used term to describe bottled water and represents 36 to 40 percent of the gallonage of bottled water sold in food stores; (2) the lack of a Federal definition allows States to adopt special, nonuniform definitions for this segment of the bottled water market; and (3) many bottlers would have to revise their drinking water labels to remove this term to come into compliance with the standard, and doing so would impose severe economic hardships to the industry. One comment noted that producers of 5-gallon returnable bottled water products have a very large investment in bottle inventories that are designed to last for a considerable time, and that a high percentage of these packages is permanently labeled as ''drinking water.'' It stated that it would be costly to dispose of these containers, and that the use of stick-on labels would present problems in its manufacturing operation.

Some comments recommended modifying paragraph § 165.110(a)(2) to define the terms ''bottled water'' and ''drinking water'' synonymously. However, other comments stated that ''drinking water'' is a classification within the bottled water category along with ''spring water,'' ''mineral water,'' and ''purified water.'' These comments suggested the following definition: ''Drinking water means bottled water obtained from an approved source that has at a minimum undergone treatment consisting of filtration (activated carbon or particulate) and ozonation or an equivalent disinfection process. Drinking water that has been treated to meet the definitions of distilled or purified water may contain added minerals for taste, provided an ingredient statement 'minerals added for taste' or optionally 'minerals added for flavor' appears on the label.''

One comment stated that it is important for FDA to define drinking water as only one type of bottled water, and that the terms ''drinking water'' and ''bottled water'' not be interchangeable. It stated that ''bottled water'' includes and describes all types of bottled water products, including bottled ''drinking water,'' but that bottled ''drinking water'' does not include or describe all types of ''bottled water.'' It stated that it is important that FDA define ''drinking water'' to prevent the consumer confusion that would result if this product type, already marketed to and accepted by the public, is not recognized by FDA as a specific type of bottled water. It stated that failure to do so could, at worst, mean that products labeled as ''drinking water'' could no longer be sold in interstate or foreign commerce involving the United States.

Conversely, two comments stated that the term ''drinking water'' should not be permitted on the label because consumers may be misled because they do not understand the meaning of the term.

The agency agrees with the comments that stated that it should define the term ''drinking water.'' Consumers are familiar with the term because, as the comments pointed out, products labeled as ''drinking water'' comprise a significant portion of the bottled water market. In addition, not defining this term would impose an economic hardship on the bottled water industry because products labeled as ''drinking water'' would have to be relabeled as ''bottled water.''

However, FDA disagrees with the comments that said that ''drinking water'' should be defined differently than ''bottled water.'' As required by the standard of quality, ''bottled water'' must meet certain quality requirements, or the water is substandard and must be labeled as such. The definition for ''drinking water'' suggested by the comments provides an apt description of the method of processing bottled water that is used by many manufacturers. Thus, FDA concludes that a separate definition of ''drinking water'' is not warranted.

In addition, EPA has standards for ''drinking water'' from public water systems (40 CFR parts 141 and 143) that are nearly identical to FDA's standards for bottled water. FDA is not aware of any reason why its standard for ''drinking water'' that is sold in a bottle should differ significantly from EPA's standard for ''drinking water.'' Therefore, the agency is including ''drinking water'' as an alternative name for ''bottled water'' in § 165.110(a)(2).

The agency agrees with the comments that pointed out that if minerals are added to bottled water or drinking water, an appropriate statement of identity must appear on the principal display panel of the label of the product

to inform consumers of this fact (e.g., ''drinking water with minerals added for taste''). An ingredient statement must also appear on the label in accordance with § 101.4(a). In addition, if sodium, calcium, or iron are present in the bottled water product in more than an insignificant amount, nutrition labeling is required.

12. One comment suggested that an alternative name for ''spring water'' or ''well water'' could be ''ground water.''

The agency agrees that ''ground water'' is an appropriate name for water from a spring or a well. The term ''ground water'' encompasses not only ''spring water'' and ''well water'' but also ''artesian water'' and ''mineral water'' because by definition all of these waters come from an underground source. A geological definition states that ''ground water'' is water in the saturated zone that is under a pressure equal to or greater than atmospheric pressure (Ref. 5). The saturated zone is the subsurface zone in which all openings are full of water (*id.*).

Because ''ground water'' is an appropriate alternative term to describe some types of bottled water, and because in the January 1993 proposal, the agency requested comments from interested persons on other terms that need to be defined, the agency concludes that it is within the scope of this rulemaking to define the term ''ground water.'' FDA concludes that the geological definition stated above is appropriate. Therefore, the agency is defining ''ground water'' in § 165.110(a)(2)(ii) to mean water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure. (Because the agency is establishing an additional definition in § 165.110(a)(2), it is recodifying the other terms in § 165.110(a)(2) so that they continue to appear in alphabetical order.) The agency is also requiring in § 165.110(a)(2)(ii) that ''ground water'' not be under the direct influence of surface water. EPA defines ground water under the direct influence of surface water as any water beneath the surface of the ground with: (1) Significant occurrence of insects or other macroorganisms, algae, or large-diameter pathogens such as *Giardia lamblia;* or (2) significant and relatively rapid shifts in water characteristics such as turbidity, temperature, conductivity, or pH which closely correlate to climatological or surface water conditions (40 CFR 141.2). Ground water under the direct influence of surface water is not ''ground water'' because water that does not meet this definition is mingling with water that otherwise would meet the definition. To clarify that ground water must not be under the direct influence of surface water, FDA concludes that this distinction should be included in the definition of ''ground water.''

13. One comment stated that FDA should establish a separate definition for ''sterilized water.'' It stated that water for the initial feeding of babies has been called ''sterilized water'' for decades. The comment held that all water intended for the initial feeding of infants should be commercially sterile, as defined in the low-acid canned food processing regulations (21 CFR part 113). The comment stated that to require a change in the statement of identity from ''sterilized water'' to ''bottled water'' or ''purified'' or ''distilled water'' would create confusion in hospitals and could result in nonsterilized ''bottled water'' or ''purified'' or ''distilled water'' being fed to newborns. The comment suggested that the following definition be added to § 165.110(a)(2)(vi): ''The name of the water intended as the initial feeding of infants may be 'sterilized water' provided it meets the definition of commercial sterility contained in 21 CFR 113.3(e)(1)(i).''

The agency agrees that the terms ''sterile water'' and ''sterilized water'' should be defined as a specific bottled water type. Doing so is the logical outgrowth of FDA's request in the proposal for other terms that need to be defined. Defining these terms will mean that the water must meet a certain minimum standard to be labeled with these terms and will allow firms to prominently label their products in the statements of identity as having been treated to achieve this standard.

The definition of commercial sterility in § 113.3(e)(1)(i) states that ''commercial sterility'' of thermally processed food means the condition achieved by the application of heat that renders the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution and of viable microorganisms (including spores) of public health significance.

FDA notes that the United States Pharmacopeia (USP) has official monographs for ''sterile water for inhalation,'' ''sterile water for injection,'' and ''sterile water for irrigation.'' The monographs require that each of these types of water meet sterility requirements set forth by the USP (Ref. 6). These requirements involve microbiological tests to determine the presence of viable microorganisms. If no evidence of microbial growth is observed, the article tested meets the requirements of the test for sterility.

The difference between the sterility standard in § 113.3(e)(1)(i) and that used by USP is that water that is commercially sterile may contain bacteria, although in an innocuous amount, whereas water that is sterile according to USP standards does not. The agency acknowledges that water for general drinking purposes need not be sterile or even commercially sterile. However, sterile water may be purchased by immunosuppressed individuals, contact lens wearers, infant caretakers, and laboratories with an expectation that the water is free of any bacteria. In addition, FDA finds that it would be confusing to consumers to have two standards for sterility, one for ''sterile water'' and another for ''sterile water, USP.''

Therefore, the agency concludes that bottled water labeled as ''sterile'' must meet the USP definition. Thus, FDA is defining the terms ''sterile water'' and ''sterilized water'' in § 165.110(a)(2)(vii) to mean water that meets the requirements under ''Sterility Tests'' <71> in the USP, 23d Revision.

14. Several comments requested that the agency clarify whether a bottler may use any name defined in § 165.110(a)(2) as long as the bottled water complies with the definition used. One comment asked whether mineral water that contains between 250 and 500 ppm TDS could be labeled as ''mineral water,'' ''mineral spring water,'' or ''mineral well water.''

The agency advises that if more than one term is applicable, bottlers may combine the terms, as appropriate, in naming the food (e.g., ''mineral spring water, low mineral content''). Thus, bottlers will be able to label their products in an informative manner because all applicable terms can be presented prominently on the labels in the statements of identity. Because this approach will ensure the informativeness of the statement of identity, FDA finds that it will promote honesty and fair dealing in the interest of consumers. Therefore, FDA is revising § 165.110(a)(2) to state that the name of the food is ''bottled water,'' ''drinking water,'' or alternatively one or more of the terms listed in that section as appropriate.

15. Two comments expressed concern that the proposed definitions for ''artesian water,'' ''mineral water,'' ''spring water,'' and ''well water'' provide an opportunity for unintended mineral content manipulation that could lead to potential consumer deception. To alleviate this problem, the comments requested that FDA revise the

definitions for each of these waters to include the following: ''Artesian water (or mineral water, spring water, or well water) shall not be altered by addition or deletion of minerals or by blending it with water from a nonartesian water source.''

FDA disagrees that the suggested revision is warranted or needed. Once a defined bottled water product (e.g., artesian water, mineral water, spring water, or well water) has been blended with water from another source, the product no longer meets the definition of that particular type of bottled water, although it remains bottled water. For example, if artesian water is blended with spring water to reduce the water hardness, the product is ''bottled water'' or ''drinking water,'' although its labeling may state the percentages of the artesian water and spring water it contains. Mineral water may be labeled as ''mineral water'' even if it is a blend of one or more waters, as long as each of the component waters complies with the source, composition, and other requirements of § 165.110(a)(2)(iii).

The agency notes that mineral addition or deletion does not change the source of the water. However, if the water has been altered significantly from the source water, under section 201(n) of the act, that the alteration has been made is a fact material in the light of representations made and must appear on the label of the product. The water is no longer unmodified ground water and differs significantly from the water that was harvested. Therefore, the fact that the water has been altered significantly must be included in the statement of identity so that consumers are aware that the source water has been modified. If minerals have been added, the statement of identity must state that fact. If minerals have been removed from the product, other than those that are removed during normal processing (e.g., filtration to remove precipitates), that fact must be included in the statement of identity of the product (e.g., partially demineralized) (§ 165.110(a)(2)(iii)). Therefore, FDA concludes that the requested revision is not necessary.

1. Artesian Water

The agency proposed to define ''artesian water'' as water from a well tapping a confined aquifer in which the water level stands above the natural water table. The agency also proposed to provide for the collection of artesian water with the assistance of an external force to enhance the natural underground pressure so long as such measures do not alter the physical properties, composition, and quality of the water.

16. One comment stated that FDA should not permit the use of the term ''artesian'' on bottled water labels because it is the most misused term in the bottled water business today.

The agency disagrees that it should prohibit the use of the name ''artesian.'' Because FDA is defining this term in the standard of identity for bottled water, manufacturers will have to label their products in accordance with the standard or face regulatory action. FDA expects that misuse of the term will cease as a result. Therefore, FDA concludes that this comment, rather than establishing why FDA should not define ''artesian water,'' only serves to point up why defining this term will promote honesty and fair dealing in the interest of consumers, and, thus, why it is appropriate for FDA to do so.

17. Several comments stated that the original and vernacular meaning of ''artesian water'' is water that is forced from below the ground to the surface through a well by natural underground pressure and collected at or above the surface. They recommended that this definition be adopted.

One comment pointed out that the geologic definition that FDA referenced in the proposal actually states that ''the water level in artesian wells stands at some height above the top of the aquifer but not necessarily above the land surface'' and does not require that the water stand above the water table. Therefore, the comment added, the water level in an artesian well may be either above or below the water table and still be considered artesian. The comment stated that the distinction in the geologic definition between the water table and the top of the confined aquifer is an important technical one, and that the proposed definition is much more restrictive and not the one that is generally accepted by groundwater scientists.

The agency disagrees with the comments that contended that the water in an artesian well must flow to the surface. As mentioned by the latter comment described above, the geologic definition states that ''the water in artesian wells stands at some height above the top of the aquifer but not necessarily above the land surface'' (Ref. 5). Therefore, the geologic definition does not require that the water flow to the surface, or that, as FDA proposed (58 FR 393 at 398), the water level stand above the natural water table. Because the agency intended that its definition for ''artesian water'' be the geologic definition, it is revising the definition of artesian water in § 165.110(a)(2)(i) to state that bottled water that is drawn from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer may be called ''artesian water'' or alternatively ''artesian well water.''

Concerning artesian water that flows to the surface, FDA notes that a typical geologic definition states that ''if the water level in an artesian well stands above the land surface, the well is a flowing artesian well'' (Ref. 5). The agency would not object to manufacturers labeling their products accordingly, as long as it is done in a truthful and nonmisleading manner. However, the name of the food remains ''artesian water'' or ''artesian well water.''

18. One comment urged that the specific name ''artesian well water'' be permitted on labels instead of ''artesian water'' to provide full disclosure to consumers.

FDA advises that both ''artesian well water'' and ''artesian water'' can be used to identify this product because both terms appropriately describe it, and consumers would recognize either term. ''Artesian water'' does indeed come from a well and only differs from ''well water'' in that the water comes from a confined aquifer where the water is under pressure and stands at some height above the top of the aquifer. Therefore, FDA is modifying § 165.110(a)(2)(i) to state that the name of water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer may be ''artesian water'' or ''artesian well water.''

19. One comment asked how someone who is reviewing the label statement ''artesian well water'' will be able to verify that the well is actually an artesian well, meeting the definition, after the well has been bored and is in production.

The agency agrees that there must be some means of verifying food labeling claims. In specific instances FDA may require that records or other means of verification be provided to FDA regulatory officials, despite the act's lack of express, general statutory records access authority for foods. The Supreme Court has recognized that FDA has authority that ''is implicit in the regulatory scheme, not spelled out *in haec verba*'' in the statute. *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973). Indeed, ''it is a fundamental principle of administrative law that the powers of an administrative agency are not limited to those expressly granted by the statutes, but include, also, all of the powers that may fairly be implied therefrom. * * * In

the construction of a grant of powers, it is a general principle of law that where the end is required the appropriate means are given and that every grant of power carries with it the use of necessary and lawful means for its effective execution.'' (See *Morrow* v. *Clayton*, 326 F.2d 35, 44 (10th Cir. 1963).)

Under section 701(a) of the act (21 U.S.C. 371(a)), the agency may promulgate regulations for the efficient enforcement of the act. Although it is possible to determine that a source of water is an artesian well after the well is in operation, in some cases it would be onerous for regulatory officials to do so. Therefore, FDA has determined that a verification requirement is necessary for the efficient enforcement of the act. FDA has previously stated that a food manufacturer is responsible for the accuracy of its food labels (58 FR 2079, 2163, and 2165, January 6, 1993). Indeed, placing a claim in food labeling that calls the consumer's attention to a water's source is a representation that the manufacturer has evidence that the product meets the requirements for the claim. See *Thompson Medical Co., Inc.* v. *FTC*, 791 F.d. 189, 193 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987). Making a claim without such a basis would be misleading, in violation of section 403(a) of the act.

The agency anticipates that, in some instances, companies will be amenable to demonstrating to FDA the basis for the claim, regardless of the existence of these regulations. The agency considers, however, that, when a product bears a claim based on information available solely to the manufacturer, it is reasonable for the agency to have access to that information. See *United States* v. *An Article of Device*, 731 F.d. 1253, 1261–62 (7th Cir. 1984) (upholding regulation requiring makers of prescription devices to be able to prove that their devices work safely for their intended purposes and stating that ''[w]here the government's access to the necessary information may be limited * * * it seems not inappropriate to put the burden of persuasion on the party who * * * presumably has better access to the relevant information''); *see also Trans-American Van Service, Inc.* v. *United States*, 421 F. Supp. 308, 331 (N.D. Tex. 1976). Therefore, FDA is modifying § 165.110(a)(2)(i) to require that plants be able to demonstrate to regulatory officials that the water level of the well stands at some height above the top of the aquifer, and, thus, that the well is an artesian well. Compliance with this provision does not entail the creation of any new information or the compilation of any special records. Rather, the requirement would obligate manufacturers simply to have access to information that they should already possess, or to make a measurement of their well, and to provide FDA with this information.

FDA considers this requirement to be the logical outgrowth of its January 1993 proposal. The purpose of this rulemaking is to ensure that terms such as ''artesian water'' are used in a manner that promotes honesty and fair dealing (see section 401 of the act (21 U.S.C. 341)). Such a result requires not only that these terms be appropriately defined, but that they be used in a manner that accurately describes the product. Thus, how FDA would enforce the definitions was a matter that was within the purview of the proposal, and that the agency would provide for such enforcement in the final rule in this proceeding was reasonably foreshadowed by the proposal. The fact that FDA received comments on how it would ensure that the defined terms are appropriately used evidences that this issue is the logical outgrowth of the proposal.

To comply with this requirement, producers may maintain records that demonstrate that the well is indeed an artesian well. The manufacturer may also rely on records from the company that drilled the well. In addition, many States and the United States Geological Survey have records of some wells and of the geology of the surrounding area. To verify that the water is at some height above the top of the aquifer and is, thus, artesian water, the pump may be shut off, and the height or the pressure of the water in the drilled hole measured. This information can then be used, along with information on the depth of the aquifer, to determine whether the water is artesian water. If the source does not meet the definition of artesian water, the product must not be labeled as artesian water, or it is misbranded under sections 403(a), 403(b), and 403(g) of the act.

20. One comment stated that water chemistry changes as wells are pumped, and that the larger the drawdown, the greater the water chemistry may change. It stated that a mineralogical analysis from a water sample taken at 10 gallons per minute (gpm) may be quite different than one taken at 500 gpm for the same well. The comment added that there would be an ongoing burden on FDA to verify that water produced by bottlers drawing on ''artesian'' groundwater resources remains constant in water chemistry.

FDA agrees with the comment. The use of external force may alter the physical properties, composition, and quality of the water, although usually not significantly, depending on the rate of extraction, because of changes in the pressure of the water as it is extracted. This fact is the basis on which the agency proposed to require that the use of external force not alter these characteristics (58 FR 393 at 398). However, because the rate of extraction from the use of external force could vary from day to day or even hour to hour, the characteristics of the water can be also altered.

As discussed in the previous comment, the agency is requiring that the manufacturer demonstrate that the source of the water is indeed an artesian source. However, the agency does not deem it necessary to require that the definition for artesian water extend to the physical properties, composition, and quality of the water. In fact, as long as the source is demonstrated to be an artesian source that meets the definition in § 165.110(a)(2)(i), the actual characteristics of the water are a quality control concern for the manufacturer rather than an attribute that defines artesian water. As stated previously, the agency intends that its definition of artesian water be the geological definition. The geological definition does not take into consideration the composition of the water. Therefore, the agency is removing the requirement in § 165.110(a)(2)(i) that the use of external force in the extraction of artesian water not alter the physical properties, composition, and quality of the water.

2. Mineral Water

The agency proposed that water coming from a source tapped at one or more bore holes or springs, originating from a geologically and physically protected underground water source, may be called ''mineral water.'' FDA further proposed that mineral water be distinguished from other types of water by its constant level of minerals and trace elements at the point it emerges from the source.

The agency tentatively concluded in the proposal that it would be contradictory for bottled water that has essentially no minerals and does not perform (e.g., taste) like mineral water to be labeled as mineral water. Consistent with this tentative conclusion, FDA proposed that ''mineral water'' be defined as water containing not less than 250 ppm TDS. The agency requested comments on the proposed minimum level of 250 ppm TDS in mineral water and stated that if it received substantive data to support another minimum level, it would consider issuing a final rule with a different minimum level.

21. A number of comments objected to FDA establishing a minimum TDS level for mineral water. The comments argued that establishing such a level would be arbitrary and contrary to the most current mineral water definitions, including international definitions which do not include a minimum level, and would prohibit many brands from being labeled as mineral water, thereby adversely affecting consumer sales with no apparent benefit to consumers.

Conversely, other comments suggested raising the minimum TDS level to 500 ppm. These comments argued that establishing the minimum TDS at the higher level would: (1) Make it closer to the definition that has been adopted by most States that have bottled water regulations and to the definition that is currently being considered by the Canadian Government; (2) provide the basis for identification of the term ''mineral water'' with the distinctive taste of a higher mineral content; (3) be less confusing to consumers in that it would not allow the same water to be marketed under several names (e.g., ''mineral water, low mineral content'' or ''spring water''); and (4) simplify application of the quality standards and the label identity statement.

Several comments expressed the view that mineral water is ground water with at least 50 ppm TDS, while several other comments supported the proposed minimum level of 250 ppm TDS in mineral water. One of these comments stated that waters having a TDS of 250 ppm or more generally have a distinctive flavor. Two comments, however, stated that actual taste thresholds for mineral water are often in the range of 100 ppm TDS. One of these comments stated that consumer identification and differentiation among the flavors of various individual source waters, which result from naturally occurring mineral variations in the water, is clearly possible below the proposed threshold of 250 ppm TDS.

The agency acknowledges that many different definitions exist for ''mineral water.'' In the January 1993 proposal, the agency compared several current definitions, including State and European standards, in arriving at its proposed definition (58 FR 393 at 396). International standards vary from requiring at least 500 ppm TDS (Canadian Province of Quebec) to no minimum requirement (ERCS). In a like manner, different States have different requirements. Therefore, no FDA action will harmonize existing State and international regulations.

As stated in the proposal (58 FR 393 at 397), the minimum level of 250 ppm TDS for mineral water is based on the apparent consumer expectation that a product identified as ''mineral water'' will contain at least a minimum level of minerals. The agency tentatively concluded that it would be misleading for bottled water that has essentially no minerals, and that does not perform (e.g., taste) like mineral water, to be labeled as mineral water. The minimum level that FDA proposed, 250 ppm TDS, is in agreement with the Association of Food and Drug Officials (AFDO) definition (Ref. 7) for light mineral water and mineral water.

The main characteristic of mineral water is, as its name implies, the presence of a significant quantity of minerals. Other important characteristics (Ref. 8) are that it be from a geologically and physically protected underground water source, and that it contain a constant level of minerals and trace elements at its point of emergence from the source. Mineral water may come from a spring or a well, including an artesian well, but must contain a significant amount of minerals. The agency considers 250 ppm TDS as a significant amount of minerals because at this level, the minerals, depending on the specific mineral content, begin to impart a particular taste to the water. Although minerals may impart some taste below this level, it is not the significant mineral taste that is characteristic of mineral water.

FDA recognizes that mineral water from a spring that contains between 250 and 500 ppm TDS may be identified as ''spring water,'' ''mineral water, low mineral content,'' or both. However, FDA disagrees that the availability of these terms will cause consumer confusion because such a product meets the definitions of both ''mineral water'' and ''spring water'' in § 165.110(a)(2)(iii) and (a)(2)(vi), and both terms appropriately describe the product. As discussed previously (see comment 14 of this document), use of all applicable terms presented prominently on the label in the statement of identity is appropriate because it will ensure the informativeness of the statement of identity.

FDA realizes that brands previously sold as ''mineral water'' that contain less than 250 ppm TDS will not be provided for under § 165.110 as ''mineral water.'' However, the brands mentioned in the comments are not being sold in the United States as mineral water but as other types of bottled water (e.g., spring water) because of the many State requirements that mineral water contain greater than 500 ppm TDS. Thus, although some of these brands cannot be labeled as ''mineral water,'' other brands that previously could not be labeled as ''mineral water'' and sold in some States now meet the definition of ''mineral water'' in § 165.110(a)(2)(iii) and can be labeled and sold as such.

Moreover, the agency has not been persuaded that this regulation will adversely influence consumer sales or put some bottled mineral water producers at a disadvantage as compared to others. The comments did not provide any information on such adverse consequences, and the agency is not aware of these adverse effects.

Therefore, for the reasons discussed above, FDA concludes that establishing a minimum level of TDS in mineral water is reasonable, and that the proposed level of 250 ppm TDS is the appropriate level.

22. One comment remarked that some bottled waters would not significantly differ from a mineral water slightly above the 250 ppm TDS minimum. Another comment stated that if companies wish to market their products on the basis of the mineral content, they can do so through a TDS disclosure statement on the principal display panel regardless of the amount present. Therefore, there would be no need to establish a minimum TDS level for mineral water.

Several comments declared that each mineral water product is unique because of its particular composition of minerals, and that this unique character imparts distinctive flavor. These comments stated that some water products with a constant mineral content of less than 250 ppm TDS might have a distinctive flavor and should be called ''mineral water—very low mineral content'' or ''mineral light.''

Comments also stated that establishing a level of 250 ppm TDS is contrary to the industry's belief that the overall mineral content is less important than the level of each particular mineral.

The agency agrees that some waters that contain slightly less than the 250 ppm TDS minimum would not significantly differ from a mineral water slightly above the minimum. Any minimum level that the agency establishes will preclude some waters from bearing the term ''mineral water'' even though they do not vary significantly from waters that are above the minimum. FDA also agrees that there is a taste aspect to the presence of minerals, although some minerals may contribute a more distinct flavor to the water than others. For example, in sufficient amounts, sodium chloride gives water a salty taste, and sulfate contributes a bitter taste (Ref. 5). In fact,

a common industry practice is to add minerals to some bottled waters for the flavor that they contribute.

However, a minimum requirement for TDS is necessary to ensure that when consumers purchase a product labeled as ''mineral water,'' the product contains minerals at a level that justifies calling the product by that name. As explained in response to the previous comment, that level is 250 ppm TDS. The minimum TDS requirement for mineral water will not preclude a product that contains less than 250 ppm TDS from being marketed under another name, such as ''ground water,'' ''spring water,'' or ''well water,'' as applicable, or from being called ''bottled water.'' In addition, manufacturers may include a truthful statement of the TDS level on the label of any bottled water product. Thus, even though FDA has carefully considered these comments, it concludes that it is appropriate to establish a minimum TDS requirement for ''mineral water.''

23. One comment stated that the definition for ''mineral water'' should include all water containing over 500 ppm TDS and argued that whether it occurs naturally or is constructed (as are other food products) is irrelevant. The comment added that if mineral solids are added, FDA should require that such additions be noted on the label.

Another comment stated that it is essential that the definition be clear that mineral water may not be altered by the addition or deletion of minerals. The comment stated that mineral water should not be water that is derived from a public water supply and to which minerals are then added.

FDA disagrees with the comment that advocated that water to which minerals have been added should be eligible to be called ''mineral water.'' The agency has reviewed a number of State and foreign standards, and none define ''mineral water'' as containing added minerals (Ref. 8). In fact, many of these standards define water with added minerals as a different type of bottled water, distinct from ''mineral water.'' Therefore, the agency concludes that the definition for ''mineral water'' should not be revised to permit the addition of minerals.

The agency agrees with the comment that stated that the addition of minerals should be clearly prohibited in the definition for mineral water. The definition for mineral water has geological as well as compositional factors. The amounts and types of minerals in mineral water is a result of the path that the water has traveled underground. Therefore, to clarify that the minerals present in mineral water must be from the underground source and not added to the water after extraction, FDA is modifying the definition of mineral water in § 165.110(a)(2)(iii) to specifically preclude the addition of minerals.

However, some mineral waters as extracted from their geological source, may contain high levels of some undesirable minerals (e.g., arsenic, precipitated manganese). In some instances, the water can be treated to selectively remove these undesirable elements. FDA is aware of no reason why it should preclude the removal of these undesirable elements, or why such removal should preclude the manufacturer from labeling the product as ''mineral water'' as long as all other requirements (e.g., source and composition) of the definition are met. Section 165.110(a)(2)(iii) provides accordingly.

24. Several comments requested that FDA more precisely define ''mineral water'' in that the agency should require that the level and relative proportions of minerals and trace elements remain constant. Comments stated that such a requirement would harmonize the definition of mineral water with the European Community and Codex concepts. These comments suggested the following definition: ''Mineral water shall be distinguished from other types of water by its constant level and relative proportions of minerals and trace elements, at the point of emergence from the source, due account being taken of the cycles of natural fluctuations.'' One comment added that this wording recognizes that minor natural fluctuations occur with any source water.

Some comments requested that the agency clarify that, in the term ''constant level of minerals,'' the ''level'' is not the characteristic element. They stated that what is fundamental is the ''constancy'' or ''stability'' of the mineral composition, which acts more as a fingerprint of the water rather than as a measure of the overall total dissolved solids content.

One comment stated that all ground water (well or spring) has a constant level of minerals and trace elements as it emerges from the source. The comment questioned the scientific basis of FDA's approach.

The agency agrees that it needs to clarify its definition of mineral water. In the proposal (58 FR 393 at 396), FDA stated that mineral waters may have very different flavors depending on the mineral content and types of minerals and trace elements present in the water. Consumers may purchase a particular mineral water from a particular source because of the flavor contributed by the mineral content. It is important to consumers that the mineral composition of a particular source remain constant. FDA considers that industry and consumers have come to expect that mineral water has a fairly stable mineral composition. Therefore, FDA proposed that mineral water be distinguished from other types of water by the constant level of minerals and trace elements in the water as it emerges from its source.

FDA further notes that the ERCS defines ''natural mineral water'' as being characterized by its content of certain mineral salts and their relative proportions and by the presence of trace elements or other constituents (Ref. 1). The ERCS also states that mineral water is characterized by the constancy of its composition, the stability of its discharge, and its temperature, due account being taken of the cycles of natural fluctuations.

As stated previously, the composition and concentration of substances dissolved in ground water depend on the chemical composition of precipitation, on the biologic and chemical reactions occurring on the land surface and in the soil zone, and on the mineral composition of the aquifers and confining beds through which the water moves (Ref. 5). Thus, under constant conditions, the mineral content of ground water will be constant. There are certain natural factors that may affect the constancy of a source such as occurrence of earthquakes and long term climatic changes. These natural factors do not preclude the water from qualifying as mineral water as long as the water continues to meet the compositional requirements in § 165.110(a)(2)(iii).

Therefore, to clarify the importance of the relative proportion of minerals and trace elements, and to take into account the cycles of natural fluctuations, FDA concludes that modification of the definition of mineral water, along the lines requested by the comments, is appropriate. The modification reflects the fact that there may be some minor variation in mineral water over time, and that absolute amounts of minerals in the water may change slightly. Thus, the agency is modifying § 165.110(a)(2)(iii) to state that mineral water shall be distinguished from other types of water not only by its constant level of minerals and trace elements at the point of emergence from the source, but also by its relative proportions of these substances, due account being taken of the cycles of natural fluctuations. Natural fluctuations in mineral content may occur, but these fluctuations must not affect the relative

proportions of minerals and trace elements. Samples of mineral water can be compared to ensure that major dissolved mineral contents are the same using several scientific methods, such as the Stiff diagram and the Piper trilinear diagram (Ref. 9).

25. Two comments urged FDA to amend the proposed definition for ''mineral water'' to require that if mineral water is taken from a bore hole tapping a spring, it be from the same underground stratum, and be of the same quality and composition, as the water derived from the natural orifice.

The comments seem to be arguing that any product drawn from a spring must meet the requirements for ''spring water.'' However, this is not the case. A product need only meet the requirements for the term used to name it. Thus, a product labeled as ''mineral water'' need only meet the requirements in § 165.110(a)(2)(iii). It need not meet the definition for ''spring water'' unless its label claims that the water is also spring water. If the product were, however, to claim to be ''mineral spring water,'' it must meet the definition of spring water in § 165.110(a)(2)(v) as well as that for ''mineral water.''

26. One comment noted that the proposed definition of mineral water refers to water ''* * * originating from a geologically and physically protected underground water source.'' The comment stated that this phrase appears to be ambiguous and meaningless because there is no indication in the definition of what would constitute protection. It stated that the terminology seems to offer the consumer some assurance of purity that may not be warranted. The comment asserted that every ground water source inherently possesses some degree of geologic and physical protection by the very fact that it is underground. It stated that there are no operational means to differentiate a protected underground water source from an unprotected one.

The agency agrees that every ground water source inherently possesses some degree of geologic and physical protection by the very fact that it is underground. However, some underground water sources are not protected. This lack of protection is evidenced by the fact that some underground sources are under the direct influence of surface water. As discussed earlier (see comment 12 of this document), EPA defines ground water under the direct influence of surface water as any water beneath the surface of the ground with: (1) Significant occurrence of insects or other macroorganisms, algae, or large-diameter pathogens such as *Giardia lamblia*; or (2) significant and relatively rapid shifts in water characteristics such as turbidity, temperature, conductivity, or pH that closely correlate to climatological or surface water conditions (40 CFR 141.2).

The latter part of EPA's definition pertains to changes in the physical characteristics of the water. Changes in these physical characteristics can have a significant influence on the mineral composition of the water. Because the definition of ''mineral water'' is geological as well as compositional, the agency concludes that it is important that ''mineral water'' be from a physically protected underground water source. Mineral water has been traditionally distinguished from other types of water by its constant level, and relative proportions, of minerals and trace elements at the point of emergence from the source, due account being taken of the cycles of natural fluctuations. This distinction is a reflection of the fact that, traditionally, the mineral composition of products labeled as mineral water does not vary significantly over time. Therefore, it is important that mineral water come from a geologically protected underground source, so that the mineral water retains its distinctive mineral content.

FDA does not agree, however, that there are no operational means to differentiate a protected underground water source from an unprotected one. The presence of insects or other macroorganisms as well as changes in physical characteristics are measurable. Thus, regulatory officials can determine whether mineral water is from a geologically and physically protected underground source.

27. One comment stated that the label statement ''mineral water'' will lead some consumers to believe that the food contains a nutritionally significant amount of minerals. It stated that this perception will occur even if the food is labeled ''low mineral content,'' because ''low'' is a relative term and not a quantitative term. Therefore, the comment asserted that all bottled water labeled as ''mineral water'' should also bear nutrition labeling or a statement such as, ''Not a significant source of _____,'' with the blank being filled in with the names of any essential minerals that are missing or present in insignificant amounts.

One comment asked whether the statement of identity for ''mineral water'' or ''mineralized water'' would constitute a health claim and, thus, trigger full nutrition disclosure, even in abbreviated form. Another comment stated that use of the term ''mineral water'' should not require additional nutrition information.

The agency stated in the preamble to the January 1993 proposal (58 FR 393 at 404), that its tentative view was that nutrition labeling should appear on bottled water labeled as ''mineral water, high mineral content'' because consumers may assume that water with a high mineral content would be of nutritional benefit. In addition, mineral water with a high mineral content could contain enough sodium, calcium, or iron to make nutrition labeling mandatory. Under § 101.9, foods that contain more than an insignificant amount of the nutrients or food components that are required to be listed, or whose label, labeling, or advertising contains a nutrient content claim or any other nutrition information, must bear nutrition labeling.

Nutrients likely to be present in bottled water products in amounts that could trigger nutrition labeling are calcium, sodium, and iron. If any of these minerals are present in a product in more than insignificant amounts, nutrition labeling is required under section 403(q) of the act. More than an insignificant amount of calcium is 20 mg or more per labeled serving, more than an insignificant amount of sodium is 5 mg or more per labeled serving, and more than an insignificant amount of iron is 0.36 mg or more per labeled serving (§ 101.9(c)(8)). The reference amount customarily consumed for bottled water is 240 milliliter (mL) (§ 101.12(b)).

The agency has considered whether the term ''mineral water'' is an implied nutrient content claim, and whether, as a result, nutrition labeling should be mandatory on any product labeled as ''mineral water'' regardless of the level of required nutrients. In the Federal Register of January 6, 1993 (58 FR 2302 at 2369), the agency concluded that when an ingredient constitutes essentially 100 percent of the food, so that the name of the ingredient is the statement of identity, the name of the ingredient does not constitute an implied nutrient content claim, even though in other contexts, reference to the ingredient could constitute such a claim (see § 101.65(b)(4)). For example, when the name of the ingredient constitutes the common or usual name of the product, as described in § 102.5 (21 CFR 102.5), or the identity of the commodity, as described in § 101.3 (e.g., ''canola oil''), it is not a nutrient content claim. In such a context, the name of the ingredient does not imply that a nutrient is present in a certain amount, but rather, it describes the nature of the

product. However, the claim ''made only with canola oil'' does characterize the level of a nutrient in the food. This claim represents an implied claim that the food is low in saturated fat (§ 101.65(c)).

The term ''mineral water,'' when used as the statement of identity of the food, does not trigger nutrition labeling because it does not make a representation, either explicit or implied, about the level of nutrients in the food. ''Mineral water'' is simply the name of the food. Although the term ''mineral water'' indicates that the water contains a significant amount of minerals, it does not imply that these minerals are nutrients. In fact, not all of the total dissolved solids in mineral water are nutrients (e.g., bicarbonates). However, labeling claims that imply the presence or absence of any nutrient in bottled water would trigger nutrition labeling.

The major dissolved inorganic constituents of ground water are sodium, magnesium, calcium, chloride, bicarbonate, and sulfate. The total concentration of these major ions comprises more than 90 percent of the TDS in the water (Ref. 9). The presence of 83 ppm calcium or 21 ppm sodium or more will trigger nutrition labeling. Therefore, because mineral water must contain at least 250 ppm TDS, it is likely that many mineral waters, especially high-mineral-content mineral waters, will contain enough calcium or sodium that the labels of these products must bear nutrition labeling.

The agency does not agree with the comment that asserted that consumers will be led to believe that the food is a significant source of minerals if the food is labeled ''low mineral content.'' Use of the term ''low'' does not suggest that minerals are present in a significant amount. The term ''low,'' as used in the statement of identity of the product, is not used in a dietary context. It is simply a qualitative term used as part of the name of the food to describe the food. Thus, use of the term ''low mineral content'' would not indicate that the mineral water was a significant source of minerals.

Therefore, for the reasons discussed above, FDA concludes that consumers will not be misled that mineral water contains more than a nutritionally insignificant amount of minerals, and nutrition labeling of all mineral water is not required.

28. Several comments stated that the product should be labeled as ''inorganic mineral water'' because all minerals found in water are in an inorganic state. They stated that the inorganic minerals found in water are only substances that have been dissolved by the water itself. The comments stated that fruits or vegetables take in inorganic material through their roots to become organic and readily accepted by the body's cells. They stated that not labeling the product as ''inorganic mineral water'' is misleading to consumers. Additionally the comments noted that many of the so-called ''minerals'' found in mineral water are not minerals at all but are in fact inorganic chemicals. They urged FDA to require the label to read: ''Inorganic mineral & inorganic chemical content _____ ppm TDS.''

FDA disagrees with the comment. Minerals by definition are inorganic elements or chemicals in any food (Ref. 10). Thus, the term ''inorganic'' is not a material fact that must be disclosed in labeling mineral water because the term ''mineral'' means that the water contains inorganic chemicals. While the agency recognizes that some minerals that are also nutrients may be more bioavailable in some foods than in mineral water (e.g., calcium in milk), the comments did not provide any data to substantiate their claim that inorganic nutrients taken into plants systemically are more bioavailable than the same nutrients in water.

In regards to a required label statement concerning TDS, as will be discussed later in this final rule, FDA does not require that the TDS appear on the label of any bottled water product, and the comments have not provided substantive grounds to do so. However, firms may include this information on the label of bottled water in a truthful and nonmisleading manner, including in the manner suggested by the comment if the firm so chooses.

3. Purified Water

The agency proposed that water that is produced by distillation, deionization, reverse osmosis, or other suitable processes, and that meets the definition of ''purified water'' in the most recent edition of the USP, can be labeled as ''purified water.'' FDA also proposed that if the water is produced by distillation and meets the USP standard, alternatively it may be called ''distilled water.''

29. Two comments stated that the term ''purified water'' should not be permitted on labels because consumers do not understand its specific meaning and, thus, may be confused by the use of this term. They requested that only the following specific names be permitted on labels in order to give full disclosure to the consumer: ''Distilled water,'' ''reverse osmosis water,'' and ''deionized water.''

FDA disagrees with these comments. The agency proposed that the name ''purified water'' be defined as water that has been processed to meet the requirements of the USP definition for ''purified water.'' An alternative name for water processed by distillation and that meets the USP standard is ''distilled water.'' ''Purified water'' and ''distilled water'' meeting the USP definition have been marketed under these names for many years, and the comments did not provide any evidence that consumers do not understand the meaning of these terms. Therefore, the agency is aware of no basis on which to conclude that these terms will confuse consumers. The agency views this rulemaking as standardizing the use of these terms, not introducing new terms into the market. Manufacturers may include more specific information concerning the method of preparation of these bottled water products on the label. Therefore, the comments have not persuaded the agency to alter its approach to the use of these terms.

However, the agency agrees that the terms ''reverse osmosis water'' and ''deionized water'' are appropriate alternative names for purified water because these terms describe how water is processed to produce purified or distilled water. Therefore, FDA is modifying § 165.110(a)(2)(iv) to provide for the alternative term ''deionized water'' if the water has been processed by deionization, and ''reverse osmosis water'' if the water has been processed by reverse osmosis.

30. Several comments objected to FDA's proposal that ''purified water'' meet the USP definition because: (1) Water for human consumption does not need to be pharmaceutical grade water; (2) USP methods of analyses for bottled water are different from EPA and FDA methods; and (3) the regulation would automatically adopt future updates of the USP, thus, providing the publisher of the USP with lawmaking power without any formal comment or review mechanism. Comments asked that FDA delete any reference to the USP in § 165.110(a)(2)(iv). Some of the comments recommended that FDA establish specific standards for purified water rather than adopt the USP standard by reference.

One comment stated that a standard for purified drinking water should require the use of ''distillation, deionization, reverse osmosis, or other suitable processes'' and impose a water conductivity testing requirement with a conductivity maximum allowable threshold level of 30 microsiemen per centimeter. It stated that the conductivity test, which would measure

the ionic strength of water based on a customarily used reverse osmosis system, would verify the purification process. Another comment stated that ''purified water'' should only be required to meet the current USP requirements for total solids, pH, and chloride.

FDA is persuaded by the comments that the definition of purified water should not be bound ''to the most recent'' USP standard as it proposed to do. However, the agency does conclude that the definition should use the USP standard because purified water meeting this standard has been sold for years and is an established product. Although water for human consumption does not need to be pharmaceutical grade, water that is labeled as ''purified water'' should meet stricter standards than other types of bottled water because the term ''purified'' asserts that the product has been processed to be of a purer quality than other types of water. Therefore, requiring that ''purified water'' meet a USP definition ensures that the water meets a stricter standard than other types of bottled water.

FDA recognizes that it would be a burden for manufacturers producing purified water and other types of bottled water to have to use different methods of analysis (USP and EPA) to test for the same contaminant. Bottlers may use EPA methods to test their purified water, although the agency notes that it will use USP methods to check for compliance. However, FDA points out that most of the USP methods do not provide a numerical water quality requirement that would parallel EPA methods but instead require testing with a positive or negative result. Thus, the methods may not be easily interchangeable.

FDA concludes that the requirement should remain as proposed because the term ''purified water'' explicitly asserts that the water has been purified, and the USP definition is a commonly used standard for what constitutes purification. This common use is evidenced by the fact that AFDO's definition of ''purified water'' is the USP definition (Ref. 7). However, FDA agrees that interested persons should have an opportunity to comment on any proposed change in the standard of identity for purified water. Therefore, FDA is referencing a specific edition of the USP monograph in the definition of ''purified water'' (§ 165.110(a)(2)(iv)). The agency is defining ''purified water'' as water that has been produced by distillation, deionization, reverse osmosis, or other suitable processes and that meets the definition of purified water in the USP, 23d Revision.

The agency notes that the USP is in the process of updating its monograph for purified water. One such revision may be a water conductivity test requirement as mentioned by one of the comments. As modifications are made to the USP definition, FDA will consider amending its definition for purified water to reflect the modification.

The agency notes that any bottled water that is labeled as ''purified water, USP,'' or that indicates in any manner that the product meets USP specifications, must, in addition to complying with FDA regulations, meet the most recent USP standard, or the product will be misbranded under section 403(a)(1) of the act in that its labeling will be false in this particular.

31. One comment asked that FDA explicitly designate the product as ''purified drinking water'' and, as a food product, differentiate it from ''purified water, USP'' usable for pharmaceutical purposes. The comment stated that a change in nomenclature from ''purified water'' to ''purified drinking water'' would reduce any potential for confusion between purified water that is suitable for use in preparation of compendial dosage forms and purified drinking water for potable purposes. It stated that the qualification would make clear to the public that products labeled as ''purified drinking water'' are not represented as, and do not purport to be, in compliance with the USP monograph for ''purified water.''

The agency disagrees that the term ''purified water'' should be replaced by ''purified drinking water'' in the standard of identity. Many products that are currently being sold as ''purified water'' for drinking purposes meet the USP definition for ''purified water,'' and FDA is not aware of any evidence of public confusion. Thus, FDA concludes that ''purified water'' remains an appropriate name.

However, ''purified drinking water'' and ''distilled drinking water'' are appropriate alternative names for the product because these names will enable consumers to identify the product as water for drinking purposes that has been processed to meet stricter purity standards. Therefore, FDA is modifying § 165.110(a)(2)(iv) to provide for alternative terms that describe the product as a type of drinking water (e.g., ''purified drinking water'').

32. One comment recommended that FDA establish a definition for ''demineralized water'' as follows: ''The name of water demineralized by distillation, reverse osmosis, or other method so that it contains not more than 10 ppm TDS may be 'demineralized water.' ''

The agency agrees that ''demineralized water'' is an appropriate name for water that has been processed to significantly decrease its mineral content. However, FDA concludes that there is no need to establish a separate definition for ''demineralized water'' because the USP definition for ''purified water'' encompasses water that has been demineralized by distillation, reverse osmosis, or other method and that contains not more than 10 ppm TDS. Therefore, the agency is including the term ''demineralized water'' as an alternative name for ''purified water'' in § 165.110(a)(2)(iv).

33. One comment recommended the establishment of a heterotrophic bacteria standard for purified water. It stated that, although the health risks from such bacteria may be small, a higher expectation exists for a product labeled as ''purified'' than for other bottled water products. The comment stated that purified water is purchased by immunosuppressed individuals, contact lens wearers, mothers of small infants, laboratories, and others with an expectation of purity from general bacteria. The comment recommended a limit of no more than 500 bacteria per milliliter for purified water because this standard will limit the suppression of coliform detection and reduce the exposure and dosage level for organisms that might have a health effect on at-risk groups. The comment also recommended that, if FDA does not establish a general bacteria standard for ''purified water,'' the agency substitute the name ''demineralized water'' for ''purified water'' so as not to mislead consumers.

FDA disagrees with the comment. Traditionally, water that is essentially free of chemical impurities is called ''purified water,'' and water that is free of microorganisms is called ''sterile'' or ''sterilized water.'' This distinction is evidenced by the fact that there are USP monographs for ''sterile water'' and for ''purified water'' that distinguish between the two types of water (Ref. 6). Thus, the labeling of a product as ''purified water'' does not imply that it is sterile water.

USP has established a general guideline for purified water for pharmaceutical purposes of 100 colony-forming units per mL. This level evidences that the water has been treated appropriately, even though bacteria are present at low levels. Purified water that has been treated by distillation or reverse osmosis may be sterile if appropriately processed. However, the agency points out that

purified water is typically low in the nutrients required by microorganisms for growth, and, thus, ordinarily has low bacterial counts. Adherence to the regulations in part 129 significantly reduces the risk of contamination. Therefore, ''purified water,'' if appropriately processed as required by part 129, should contain less than the comment's requested 500 bacteria per mL. The agency consequently concludes that the establishment of a bacterial standard for ''purified water'' is not necessary.

The agency is defining ''sterile water'' in this final rule. Use of this term in the statement of identity of qualifying bottled waters will allow consumers desiring to purchase water that is bacteriologically pure to easily identify this type of water and to distinguish it from purified water that is chemically pure.

4. Spring Water

FDA proposed that bottled water derived from an underground formation from which water flows naturally to the surface of the earth, or would flow naturally to the surface of the earth if not for its collection below the earth's surface, may be called ''spring water.'' The agency proposed to provide for the collection of spring water only at the spring or through a bore hole adjacent to the point of emergence. FDA also proposed that spring water collected with the assistance of a bore hole to protect the water shall be from the same underground stratum as the spring and shall retain all the physical properties and be of the same composition and quality as the water that flows naturally to the surface of the earth or that would flow naturally to the surface of the earth if not for its collection below the earth's surface. FDA requested comments from interested persons concerning the definition for ''spring water'' and on the use of a bore hole adjacent to the point of emergence of the spring to facilitate collection of the water.

a. Consumer Surveys

34. Two comments included consumer telephone surveys, each conducted by a different bottled water producer, that addressed issues of consumer understanding and preferences for bottled water labeled as ''spring water.'' A number of subsequent comments pointed to methodological shortcomings in one or the other of the two consumer surveys, including inadequate sample size, nonrepresentative sampling, ambiguous and biased question wording, failure to counterbalance order of questions, improper survey approach, and flawed interpretations of results.

The agency recognizes that such problems exist to some extent in both studies, as they do in virtually all survey studies, but it is not convinced that there is sufficient basis for dismissing the results of these studies. Each study has some merit, and there is a surprising degree of agreement between the two studies in their primary findings. Therefore, FDA finds that both studies provide useful information concerning consumer opinions on spring water, and that it is appropriate to use this information in arriving at a definition for ''spring water.''

35. The principal concern of both surveys, and the primary subject of comments about the respective survey results, was an attempt to describe consumer understanding of the use of the term ''spring water'' with respect to the method of extraction, bore hole or surface collection, used to obtain the water. In study 1 (C302 in this docket), respondents were asked about which extraction method they would expect would be used to collect a product called ''spring water.'' In study 2 (MM5 in this docket), respondents were asked which extraction method is used to collect ''spring water.''

Many comments criticized one or the other of the studies for the way the different methods of extraction (borehole or surface collection) were described to respondents, usually alleging that the wording introduced a bias in respondents' answers. In study 1, for example, surface extraction was described as ''water that flows naturally to the surface,'' and bore hole extraction was described as ''water pumped * * * through a bore hole.'' In study 2, surface extraction was described as ''water taken from springs whose water is captured above ground level,'' and bore hole extraction was described as ''water taken from springs whose water is captured below ground level.''

FDA agrees that biases were introduced by the wording of these questions. However, despite the difficulties in communicating to consumers about methods of extraction for spring water in a telephone survey, the results of both surveys show that there is considerable uncertainty among consumers about which extraction method is or should be used for spring water.

Study 1 asks the question, ''When you see spring water on the label of a bottle, which of the following describes the water you would expect to be in the bottle?'' in a forced-choice form such that ''not sure'' answers are not allowed. Although 54 percent of respondents responded that the water naturally flows to the surface, 46 percent of respondents expressed the possibility that spring water was extracted from a bore hole. In addition, even though the question context strongly encouraged selecting one or the other of the alternatives provided, 34 percent of respondents choose to answer ''either of the above'' when asked which extraction method they would expect for spring water. FDA considers this level of response to the ''either of the above'' alternative to indicate considerable consumer uncertainty. Because of the observed uncertainty, the study documents that there is no consensus among consumers about how spring water is or should be extracted.

In study 2, a ''not sure'' alternative was allowed for each of the two yes/no questions, ''Is bottled spring water taken from springs whose water is captured above the ground level?'' and ''Is bottled spring water taken from springs whose water is captured below the ground level?'' Forty one percent of respondents answered ''not sure'' to both questions, and an additional 13 percent answered ''not sure'' to one of the two questions. These responses mean that, overall, 54 percent of respondents indicated that they were not sure about the extraction methods used for bottled spring water.

Given the high levels of consumer uncertainty about extraction methods used for bottled water that were found in both studies, FDA concludes that the issue of how spring water is or should be extracted is not an issue to which many consumers have given much thought. At the same time, however, FDA considers the finding that consumers have limited opinions about the extraction methods used for bottled spring water to be very relevant to its objective of developing bottled water definitions that promote honesty and fair dealing in the marketplace. The fact that consumers do not appear to be informed or concerned about issues related to the extraction methods used for spring water suggests that FDA has little reason to suggest major changes in the usage of the ''spring water'' designation on bottled water on the grounds of promoting honesty and fair dealing in the marketplace. Currently, as many comments stated, spring water products on the market are produced using both methods of extraction. In addition, most State and international definitions provide for both methods of extraction for spring water (Comment 91 and Refs. 2, 7, 11, 12). Thus, FDA concludes that the use of the term ''spring water'' does not imply a particular extraction method, and that

providing for the use of either surface or bore hole collection of spring water will not mislead consumers.

36. A number of comments cited survey results indicating that consumers perceive that spring water has a higher quality and a better taste than other kinds of bottled water, and that, therefore, consumers are more likely to buy it. They argued that, because spring water has greater consumer appeal, it is incumbent on FDA to ensure that the definition of spring water is not misleading to consumers.

FDA agrees with these comments and with the conclusion, based mainly on Study 1 findings, that consumers consider bottled water labeled as spring water to be of a higher quality than other kinds of bottled water. FDA notes, however, that the favorable state of consumer opinion toward spring water has developed under circumstances in the marketplace in which the term ''spring water'' has been used to describe both water extracted at the surface and water extracted by the bore hole method. Given that it has been extracted in both ways, with apparent consumer satisfaction, how the water is extracted does not appear to be the key factor.

There is a second aspect of the definition of ''spring water''—from where the water comes. By the process of elimination, this factor appears to be key. Thus, it is this aspect of the definition that FDA has made most rigorous.

FDA concludes, therefore, that its requirement in § 165.110(a)(2)(vi) that bottled water labeled as ''spring water'' be from the same underground stratum as the spring and always have the same physical properties, composition, and quality as water that flows naturally to the surface of the earth, without specifying a necessary method of extraction, will provide appropriate protection against use of the term to mislead consumers about quality characteristics of bottled water.

37. A number of comments, based principally on Study 2 findings, argued that safety considerations were the primary consumer concerns about bottled water, that FDA should take these concerns into account when deciding on the appropriate definition of ''spring water,'' and that these concerns provided a sufficient basis for including water obtained by bore hole extraction in the definition of ''spring water.''

FDA agrees that safety considerations are important in the regulation of bottled water. However, the agency does not generally view the standard of identity for a product as the means to ensure its safety. FDA stated in the proposed rule (58 FR 393) that it was developing definitions for types of bottled water to ensure honesty and fair dealing in the interest of consumers, and this remains the agency's basic purpose for defining these terms.

FDA has established quality standards for bottled water to satisfy consumer expectations that bottled water will be of appropriate quality. To be of appropriate quality, the water must be safe. Thus, the quality standard sets maximum levels that are well within safe levels for a number of water contaminants. FDA has also adopted a good manufacturing practice (GMP) regulation for bottled water to ensure that bottled drinking water is processed, bottled, held, and transported under sanitary conditions that will not render the product injurious to health. Thus, regardless of the extraction method used to obtain bottled water, the water will be safe.

For these reasons, FDA does not see consumers' concerns about safety as a particular reason for including water that is obtained by bore hole extraction in the definition of ''spring water.'' FDA is including water obtained in this way in the definition because, as explained above, bore hole collection of spring water is a common industry practice, and consumers are not misled by the use of this collection method. The key to the definition, as FDA stated in response to comment 36 of this document is from where the water comes.

b. Use of a Bore Hole

38. A number of comments objected to a definition of ''spring water'' that would allow the use of a bore hole to collect the water. Comments stated that the definition would allow ''well water'' or ''bore hole water'' to be labeled as ''spring water.'' Comments requested that the reference to bore hole extraction be deleted from the proposed regulation because the water is not ''spring water.''

Some comments stated that ground water derived by the use of bore holes is not compatible with the geological definition of a spring and should not be permitted to be labeled as ''spring water.'' One of the comments added that the proposed definition is inaccurate and does not represent the common usage of this term by professional hydrogeologists, professional ground water hydrologists, or the general public. It stated that springs are naturally occurring discharges or flows of ground water that occur at the land surface.

On the other hand, a number of comments argued that water extracted through the use of a bore hole should be eligible to be called ''spring water.'' Comments stated that a bore hole is a preferred method of spring water collection, and that inclusion of this method of collection in the definition of ''spring water'' would provide flexibility to manufacturers. One comment from a hydrogeologist stated that the use of bore hole collection methods is widely recognized throughout the United States and the rest of the world as a safe, convenient, sanitary, and reliable method for intercepting spring water before it emerges to the earth's surface, where it can be exposed to sources of pollution or alteration.

A number of comments noted that the use of bore holes has long been recognized in this country, Canada, Europe, and elsewhere as a preferred and sometimes necessary method for extracting spring water. Comments stated that bore hole collection of spring water is practiced exclusively in Europe and many other parts of the world for sanitary reasons. Comments added that the proposed definition recognizes that over 50 percent of the water used in domestic spring water production is currently collected through the use of a bore hole, and that the definition provides a consistent standard of identity regardless of the technology used for extraction and collection.

One comment stated that some advance the view that spring water collected at the surface is natural because its collection involves no physical or technological intervention into, or development of, the spring source or of the water, and that subsurface collection of spring water is not natural because it involves extraction and piping through a bore hole, which means that the finished product is produced through physical alteration of, and intervention into, the source. The comment said that this view is misleading because even when spring water is collected at the surface, piping must be used, a bore must be drilled, and technology must be employed in the collection process. The comment said that frequently, physical alteration of the natural orifice also must be undertaken.

The agency has decided to adopt the proposed definition of ''spring water'' as water that is derived from an underground formation from which water flows naturally to the surface of the earth. FDA has also decided to provide that ''spring water'' may be collected below the earth's surface through a bore hole. As previously discussed in response to comment 35 in this final rule, consumers do not necessarily believe that spring water is

collected at the surface of the earth. In addition, over half of the spring water sold in the United States is extracted through a bore hole. Therefore, the agency has concluded that providing for the use of a bore hole in addition to surface collection will permit production flexibility without interfering with established consumer understanding or expectations in any way.

FDA recognizes that some geologists and hydrogeologists disagree with the use of a bore hole in the collection of spring water. However, FDA finds that as long as the physical properties, composition, and quality of the water that is captured by a bore hole are the same as those of the water from the same underground formation that flows to the surface, it is appropriate to label the water as spring water. If the use of a bore hole does not change the characteristics of that water, then the bore hole is only tapping the underground water source that feeds the spring. However, if the water collected through the bore hole has different characteristics from the water emerging from the spring orifice, the water is not spring water. To clarify that the source of the water must be the same underground formation, the agency is adding a provision to § 165.110(a)(2)(vi) that the bore hole collection of spring water must be through a bore hole tapping the underground formation feeding the spring.

A spring is a natural flow of water from the earth (Ref. 13). An aquifer is a porous rock stratum that yields water in a usable quantity to a well or spring (Ref. 5). A stratum is a single layer of rock. Spring water is water that emerges from the spring orifice or water from the stratum that feeds the spring. Scientific field methods can demonstrate that water that emerges from a spring and water from an adjacent bore hole are from the same underground source. Geochemical methods may be used to demonstrate that water extracted from a spring and water extracted from an adjacent bore hole are of the same chemical quality.

FDA agrees that there must be appropriate development of an approved source, whether the water is to be collected at the natural orifice or with the use of a bore hole. Both methods of collection require careful engineering for proper water collection. A source must be appropriately developed, in accordance with the GMP's in part 129, to qualify as an approved source. Under § 129.3(a), an approved source is one that has been inspected by the State and local government agencies having jurisdiction. Under § 129.35(a)(1), the source must be properly located, protected, and operated and be easily accessible and adequate.

In summary, FDA finds that water that is collected by use of a bore hole tapping the underground stratum of a spring is appropriately included in the definition of ''spring water'' in § 165.110(a)(2)(vi), as long as the source of the water is the same no matter which method of collection is used, and the method of collection does not interfere with the quality or composition of the water.

39. Comments contended that this rulemaking is being orchestrated by parties who will profit from being able to legally increase their production of spring water by using pumping mechanisms. One comment stated that the reason that anyone would bore a well next to a spring is because the flow of water from the spring has decreased. Another comment added that the bottled water industry wants a loophole that would allow companies to call their well water by the better perceived term ''spring water.''

One comment stated that to allow ''spring water'' to be collected through a bore hole that is adjacent to the point of emergence is being less than honest with consumers. This comment maintained that allowing this practice only serves the interest of a special segment of the bottled water industry. The comment stated that when bore holes have to be qualified to determine whether they are adjacent to the spring and to determine whether the water is from the same underground stratum, and has all the same physical properties, composition, and quality, as the water emerging at the surface, then fair dealing will be lost in the many ways that these provisions will be interpreted.

Conversely, a comment that supported the use of a bore hole stated that adoption of the standard as proposed would protect consumers against artificial barriers to commerce and restraints on competition that ultimately raise consumer prices and reduce product quality. Another comment stated that the controversy about the use of a bore hole stems partly from a lack of understanding of practices accepted around the world and partly by small companies striving to use regulations for competitive advantages.

One comment asserted that differentiating between the same water, whether it comes from a natural orifice or from a bore hole tapping an aquifer, is an artificial marketing difference.

Some comments stated that if the definition of ''spring water'' were to preclude the use of bore holes, many smaller companies would be constrained from expanding their businesses. These comments added that as long as the water is compositionally identical, the method of extraction is a production matter and should not be a factor in classifying the water.

The agency disagrees with the comment that stated that consumer interests would be compromised by providing for the use of a bore hole in the definition of spring water. As discussed in the response to comment 35 in this document, many consumers have not formed opinions concerning an appropriate method of extraction of spring water, and, based on information from the consumer surveys and other comments received, FDA has concluded that consumers are not misled because of the use of a bore hole.

FDA also disagrees that its position only serves the interest of a special segment of the bottled water industry. Currently, as stated by many comments, over half of the spring water produced in the United States is collected through bore holes. Not providing for the use of a bore hole in the definition of spring water would thus force a significant segment of the industry to relabel their products as other types of bottled water products. Given that most consumers are not concerned about whether a bore hole or a spring collection box is used, and that FDA can control the source of the water and its composition and quality by means of its standard, the agency advises that it is not aware of any factor that compels such a result.

In addition, the agency disagrees that its definition will provide a loophole to allow water that is not spring water to be called ''spring water,'' with certain parties profiting from a broadened definition. FDA's definition is no broader than the definition used by most States, most notably the major bottled water-producing States of New York, California, Texas, and Florida. These States already provide for the use of a bore hole, although the State of North Carolina has a stricter definition for ''spring water.'' Many foreign governments have even broader definitions for ''spring water'' than is provided by FDA's definition. For example, the government of the province of Quebec defines ''spring water'' as ground water containing greater than 10 ppm TDS and less than 500 ppm TDS, regardless of whether the water flowed to the surface of the earth or was collected through a well. Therefore, FDA concludes that its definition will not create a loophole to

market water that is not spring water. FDA's definition is generally consistent with worldwide industry practice and most government regulations. Thus, if anything, FDA's definition will help to eliminate artificial barriers to competition and commerce.

Although how the determination of whether a bore hole actually is tapping a spring is made may vary because of regional geological differences (e.g., limestone formations versus granite formations), the water collected from a bore hole must be the same water that feeds the spring's natural orifice. To be called ''spring water,'' the water must be from a stream that flows naturally to the surface of the earth. No matter what method of extraction is used, the water must have the same physical properties, quality, and composition as the water that actually flows to the surface.

The agency recognizes that there is the possibility of a bore hole extracting water from an aquifer that does not feed the spring. However, the agency is requiring in § 165.110(a)(2)(vi) that the water be from the same underground stratum, retain all the physical properties, and be of the same composition and quality as the water that flows naturally to the surface of the earth. Water from a different underground stratum will have different properties and characteristics. Thus, the water will not meet the definition of spring water unless it has the same properties and characteristics as the water that flows through the spring's natural orifice. Therefore, § 165.110(a)(2)(vi) will protect against the possibility of a bore hole extracting water that does not feed the spring.

40. Comments noted that a domestically produced beer that is identical to a German beer could not be called German beer because it does not come from Germany. They stated that, similarly, spring water must come from a spring, not a bore hole.

Another comment maintained that under the law, ''the public is entitled to get what it chooses, though the choice may be dictated by caprice or by fashion or perhaps by ignorance'' (*F.T.C.* v. *Algoma Lumber Co.*, 291 U.S. 67, 79 (1934)). It concluded that bottlers should not be allowed to tell consumers that a product is spring water when it actually comes from a bore hole.

The agency disagrees with the comments. In the example of the German beer, FDA recognizes that a German source does indeed make the product a German beer, and that if the beer was not produced in Germany the product would not be German beer. However, in the case of spring water, the underground source of the water, that is, the spring, will be the same whether collected at the surface or through use of a bore hole. It is only the method of extraction that is different. Therefore, water that is from an underground formation from which water flows to the surface, and that has the same physical properties, quality, and composition as the water that flows to the surface, is fairly and appropriately considered to be spring water even if it is extracted by use of a bore hole.

41. Several comments stated that natural spring water is free flowing, and that if a bore hole is used by a bottler, it should be so noted on the label to allow consumers to make the ultimate decision on this issue.

Other comments suggested that to differentiate between spring water that is naturally flowing and spring water that is collected from a bore hole, FDA should define ''natural spring water'' as water that is derived from an underground formation from which water flows naturally to the surface of the earth and ''spring water'' as water derived from an underground source from which water flows naturally or through a bore hole adjacent to the point of emergence. One comment added that to not differentiate between ''natural spring'' and ''spring'' waters would be to perpetuate a fraud.

The agency disagrees with the comments. As defined in § 165.110(a)(2)(vi), the underground source of ''spring water'' must be the same whether it is extracted from the natural orifice or from a bore hole. In addition, as shown by the submitted surveys, many consumers did not object to the use of a bore hole to extract spring water. Therefore, it is not necessary to establish mandatory labeling regulations to distinguish between spring water extracted through a bore hole or through the natural orifice. However, FDA would not object to a truthful, nonmisleading statement on the label that stated that the water flowed naturally to the surface, if indeed the water was extracted from the natural orifice without the use of external force, or to a statement that the water was extracted through a bore hole.

42. One comment suggested that bore hole-collected water more clearly fits the definition of ''artesian well water.'' It stated that FDA defined the other types of water with their proper historic geologic definitions, and that spring water should also be defined in this manner.

The agency disagrees that spring water collected from a bore hole more clearly meets the definition of ''artesian water.'' The definition for ''spring water'' mandates that the water come from an underground source where water flows naturally to the earth's surface before the drilling of a bore hole. Artesian water comes from a well tapping a confined aquifer. Artesian water does not flow to the earth's surface unless a well is drilled to tap the source, and the natural hydraulic pressure is great enough to force the water to the earth's surface. Therefore, spring water and artesian water are from distinct sources. However, to clearly distinguish between the definitions of ''artesian water'' and ''spring water,'' FDA is modifying § 165.110(a)(2)(vi) to state that there must be a natural force causing the water to flow to the surface through a natural orifice for the water to be labeled as ''spring water.''

c. Adjacency

43. Some comments asked how one could be assured that water collected through a bore hole would have emerged from the ground through a free-flowing spring at a point adjacent to the bore hole had it not been extracted through the bore hole.

Several comments suggested that FDA incorporate a requirement for hydrogeological data to demonstrate a hydraulic link between a bore hole and a spring to document that the source is a spring. One comment added that the spring water definition will not resolve the matter of whether a bore hole is adjacent to a spring unless scientific support for the term ''adjacent'' is presented.

Some comments suggested specific methods to determine the hydraulic linkage. These included using dye tracer tests, geophysical conductivity tests, water analyses, and graphical methods, such as the Stiff diagram and the Piper trilinear diagram, to demonstrate that the chemical and physical characteristics of the water correspond to those of the spring. Comments stated that pumping should cause a measurable decline in the spring's discharge rate if the well is tapping spring water, although if the withdrawal rate from the bore hole is small relative to the discharge rate of the spring, or if the spring is submerged, this decline may not be measurable.

The comments stated that because of the differences in the mineral composition of geological strata, no one set of analyses will apply to all spring formations to demonstrate compliance with these criteria.

Some comments suggested that the criterion of adjacency used in the hydrogeological context of hydraulic connection is reasonable and logical and objectively addresses this important and

controversial issue. They requested that language be added to the regulation to require that bore hole adjacency to the spring be verified by its measurable hydraulic influence on the spring flow from the natural orifice at the time of collection, as certified by a professional hydrogeologist.

However, some comments asserted that it will be difficult to establish the uniformity or sameness of actual spring water and water collected through an adjacent bore hole.

The agency agrees that hydraulic linkage is important in the definition of ''spring water.'' If the bore hole taps the same underground water source as that which feeds the natural spring, and has the same physical properties, composition, and quality as the water emerging from the natural orifice, it is clear that the location of the bore hole relative to that of the point of emergence is not relevant. However, a bore hole adjacent to a natural emergence can actually tap another water bed far below the aquifer feeding the natural spring source and thus collect water of a totally different composition from that of the water which emerges from the natural spring.

The agency concludes that requiring a hydraulic (i.e., physical) connection between a bore hole and a spring will clarify the definition of spring water and will eliminate the possibility of indiscriminate bore hole use. Therefore, FDA is modifying its definition of ''spring water'' in § 165.110(a)(2)(vi) to require that a measurable hydraulic connection, using a hydrogeologically valid method, between the bore hole and the natural spring be established to show that the water is from the same underground stratum as the spring.

The comments suggested several different methods to determine hydraulic linkage. One or more hydrogeologically valid methods may be used as appropriate to determine hydraulic linkage. However, not all methods may be appropriate for different geologic regions or for the specific bore hole site. Therefore, the agency is not recommending or requiring any specific method or methods.

44. Some comments stated that the location of the bore hole relative to that of the point of emergence is not relevant as long as the bore hole taps the same underground water source as that that feeds, or that would feed, the natural spring if not for the collection below the earth's surface. Other comments objected to the use of the word ''adjacent'' in the definition because they believe that it is ambiguous. Comments suggested that the agency modify the definition for ''spring water'' to delete the use of the term ''adjacent.'' One comment added that such a definition would be easier to enforce and would eliminate the need to arbitrarily decide what ''adjacent'' means in terms of a measurable distance.

Conversely, one comment stated that if bore hole access is permitted in the final definition of ''spring water,'' then it is crucial to retain the requirement that the bore hole be adjacent or near to the point of natural emergence of the spring. The comment stated that this requirement is necessary to assure that the bore hole is tapping only water that would otherwise emerge at that point, and that consumers are not misled that they are purchasing spring water from a specifically identified spring source.

The agency agrees with the comments that suggested that the term ''adjacent'' be deleted from the definition of spring water. As discussed in the previous comment, the agency is requiring that there be a measurable hydraulic connection, using a hydrogeologically valid method, between the bore hole and the natural spring established to show that the water is from the same underground stratum as the spring. To meet the definition of ''spring water,'' the manufacturer must ensure that the water collected through a bore hole is from the same underground stratum as the spring and has the same physical properties, composition, and quality as the water that flows naturally to the surface of the earth from the spring. Water collected at a distance from the natural orifice will not have traveled the same path as the water that flows from the natural orifice of the spring and, therefore, could have a different composition. FDA is accommodating the use of bore hole technology so long as there is assurance that the water from the bore hole has the same composition and characteristics as the water from the natural orifice. If the bore hole is too far from the natural orifice, the latter assurance would not exist.

FDA concludes that the requirement of a measurable hydraulic connection between the bore hole and the spring's natural orifice adequately encompasses the intent of the proposed adjacency requirement. Therefore, the agency is deleting the requirement in § 165.110(a)(2)(vi) that the bore hole be adjacent to the point of emergence of a spring.

45. A number of comments asked FDA to explain or define the terms ''adjacent'' and ''point of emergence.'' Comments requested that FDA designate a specific distance (e.g., 50 feet, 100 feet, 250 feet, 1 mile) for how far bore holes could be located from the source and still meet the criterion of ''adjacent to the point of emergence.'' One comment suggested that a person should be able to see the spring and bore hole at the same time. Some comments held that the rule should specify that the bore hole must be as close as possible to a specifically identified spring discharge, and that the bore hole must be closer to the spring discharge than to any other source of ground or surface water.

One comment stated that the State of California informally defines ''adjacent'' as a distance of approximately 250 feet. It stated that this definition avoids cases of confusion, such as the installation of spring bore holes several miles from the spring location. Other comments stated that some States have used a ballpark figure of 200 feet for adjacent, others more or less than 200 feet.

Another comment stated that the reasoning provided in the preamble of the proposal necessitates a relatively narrow interpretation of ''adjacent'' as a point located a minimal distance from the spring orifice and asked that a statement to this effect be included in the regulation.

In the preamble of the January 1993 proposal (58 FR 393 at 399), FDA stated that allowing for a bore hole adjacent to a spring would provide for the tapping of the source at a point near the mouth of the spring. The agency is not specifying a particular distance between a bore hole and the mouth of the spring because the appropriate distance will vary significantly in different geological areas. FDA is also not adopting a requirement that a person be able to see the spring and bore hole at the same time because, depending on the terrain, a person may be able to see a great distance or only a small distance. Therefore, FDA finds that defining ''adjacent'' in these terms would not be appropriate. As discussed in the previous comment, the agency is defining adjacency in terms of a measurable hydraulic connection.

FDA agrees that the collection apparatus should be as close as possible to the specifically identified spring discharge. The agency also agrees that the bore hole should normally be closer to the spring discharge than to any other source of ground or surface water. However, the agency does not agree that this distance need be specified in the regulation because it is requiring that a measurable hydraulic connection, using a hydrogeologically valid method, between the bore hole and the natural spring be established to show that the water is from the same underground stratum as the spring (§ 165.110(a)(2)(vi)). The agency

concludes that the requirement for a hydraulic connection is appropriate and avoids uncertainty concerning any specific distance implied by the term ''adjacent.''

46. Comments requested that FDA address the issues of ownership and control in the regulations. Comments questioned whether proper inspections could be mandated in a case where a spring is located on one owner's property, and the bore hole is on another's property. One comment stated that the ownership and control of the bore hole should be the same as that of the spring for quality control purposes. One comment stated that, if a company owns, or owns the rights to, a legitimate spring, it should not matter how it collects the water as long as it does so in a sanitary way.

The issues raised by these comments are outside the scope of this rulemaking and really beyond the coverage of the act. Issues of ownership and control turn on property laws, water rights, and access to the spring's natural orifice. However, FDA cautions that a manufacturer must be able to test the water that flows naturally to the surface of the earth to ensure that the water that it is collecting from the bore hole is the same water as that from the spring that flows to the surface, and that there is a hydraulic connection between the bore hole and the natural spring. If the manufacturer cannot establish that the water that it is calling ''spring water'' is the same as that from the identified spring, it runs a significant risk that its product is misbranded, and, thus, that it will be the subject of a regulatory action.

d. External Force

47. Several comments objected to the use of external force in the collection of spring water. One of the comments stated that consumers believe that spring water has no unique taste, color, or other characteristic other than being water that comes to the surface through a natural orifice, and that most believe that the water flowed to the surface by the spring's natural pressure. Comments stated that to furnish other than a natural flow rate by supplemental pressure is misleading, and that such a product should be labeled as ''well water.''

Comments stated that the use of a bore hole is appropriate only if external force is not used. One comment stated that the freely flowing water from a natural spring site represents the overflow of the underlying aquifer, and that, by contrast, pumped water from a vertical well of arbitrary depth may tap many hydrogeologic layers, drawing against the storage of the aquifer. The comment asserted that some trace of the natural flow should be visible at the original spring orifice.

One comment stated that some of the problems associated with pumped wells are: (1) The cone of depression caused by pumping an unconfined aquifer triggers a series of changes in the ground water and aquifer; (2) dewatering the aquifer around a well allows air intrusion into the formation voids, which can oxidize iron and other metals resulting in reduced water storage capacity, thereby increasing the size of the cone of depression; (3) pumping from an aquifer that yields water to a spring can induce recharge from neighboring hydrogeologic units that are not normally hydraulically connected to the spring; and (4) pumping an aquifer causes changes in flow velocity and direction of flow and creates turbulence.

The agency does not agree that the use of external force should be prohibited for the extraction of spring water. Although there must be a natural force that causes at least some of the water to flow to the surface through a natural orifice, this force may not be sufficient to cause the water to flow through some bore holes. The angle and the distance of the bore hole from the mouth of the spring may not provide adequate water pressure for the water to flow through the bore hole.

It is true, as described by the comment, that changes may occur in the underground strata as a result of pumping. The creation of a cone of depression, changes in water flow, and the nature of the recharge can alter the composition of the ground water. However, if the properties of the water change as a result of the use of external force, the water is no longer spring water because the water is no longer the same water that flows through the natural spring orifice. If pumping action alters the properties of the water, pumping will have to cease, and the area allowed to return to its natural equilibrium, so that water collected from the bore hole with the aid of external force will once again have the same properties as the water flowing from the natural spring orifice. If not, while pumping may continue, the water can no longer be labeled as ''spring water.''

Finally, the agency points out, in response to one comment, that if water is pumped from a vertical bore hole of any depth that taps other hydrologic strata, that water is not spring water.

FDA concludes that the use of external force in the collection of spring water is not misleading to consumers because the agency is requiring in § 165.110(a)(2)(vi) that the water be derived from an underground formation from which water flows naturally to the surface of the earth; that the water have the same physical properties, composition, and quality as the water that emerges from the natural orifice; and that there be a hydraulic connection between the bore hole and the spring stratum. Thus, the agency concludes that the definition will ensure that water labeled as ''spring water'' meets consumers' expectations.

48. Three comments stated that FDA should require that the spring continue to flow to the surface naturally. They stated that if the spring ceases to flow for a period of 90 days, then the water from the bore hole should no longer be considered to be spring water, and any labeling of the product as such must cease. One of the comments stated that such a requirement would help to ensure the integrity of the spring source and prevent contamination caused by a reversed flow close to the ground surface.

One comment stated that if the spring ceases to flow to the earth's surface, the pumping mechanism is at fault, and comparative samples would not be available. Another comment asked whether, if the spring ceases to flow as a result of pumping, the water may still be called ''spring water.''

The agency agrees with the concerns of the comments. In some cases pumping may cause the spring to cease flowing through the natural orifice, and, thus, comparative samples of the water would not be available because of the use of external force when the water is collected through a bore hole. It is important to maintain some flow of water through the natural orifice to prevent any reverse flow of surface water, which could then be pumped through the bore hole. As previously stated in the response to comment 12 of this document, ground water under the influence of surface water cannot be called ''spring water.''

FDA recognizes that occasionally a spring may cease flowing temporarily because of fluctuations in ground water levels. Ground water fluctuations may be caused by natural conditions (e.g., drought) or man-induced (e.g., pumping) and are classified as short-lived, diurnal, seasonal, and long-term changes (Ref. 9). If the spring has ceased flowing, and this cessation is not a temporary condition, the water is not spring water. In addition, if the external force is routinely (e.g., more often than during the time of year when the water table is typically low) causing cessation of the spring's flow to the surface, this too is not a temporary condition, and

the water does not qualify to be called ''spring water.''

The State of Florida's definition for ''spring water'' does not include water from a strata feeding a spring that ceases to flow naturally to the surface for a period of 90 days (Comment 184). The agency agrees that there must be an expectation that the spring will continue to naturally flow to the surface for the water to qualify as spring water. Thus, any cessation in the flow of the spring from the natural orifice must be for a limited period of time. Ninety days is an appropriate time limit for seasonal types of changes in ground water. However, the agency will consider each situation on a case-by-case basis and take into consideration all circumstances (e.g., climatic conditions and effect of pumping) causing the flow cessation.

To clarify in § 165.110(a)(2)(vi) that the spring must continue to flow when external force is applied to a bore hole in the collection of spring water, FDA is deleting the statement that it included in the proposed regulation that the water would flow naturally to the surface of the earth if not for its collection below the earth's surface. In addition, the agency is adding a requirement in § 165.110(a)(2)(vi) that if spring water is collected with the use of external force, water must continue to naturally flow to the surface of the earth through the spring's natural orifice.

49. A number of comments expressed concern that the use of external force will allow a spring water bottler to extract more water from the ground than would have naturally flowed to the surface of the earth through the spring's natural orifice. Comments requested that the agency include a provision in the definition of ''spring water'' to require that the quantity of water extracted through external force not exceed the quantity of the water that would flow naturally to the surface of the earth if not for its collection below the earth's surface.

Two comments asked what the purpose of permitting the use of a bore hole was if the quality of the water from the bore hole must equal that of the water that flows naturally to the earth's surface except to enable the pumping of larger volumes of water from a stratum. Another comment held that under the proposed rule, there will be few springs developed with collection boxes because bore holes will be generally more economically advantageous, and greater volumes of water will normally be available through the use of bore holes than through the use of collection boxes.

One comment added that provision for the use of bore holes could encourage bottlers to exceed the safe yield from the spring's aquifer. It stated that excessive withdrawal is usually discussed in terms of ''mining'' of the water (defined as when more water is withdrawn than is replaced by recharge). The comment stated that the real issue as far as surface contamination is concerned is not the ''mining'' of water or the collection device but the quality and purity of the aquifer as determined by the source of recharge.

One comment expressed concern that the proposed rule is silent on any method to identify when, because of overpumping, wells are capturing water that would otherwise not flow to the spring. It stated that overpumped bore holes (i.e., those that pump more water than the spring naturally discharges) could induce flow from surface water or nearby contaminant sources, such as septic tanks. The comment stated that possible solutions to this problem would be to: (1) Restrict the allowable daily pumping volume to that volume equal to the natural average (mean) daily flow from the spring; (2) restrict the use of bore holes to those that do not require the ''assistance of external force'' (i.e., pumping); or (3) require a demonstration that any additional pumping is not altering the flow paths to the spring such that flow is induced from nearby potential sources of contamination to the well.

FDA agrees that there may be adverse effects of overpumping (i.e., mining) a bore hole that is tapping a spring. There may be public health concerns if the recharge to the aquifer is contaminated by surface water. In addition, ground water extracted with external force, and under the direct influence of surface water because of overpumping, is not spring water because the source of the water is not entirely the source that feeds the spring. However, such water may be treated and called ''bottled water'' or another applicable name.

FDA does not object to the use of external force, and does not deem it necessary to restrict the amount of water that may be extracted through the use of external force, as long as the water meets the requirements of § 165.110(a)(2)(vi) (e.g., it is compositionally the same as the water flowing from the natural orifice). Water that has not traveled the same course as the water feeding the spring, and, thus, that does not have the same characteristics as water from the spring, cannot be labeled as ''spring water.''

The agency disagrees that allowing the use of a bore hole and external force will decrease the number of springs developed with collection boxes. Many States already allow the use of both extraction methods, and both methods are already used by manufacturers. Providing for the use of both methods of collection of spring water allows manufacturers the flexibility to use the method best suited for their spring site.

A demonstration that pumping is altering the flow paths to the spring, such that flow is induced from nearby potential sources of contamination to the bore hole, could include bore hole pump tests, monitoring of observation wells, and ground water flow modeling. EPA's Ground Water Protection Division has developed a variety of tools designed to assist State and local governments in the task of identifying the capture zones of pumping as part of the Wellhead Protection Program (WHPA). A capture zone is the area around a bore hole containing ground water that is destined to flow to that bore hole within a specified time. EPA's existing ground water flow model (WHPA 2.1) can identify induced flow from surface water caused by changes in pumping rates. Should a demonstration of the effects of pumping be required, this model could be used as a tool by government agencies to determine the impact of the aquifer's recharge. FDA concludes that a ground water flow model could be used to ascertain whether allowable overpumping is inducing deleterious results. However, regardless of the use of external force to extract spring water, the water must still comply with the definition in § 165.110(a)(2)(vi) to be labeled as ''spring water.''

e. Source Approval and Enforcement Issues

50. Comments asked how it can be proven that the water from the bore hole is from the same stratum as the water that is actually emerging from the spring. They stated that once the bore hole at the spring has been constructed and the establishment is in operation, it would be difficult to verify that the water from the bore hole met the definition of spring water. One comment asked what type of documentation the producer could keep that would satisfy the requirements of the regulation concerning source. It asked whether the records or a certification statement from the drilling company that drilled the holes would be necessary, or whether a site examination and the manufacturer's word on source would be adequate.

One comment expressed concern about potential abuse from the use of a bore hole because the nonexistence of a

spring can be readily attributed to the effect of the bore hole, and no confirmation of the prior existence of a spring at that location is required.

The agency acknowledges the concerns of the comments. Section 129.35(a)(1) states that the product water supply for each plant shall be: (1) From an approved source that is properly located, protected, and operated; (2) easily accessible, adequate, and of a safe, sanitary quality; and (3) in conformance at all times with the applicable laws and regulations of the government agency or agencies having jurisdiction. However, part 129 does not require that the government agency having jurisdiction identify or certify that the source is a spring source.

As discussed in the response to comment 48, FDA has modified § 165.110(a)(2)(vi) to mandate that the spring continue to flow, although it may be at a diminished rate, for the product to qualify as ''spring water.'' In addition, it is important that manufacturers identify the location of the spring to determine that the water is, in fact, flowing and, thus is spring water. A spring is a flow of water from the earth. If there is no identifiable spring, the water can not be labeled as ''spring water.'' Thus, it is critical that manufacturers of ''spring water'' identify the exact location of the natural orifice where the spring flows from the earth. Therefore, the agency is modifying § 165.110(a)(2)(vi) to include a requirement that the location of the spring be identified.

There must be other means of verifying labeling claims once the bore hole at the spring has been constructed, and the establishment is in operation. As discussed above under ''1. Artesian Water,'' the agency may promulgate regulations for the efficient enforcement of the Act under section 701(a) of the Act. Although it is possible to determine that a source of water is a spring after the bore hole is in operation, in some cases it would be onerous for regulatory officials to do so. Therefore, FDA has determined that a requirement to demonstrate the hydraulic connection between the bore hole and the spring's natural orifice is necessary for the efficient enforcement of the Act.

As FDA has stated, a food manufacturer is responsible for the accuracy of its food labels (58 FR 2079, 2163, and 2165 January 6, 1993). Indeed, placing a claim in food labeling that calls the consumers's attention to a water's source is a representation that the manufacturer has evidence that the product meets the requirements for the claim. See *Thompson Medical Co., Inc.* v. *FTC,* 791 F.2d 189, 193 (D.C. Cir. 1986), *cert. denied,* 479 U.S. 1086 (1987). Thus, making a claim without such a basis would be misleading and in violation of section 403(a) of the Act.

The evidence that manufacturers compile in response to the requirement in § 165.110(a)(2)(vi) that they be able to demonstrate to regulatory officials that a measurable hydraulic connection exists between the bore hole and the natural spring orifice (see comment 43 of this document) should also establish that the spring is the source of water for the bore hole. To comply with this requirement, producers may maintain records that demonstrate that a measurable hydraulic connection does indeed exist between the natural orifice and the bore hole. In addition, many States and the United States Geological Survey may have records of the development of some springs and the geology of the surrounding area. Records or a certification statement from a professional hydrogeologist or the drilling company that drilled the holes are appropriate sources of documentation. In addition, manufacturers may use methods such as the dye tracer test to demonstrate the hydraulic connection during an inspection.

If the source does not meet the definition of spring water then the product must not be labeled as ''spring water,'' or it is misbranded under sections 403(a), 403(b), and 403(g) of the Act. Compliance with this provision does not entail the creation of any new information or the compilation of any special records. Rather, the requirement would obligate manufacturers simply to have access to information that they should already possess and be able to provide FDA with this information upon request.

51. Several comments expressed concern about the requirements that spring water be ''from the same underground stratum,'' ''retain all the physical properties,'' and ''be of the same composition and quality.'' They stated that these requirements are too general and are undefined, leaving many questions relative to acceptable differences in such parameters as temperature, pH, turbidity, hardness, iron content, and calcium content. One comment stated that it will be difficult for FDA or any other government agency to monitor the conditions required for ''spring water.''

One comment requested clarification of the requirement in part 129 that product and source waters be approved by State regulatory agencies having approval authority. It asked whether the proposed regulations mandated approval of the bore hole and the spring, whether the spring must be validated as a natural spring, and whether engineering had to be performed to protect the spring site if a bore hole is to be utilized. The comment stated that there is no reference to continuous maintenance of the spring. Comments asked how many, and at what frequency, tests are necessary to show that water from the bore hole is identical to water from the spring.

Comments stated that manufacturers should present geological information about the vicinity of the orifice and bore hole so that the State can devise a representative set of water quality analyses specific to the situation.

FDA notes that the source is approved by the government agency or agencies having jurisdiction (§ 129.3(a)), and that in many cases, it will be a State agency. However, the approval mandated under part 129 is to inspect the source and sample the water to ascertain that the water is of a safe and sanitary quality. Firms are responsible for ensuring that their products comply with the particular source requirements in § 165.110(a)(2)(vi). As discussed previously, the bottled water firm must be able to demonstrate to regulatory officials that a measurable hydraulic connection exists between the bore hole and the natural spring, and that the water complies in all other respects with § 165.110(a)(2)(vi).

Concerning continuous maintenance of the spring, the firm is responsible for ensuring that their products comply with all applicable regulations. The quality of the source water is critical to the quality of the final product. Without proper maintenance of the spring, the quality of the source water will decrease, and the firm is taking a risk that the water will not meet FDA requirements. Thus it is in the interest of the firm to maintain the source in appropriate condition.

In regards to methods of testing for comparative purposes, one or more hydrogeologically valid methods may be used as appropriate to verify that the product is in compliance. However, not all methods may be suitable for different geologic regions or for the specific bore hole site. Therefore, the agency is not recommending or requiring any specific method or methods.

Under § 165.110(a)(2)(vi), manufacturers must be able to demonstrate, upon request, to regulatory officials that there is a measurable hydraulic connection between the natural spring and the bore hole. This verification must be current to be satisfactory. It is the responsibility of the firm to be in compliance at all times.

52. Two comments asked for clarification of whether water emerging at the surface not as a result of flow from an underground formation or aquifer, but as the result of seepage from a higher elevation surface water source reemerging at a lower elevation, is really spring water (e.g., springs fed by higher level lakes; underground creeks popping up to the surface; or other surface water that originates high in a mountain which emerges at a lower elevation).

The agency considers that surface water from a higher elevation reemerging through a natural orifice at a lower elevation is spring water if the water has traveled sufficiently through the ground so as not to be under the direct influence of surface water. According to 40 CFR 141.2, ground water under the direct influence of surface water means any water beneath the surface of the ground with: (1) Significant occurrence of insects or other macroorganisms, algae, or large diameter pathogens such as *Giardia lamblia*; or (2) significant and relatively rapid shifts in water characteristics such as turbidity, temperature, conductivity, or pH which closely correlate to climatological or surface water conditions. The existence of any of these factors indicates that the source is under the direct influence of surface water and is, therefore, not a ground water source that meets the definition of ''spring water.''

A spring is water from an underground source that flows naturally to the surface of the earth. Under normal conditions, aquifers feeding springs are in a stable environment. On the other hand, surface water is subject to a changing environment and may assimilate these changes. Thus, if water flowing naturally to the surface of the earth exhibits the characteristics of surface water, it does not comply with the definition of ''spring water'' in § 165.110(a)(2)(vi) and is not spring water.

53. One comment claimed that some members of industry consider any wet location on an otherwise dry mountainside or flat pasture to be a spring. The comment stated that sometimes these wet spots can bead water, producing a small trickle. The comment contended that after development, these wet spots can sometimes produce a considerable flow of water. It also stated that water has been known to come up in natural depressions in hillsides without flowing until the water is pumped. The comment requested clarification on these questions. It asked whether any alteration to the natural terrain that results in water coming spontaneously to the surface of the alteration should be deemed a spring (e.g., a road cut into a mountain and in this cut water trickles (or gushes) out).

FDA is defining ''spring water'' in § 165.110(a)(2)(vi) as water derived from an underground formation from which water flows naturally to the surface of the earth. There must be a natural force causing the water to flow to the surface through a natural orifice. If the water does not flow to the surface of the earth from the underground source without development of the area or the use of external force, then the water does not qualify for use of the name ''spring water.''

54. One comment complained that the January 5, 1993 proposal, if adopted, would be yet another Federal mandate, without Federal funding, to State agencies having the responsibility of ensuring compliance. It stated that justification for additional program expenditures must be based on need and public safety. The comment stated that there has been no evidence presented that adoption of the proposed rules would increase product safety.

One comment stated that the very general nature of FDA's proposal would create problems for regulatory agencies attempting to implement and enforce the rule by generating additional workload, controversy within the bottled water industry, and legal battles over whether a ''bore hole'' is tapping ''spring water'' or ''well water.''

Comments stated that the use of a bore hole in the collection of spring water would make enforcement of the provision not only expensive but most difficult.

The agency disagrees that it is imposing a burden on State regulatory agencies by establishing a standard of identity for spring water. There is no requirement that a State ensure that a firm is complying with FDA regulations. However, a State may elect to enforce § 165.110 under section 310(b) of the Act (21 U.S.C. 337).

In response to comments, the agency has added provisions to its definition of spring water that make it more specific and that should make its requirements more understandable both to the regulated and the regulators. Manufacturers must identify the location of the spring; there must be evidence that the water is flowing naturally to the surface through a natural orifice; firms must demonstrate and be able to verify to regulatory officials that there is a measurable hydraulic connection between the bore hole and the natural spring; and water must continue to flow naturally to the surface of the earth through the springs' natural orifice. FDA concludes that these provisions will aid in enforcement of the definition of ''spring water.''

f. Contamination and Sanitary Bottling

55. A number of comments disagreed with FDA's statement in the preamble to the proposal that use of a bore hole will reduce the possibility of contamination and is an aid in the sanitary bottling of spring water (58 FR 393 at 399). Two comments argued that the available evidence did not support that a bore hole is a more sanitary method to collect spring water than a collection box. Comments stated that a properly engineered and constructed spring collection box system can adequately protect a natural spring from outside microbial contamination.

A comment stated that if the quality of spring water is an issue, then it can and should be addressed by quality standards rather than by altering the common definition of spring water to permit use of a bore hole. It argued that the evidence of record on this rule does not justify any departure from the accepted definitions of ''spring'' and ''spring water.'' Another comment stated that with respect to bore holes serving as an aid in the sanitary bottling of the water, FDA already has provisions for this purpose in part 129. It stated that bore holes as aids in sanitary bottling of water should not be a consideration under the standard of identity.

Another comment stated that the proposed rule provides no specifications for the construction of bore holes, and that, if improperly constructed, sources of contamination could enter the aquifer through the bore hole. It stated that the technology exists to protect a spring water source at its point of discharge, and that treatment systems can be incorporated at the point of discharge to provide protection from a number of types of potential contaminants.

The agency points out that both properly engineered and constructed bore holes and properly engineered and constructed spring collection boxes are appropriate methods to collect spring water. However, in some circumstances, use of a bore hole instead of a collection box will reduce the possibility of contamination and thus aid in the sanitary bottling of the water. For example, springs may surface in areas where it would be difficult to collect the water at the orifice without contaminating the water. In such cases, use of a bore hole can be an effective means to extract the water in a sanitary manner. In all cases the processing and

bottling of drinking water must comply with part 129.

FDA agrees with the comments that stated that sanitation is a function of GMP and not a standard of identity. The agency stated in the preamble of the proposed rule that the use of a bore hole would reduce the possibility of contamination and would be an aid in the sanitary bottling of the water (58 FR 393 at 399), but the intent of this statement was not to say that use of a bore hole is a superior method of collecting the water. Rather, the agency was saying that even though the geological definition of ''spring water'' does not provide for bore holes, it is a good idea to include their use in the definition of ''spring water'' because it would provide an alternative sanitary means of extracting the water. Thus, the statement was intended to be a basis for what the agency was proposing to do, not to be an end in itself. The usefulness of bore holes is one of several factors that have convinced the agency that it is appropriate to include water collected by means of their use in the definition of ''spring water.''

External force is often used with bore holes to extract the water. To clarify the agency's intent that use of bore holes, including those using external force, or properly engineered and constructed spring collection box systems must adequately protect the water, FDA is modifying § 165.110(a)(2)(vi) to remove any inference that manufacturers may use external force to protect the water. Under part 129, any method of collection of spring water must protect the water (§ 129.35(a)(1)).

The agency is not providing detailed specifications for the construction of bore holes or for the construction of spring collection boxes. Appropriate construction specifications may vary according to the site. However, construction of either type of collection mechanism must be in accordance with current good engineering practice. In addition, under § 129.3(a), the source water must be of a safe and sanitary quality. Proper construction will greatly assist in complying with this requirement.

56. Comments asserted that a main concern is that drilling a bore hole next to a free flowing spring orifice may create a hydraulic connection or direct communication between any nearby surface water (river, creek, lake, pond, or swamp) and the spring source and, thus serve only to increase the risk of contamination. Comments were concerned about altering the patterns of recharge by the use of external force and lowering the quality of the water as a result. One comment stated that the use of bore hole collection systems runs contrary to the standards set by EPA regulations (40 CFR part 141) because, almost by definition, the bore hole will be shallow, and it can be sited near surface waters created by the discharging spring.

Conversely, one comment stated that, in a properly equipped bore hole, reverse ground water flow from the surface should not occur. It stated that pumping may change the flow of ground water in a horizontal direction within the aquifer, specifically within the cone of depression created by pumping, and that if a bore hole is properly equipped and managed, vertical movement of surface water downward into the screen will not occur. It added that properly equipped bore holes are accepted by both Federal and State agencies as safe supplies of both domestic and municipal drinking water.

FDA agrees that the potential exists for improper recharge of an aquifer feeding a spring. Water recharge is an issue that must be considered during source approval because there is the potential that the recharge may come from surface sources that may contaminate the underground source. For source approval, the government agency having jurisdiction must determine whether the water will be of a safe and sanitary quality. The States, however, have experience with issues of this type.

The establishment of a definition for ''spring water'' does not have any effect on the State's burden in reviewing a site for approval, whether a bore hole or a collection box is to be used. The State's decision on whether to approve a source has nothing to do with how water collected from that source and bottled is to be labeled. That decision is made by the bottler, subject to the definitions in § 165.110(a)(2)(vi) and the scrutiny of FDA.

57. One comment stated that the language of the proposed rule creates the impression that spring water may be collected from the surface, which is unlikely, and that bottlers may bottle untreated surface water. The comment stated that surface water intended for drinking must undergo treatment that may result in alteration of the original chemical properties of the water, which would destroy the product's identity as ''spring water'' in the public's perception. It recommended that the following language be added to the definition of spring water: ''After treatment, spring water shall maintain the same physical properties and chemical composition as the water that does or would flow naturally to the surface of the earth.''

FDA disagrees with the comment. Spring water may be collected from the surface by means of a collection box. A properly engineered collection box captures the water as it surfaces, before it can be contaminated by surface elements and become surface water. However, spring water collected under the most sanitary conditions may still require some treatment.

The definition of ''spring water'' is based on the underground source of the water. Thus, water meeting the definition of ''spring water'' in § 165.110(a)(2)(vi) would remain spring water after treatment, even if the physical properties and chemical composition of the water are altered from such treatment. For example, ozonation is commonly used to treat bottled water and may cause some dissolved minerals, such as manganese, to precipitate. Other treatments, such as filtering, may also cause changes in the water. As long as the water meets the definition of ''spring water,'' however, even though it has been treated, it may be called ''spring water.''

In the case of spring water extracted from a bore hole, the water must be compared with the water extracted from the natural spring. When that comparison occurs, either before or after any treatment, may have a significant impact on whether the water collected from the bore hole maintains the same physical properties and chemical composition as the water from the natural orifice. To clarify the intent of the regulation, FDA is modifying § 165.110(a)(2)(vi) to state that, before treatment, the water collected from the bore hole must have the same physical properties and chemical composition and quality as water from the natural spring.

However under section 201(n) of the Act, if the water has been treated in such a way that it differs significantly from the source water, regardless of whether that source water is from a natural spring or a bore hole, the fact that that alteration has been made is a fact material in light of representations made and must appear on the label of the product. The water is no longer unmodified spring water and differs significantly from the water that was harvested. Therefore, the fact that the water has been altered significantly must be disclosed in the statement of identity, so that consumers are aware that the source water has been modified. If minerals have been added, the statement of identity must state that fact. If minerals have been removed from the product, other than those that are removed during normal processing (e.g., filtration to remove precipitates),

that fact must be included in the statement of identity of the product as well (e.g., demineralized) (§ 165.110(a)(2)(iv)).

5. Well Water

FDA proposed that the name of bottled water from a hole bored, drilled, or otherwise constructed in the ground that taps the water of an aquifer may be ''well water.'' The agency received no comments requesting modifications to this source definition. Therefore, the definition for ''well water'' is the same as FDA proposed (58 FR 393), although it is now codified at § 165.110(a)(2)(viii) as a result of the additions that FDA has made to § 165.110(a)(2).

6. Other Water Definitions

58. Several comments urged FDA to define ''natural water.'' Comments suggested that ''natural water'' means bottled spring, artesian, mineral, or well water that is unmodified by mineral addition or deletion, except that ''natural water'' may be filtered and must be sanitized with ozone or an equivalent disinfection process and treated to reduce the concentration of any substance that exceeds an allowable level established by the agency.

One comment urged FDA to define ''natural water'' as in the IBWA Model Code. IBWA defines ''natural water'' as spring, mineral, artesian, or well water that is derived from an underground formation and that is not derived from a municipal system or public water supply.

Some comments recommended that FDA define ''natural'' for use on bottled water labels because the term is often used on labels and may be misused. One comment stated that water to be called and labeled ''natural'' must come from the ground and may be sanitized with ozone or an equivalent disinfection process. It added that any removal of excessive substances should not allow that water to be labeled as ''natural.'' Another comment stated that the word ''natural'' should be used only if the mineral content of the water is not altered during the production process. Therefore, distilled, purified, or drinking water products that use reverse osmosis to remove solids, then add back minerals, could not be described as ''natural.''

One comment suggested that FDA provide for the use of the term ''natural'' in conjunction with ''mineral water'' (i.e., ''natural mineral water'') as it is allowed in the European standard. The comment stated that consumers want to be assured that the product that they are purchasing is from a natural source and has not been blended or manipulated in any fashion with surface or municipal water sources. The comment added that the use of the term ''natural'' also implies that, because of the bacterial purity of the product, chemical disinfection is not necessary.

Two comments suggested the addition of the word ''natural'' to the definition of ''spring water'' to fully ensure that the spring water has the same composition, whether collected through a bore hole or at the surface, and that it has not been treated except for the addition of carbon dioxide or the removal of iron and manganese and suspended solids.

However, two comments stated that the term ''natural water'' should not be permitted on a label because consumers do not understand what it means.

The agency considered establishing a definition for ''natural'' in a proposal on food labeling that it published in the Federal Register of November 27, 1991 (56 FR 60421 at 60466), because of the widespread use of the term and the evidence that consumers regard many uses of this term as noninformative. After considering the comments that it received in response to the November 27, 1991 proposal, the agency stated that if the term ''natural'' were adequately defined, the ambiguity surrounding use of this term that results in misleading claims could be abated (58 FR 2302 at 2407, January 6, 1993). Because of resource limitations and other agency priorities, however, FDA did not undertake rulemaking to define ''natural'' at that time. The agency stated that, while it regarded the term as meaning that nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food, it would maintain its policy of not restricting the use of the term except as provided for in § 101.22 (*id.*).

A number of States, AFDO, and IBWA have defined ''natural water'' (Refs. 2, 7, 11, 12, 14, and 15). All of the definitions require that the water be derived from an underground formation (spring, artesian, or well water) and be unmodified except for limited treatment (e.g., filtration and ozonation or equivalent disinfection process). Those States that have adopted the IBWA model regulation as their State regulation provide for treatment of ''natural water'' to reduce the concentration of any substance that exceeds safety standards. The IBWA model regulation also states that the water ''may be collected and transported by pumps, pipes, tunnels, trucks, or similar devices.''

The Codex Standard for Natural Mineral Waters and Edible Ices and Ice Mixes (Codex Standard) (Ref. 1) defines ''natural mineral water'' and ''naturally carbonated natural mineral water.'' These waters are obtained from underground water-bearing strata either through natural flow or drilling. Treatments permitted for ''natural mineral water'' under the Codex standard include separation from unstable constituents by decantation or filtration that is, if necessary, accelerated by previous aeration.

The agency finds that the IBWA code and State requirements are basically consistent with FDA's informal policy on ''natural'' because the product is only minimally processed. However, there are some surface waters (e.g., water collected from glacier runoff) that may only require minimal processing to be acceptable bottled waters and, thus could qualify to be called ''natural.'' Most surface waters and ground waters under the influence of surface water require additional processing to ensure that the water is consistent in quality and, thus could not be labeled as ''natural.'' Therefore, because FDA's informal policy already encompasses bottled water, the agency concludes that it is not necessary to establish a regulation that specifically defines ''natural'' for use with bottled water.

59. One comment noted that no consideration was given to the proper use of the word ''pure.'' It stated that many bottlers misuse this word.

The agency advises that while there is no specific prohibition against the use of the term ''pure,'' it has discouraged the use of the term because it is ambiguous and may be misleading (58 FR 2897 at 2903). For example, ''spring water'' and ''pure spring water'' may be identical foods, but ''pure,'' as applied to the food, implies that other identical products are ''impure'' or ''not pure'' if they do not bear the same term on their label. In addition, the agency notes that the term ''pure'' may be confused with the term ''purified,'' and consumers may be misled into believing that bottled water labeled as ''pure'' has been treated to substantially decrease the total dissolved solids content.

The agency is not convinced that it should use its resources to define the term ''pure'' at this time but will continue to discourage its use. In addition, the agency will continue to deal with this issue on a case-by-case basis.

60. Two comments asked what bottled waters made by using well water for a source, and then diluting the water with distilled or purified water to improve hardness and taste, could be called.

Blends of different types of water, such as well water and purified water,

may be appropriately labeled as ''bottled water'' or ''drinking water.'' Truthful statements may also be made on the label to inform consumers that the product is blended, with the percentage of each type of water included.

61. Two comments stated that the name ''mountain water'' should not be permitted on the label because it is misleading to consumers.

The agency is not providing for the use of the term ''mountain water'' as the name of a bottled water product. The name of the product is ''bottled water,'' ''drinking water,'' or one or more of the terms defined in § 165.110(a)(2) as appropriate. However, if the water is from a mountain source, manufacturers may include a truthful and nonmisleading statement reflecting that fact.

62. One comment stated that there are bottlers in Canada and Alaska that bottle ''glacier water'' and asked whether they could continue to use this term to label their bottled water. It provided a definition for ''glaciofluvial'' as ''of or relating to or coming from streams deriving much or all of their water from the melting of a glacier.'' The comment stated that minerals are rarely detectable in this water, let alone environmental pollutants, and noted that the water requires little if any filtration. The comments said that the water is passed through ozonation or ultraviolet light as a precaution for total and fecal coliform bacterial counts.

FDA notes that the definition that the comment provided is not a clear definition because, under it, not all of the water need come from the melting of the glacier, and the percentage of the water actually coming from the glacier would vary significantly according to the season of the year. Therefore, FDA is not providing for this term.

FDA notes that manufacturers that bottle this category of water may state in the labeling that the source of the water is glaciofluvial. However, the statement of identity for the product is ''bottled water'' or ''drinking water.''

D. Other Label Statements

1. Mineral Content of Mineral Water

The agency tentatively concluded in the January 1993 proposal that the listing of relative mineral content is useful to consumers to characterize a given mineral water product. FDA proposed to require that if the TDS is below 500 ppm, the statement ''low mineral content'' appear on the label. In addition, the agency proposed that if the TDS of mineral water is more than 1,500 ppm, the statement ''high mineral content'' must appear on the label. FDA did not propose to define the term ''light'' or other descriptive terms as they apply to mineral water because FDA tentatively concluded that the use of only the statements ''low mineral content'' and ''high mineral content'' would be less confusing to consumers. FDA proposed that the statement of mineral content appear on the principal display panel following the statement of identity in type at least one-half the size of the type used for the statement of identity but in no case of less than one-sixteenth of an inch. The agency requested comments concerning the proposed levels defining high or low mineral content.

63. A number of comments noted that § 165.110(a)(3)(i) concerning the labeling of a product as ''low mineral content'' or ''high mineral content,'' does not refer solely to ''mineral water'' and objected to this labeling if it were to apply to all bottled waters. One comment stated that the statement ''low mineral content'' would be misleading on products such as ''artesian water,'' ''spring water,'' ''well water,'' or ''bottled water'' when they in no way claim to be mineral water, and this statement would imply a less-than-normal mineral content. One comment recommended that the regulation state ''if the TDS content of mineral water is below * * *,'' so that the regulation only would apply to products labeled as mineral water.

FDA agrees with the comments. The normal mineral content of artesian water, spring water, well water, bottled water, or any other bottled water product except for the majority of mineral waters is less than 500 ppm TDS. In fact, bottled water, except for mineral water, must comply with the provisions in the quality standard for bottled water that require that if the product contains more than 500 ppm TDS, the product be labeled as substandard (§§ 165.110 (b)(4) and (c)). In the preamble to the proposal, the agency only discussed labeling a product as ''low mineral content'' or ''high mineral content'' if the product was ''mineral water'' (58 FR 393 at 397), although the agency failed to specifically mention in the regulation that it applied only to ''mineral water.'' This failure was an oversight. Therefore, the agency is modifying § 165.110(a)(3)(i) to state that if the total dissolved solids (TDS) content of mineral water is below 500 ppm, or if it is greater than 1,500 ppm, the statement ''low mineral content'' or ''high mineral content'', respectively, shall appear on the principal display panel.

64. A number of comments objected to the labeling of mineral water as ''low mineral content'' and ''high mineral content'' and requested that § 165.110(a)(3)(i) be deleted because this labeling would be confusing to consumers. One comment opposed denoting the ''low'' or ''high'' mineral content of mineral water because flavor is more affected by specific minerals than by TDS.

FDA disagrees that the label statements concerning low or high mineral content should be deleted from the regulation. As discussed previously, the agency is requiring that mineral water contain a certain amount of minerals because consumers expect that mineral water contains some minerals. Because the mineral content of mineral water may vary greatly, and because the high and low ends of the range of mineral contents may have a significant bearing on the characteristics of the water, the agency concludes that information about the mineral level is a material fact, under section 201(n) of the act, in conjunction with the term ''mineral water.'' The agency's action establishes three broad categories, but only manufacturers of mineral waters below 500 ppm TDS or above 1,500 ppm TDS need provide the additional information on the label.

FDA agrees that the taste of some mineral waters may be affected more by specific minerals than by total mineral content. Nevertheless, if a mineral water contains less than 500 ppm TDS, it is important that consumers be made aware that the product has a low mineral content, and that it may not have the mineral taste that another mineral water may have. Many State regulations have required that mineral water contain more than 500 ppm TDS (Ref. 8), and most mineral water sold in the United States has complied with this minimum so that it could be sold in those particular States. Therefore, FDA concludes that the use of the statement ''low mineral content'' on mineral water containing less than 500 ppm TDS is appropriate to alert consumers to the fact that the water may have a lower mineral content than mineral waters that they have previously purchased.

Additionally, the agency notes that, as discussed in the proposal to this final rule (58 FR 393 at 397), a mineral content of over 1,500 ppm TDS greatly affects the taste of the water no matter what the specific minerals may be. Therefore, the agency concludes that because this information is a material fact, consumers should be informed that the product contains a high mineral content.

65. Two comments held that the statement ''low mineral content water'' on mineral water could be misleading to some consumers if, for example, they interpret it as saying that the water is low in sodium. The comment stated that low mineral content mineral waters may be relatively high in sodium.

FDA disagrees that the statement ''low mineral content'' would be misleading to consumers. The term ''low'' in this statement is referring to the overall total dissolved solids content and not to any specific mineral. However, the agency agrees that some mineral waters containing between 250 and 500 ppm TDS may contain more than an insignificant amount of sodium. Under § 101.9(a), nutrition labeling is required if the product contains more than an insignificant amount of any nutrient that is required to be included in the declaration of nutrition information under § 101.9(c). If a product labeled as ''low mineral content'' is not sodium free (i.e., contains 5 or more mg sodium per serving), nutrition labeling is mandatory, and consumers will be informed that, although the product is low in mineral content, it contains more than an insignificant amount of sodium.

66. Four comments asked whether mineral waters with a mineral content greater than 1,500 ppm could be labeled as ''rich in mineral salts.''

Another comment stated there may be confusion about the term ''high mineral content'' because it appears to be substantially similar to nutrient content claims that are allowed under the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), and in fact it may be misinterpreted by many consumers as an indication that the product may be useful as a mineral supplement.

The agency finds no merit to these comments. In the Federal Register of January 6, 1993 (58 FR 2302 at 2414), FDA adopted § 101.54(b)(1), which defines the terms ''high,'' ''rich in,'' and ''excellent source of'' to mean that the food contains 20 percent or more of the reference daily intake (RDI) or the daily reference value (DRV) of the nutrient in question per reference amount customarily consumed. The claim ''high mineral content'' is not subject to § 101.54 because the term does not describe the nutrient content of the water. FDA has not defined nutrient content claims for minerals as a category, only for individual minerals. While FDA has authorized some nutrient content claims concerning mineral content of foods, such as ''high in three minerals,'' it has not authorized ''high mineral content.'' Thus, this claim only applies to mineral water.

There is no authorization in FDA's regulations for use of a synonym for ''high'' in the statement ''high mineral content'' for bottled water because the statement is not a nutrient content claim but part of the statement of identity of the product. The term ''rich'' is not appropriate in this context because it means that a product is abundantly supplied with something of value. Although the terms ''high,'' ''rich in,'' and ''excellent source of'' have been defined as synonymous nutrient content claims, not all of these terms are appropriate when used to describe the mineral content of mineral water containing more than 1,500 ppm TDS because such water may not be an ''excellent'' or ''rich'' source of minerals of nutritional significance. Use of the term ''high mineral content,'' however, provides a quantitative contrast to the term ''low mineral content'' of mineral water containing less than 500 ppm TDS.

Therefore, FDA concludes that only the declaration ''high mineral content'' is appropriate for mineral water. Given that the statement is part of the statement of identity of the product, FDA has not provided for the use of synonyms. The statement appropriately should be as simple and as straightforward as possible.

67. One comment stated that 1,500 ppm TDS as the triggering level for the label statement ''high mineral content'' is an extremely high level. The comment suggested that the statement ''exceeds the secondary maximum contaminant level of 500 ppm,'' for mineral water containing greater than 500 ppm TDS, is a better disclosure and would help to eliminate consumer confusion over the differences in water quality standards between bottled water and public tap water.

The agency disagrees with the comment. The term ''mineral water'' has traditionally implied that the water has a higher mineral content than most water, including public tap water. As discussed in the proposal (58 FR 393 at 397), all water contains some minerals, unless it has been demineralized (Ref. 16). Thus, the agency tentatively concluded that consumers expect that a product identified as ''mineral water'' would contain at least a minimum level of minerals. This expectation is reinforced by the fact that some States (Ref. 8) have only included water that contains more than 500 ppm TDS in their definition of ''mineral water.''

The label declaration ''high mineral content'' is to inform consumers that the mineral content is high in comparison to other mineral waters. As discussed in the proposal (58 FR 393 at 397), a mineral content of more that 1,500 ppm TDS greatly affects the flavor of the water. This level is consistent with the European Community definition of ''mineral water—rich in mineral salts'' (Ref. 17) and will not hinder international trade. Thus, the comment has not persuaded the agency that 500 ppm TDS is a more appropriate minimum level than 1,500 ppm TDS for a product labeled as ''mineral water, high mineral content.''

Therefore, to ensure that consumers know that the product that they are purchasing is high in minerals as compared to other mineral waters, the agency is requiring in § 165.110(a)(3)(i) that the label of mineral water containing more than 1,500 ppm TDS include the statement ''high mineral content.''

68. Several comments recommended that FDA require that TDS content appear on the label of all bottled waters because: (1) Consumers will more easily relate bottled water designations to their specific TDS ranges, (2) consumers will have a better chance of purchasing a bottled water corresponding to their tastes if they learn to associate a particular level of TDS with those tastes, and (3) it renders unnecessary the ruling that a mineral water with a TDS higher than 1,500 ppm be labeled as ''high mineral content.'' One comment stated that consumers will rapidly relate TDS content values in the range of ''thousand(s)'' with a ''high mineral taste'' without the need for arbitrary qualifiers. It added that a TDS labeling requirement works towards establishing similar standards between Canada and the United States.

One comment stated that it would be more informative to consumers to list the TDS in the side panel because concerned consumers want hard information, not generalities like the relative mineral content statements that the agency proposed. It stated that there is a gray area between 250 and 500 ppm TDS in which some waters may taste distinctive and others may taste undistinctive, like low-TDS spring water.

FDA disagrees that it should require mandatory declaration of TDS level. The agency stated in the proposal that many consumers may not understand the relevance of a specific TDS and, thus, tentatively concluded that there is no substantive basis on which to require that this information appear on the label (58 FR 393 at 397). None of the comments provided any information that showed that consumers would understand the significance of this information and that would support a conclusion different than FDA's

tentative determination. However, the agency will not object if manufacturers include information concerning the TDS content, or any information relating to a distinctive taste of a specific product, on their labels as long as the information is truthful and not misleading.

Because many consumers will not understand the relevance of a specific TDS (Ref. 16), FDA concludes that the requirement to label mineral water as ''low mineral content'' or ''high mineral content,'' as appropriate, will be generally more informative to consumers than TDS labeling. Therefore, the agency concludes that mandatory labeling of TDS is not necessary, and that there is no substantive basis on which to require that this information appear on the label.

69. One comment remarked that all bottled water should be labeled with the percentage of minerals present and the limits allowed. Another comment encouraged actual content disclosure on bottled water labels, stating that consumers have a right to know whether any substance regulated under the Safe Drinking Water Act (the SDWA) is contained in the bottled water they purchase, even though it would have to be present at a level below the Maximum Contaminant Level (MCL) established as being permissible.

The agency disagrees that this additional labeling should be required. MCL's have not been established for all minerals or other substances that may be in bottled water. FDA established the standard of quality for bottled water to require that bottled water meet certain quality specifications or else be clearly labeled as ''substandard.'' The quality standard for bottled water is based on EPA's regulations for public drinking water (40 CFR parts 141 and 143), and EPA establishes its regulations based on health and aesthetic considerations. Thus, any contaminant present at a level lower than its maximum allowable level is not considered a safety or quality concern.

Given this fact, there is no basis to require the information that the comments requested. The information would not be a material fact, and thus there would be no basis to claim that the product is misbranded if the information is not disclosed. The presence of these substances in bottled water at levels meeting the quality standard is inconsequential. The appearance of this information on the label may be confusing and may imply that the substance is present in excessive amounts when it is not. Therefore, the agency concludes that the requested additional labeling is not warranted.

70. One comment requested that FDA add the following language to § 165.110(a)(3)(i): ''Mineral water products falling between the TDS values of 500 to 1,500 mg/L do not have to add additional terms.''

The agency notes that mineral water containing more than 500 ppm TDS and less than 1,500 ppm TDS need not bear labeling on relative mineral content. Although a specific statement to this effect is not necessary in the regulation, FDA is modifying § 165.110(a)(3)(i) to state that if the TDS of mineral water is between 500 and 1,500 ppm, no additional statement need appear. The agency concludes that this modification will clarify the regulation.

71. One comment suggested that the producers of identified, sole-source bottled water products (e.g., artesian or mineral waters) that desire to market their products based on the naturally occurring mineral contents be allowed to label their products: ''Water with (or containing) naturally occurring minerals,'' provided that the product labeling clearly identifies the water's sole source and also identifies the naturally occurring minerals. It stated that such mineral identification in the labeling of natural, identified sole-source water should not require additional nutrition information.

The agency disagrees with the comment. All water, unless it has been treated to remove minerals or has had minerals added, contains naturally occurring minerals, regardless of whether it comes from an identified single source. A statement such as ''water with naturally occurring minerals'' has the potential to be misleading to consumers because it implies that the products of competitors may contain added minerals or have had minerals removed, when, in fact, they have not. However, manufacturers may use the term ''natural'' on their bottled water labels if they follow FDA's informal policy as discussed previously (see comment 58) of this document.

The agency is not defining the statement ''water with naturally occurring minerals'' for bottled water labels at this time because it has no basis to conclude that use of the statement would not be misleading, or that it would be useful to consumers. The comment did not provide sufficient information on which to base a regulation.

2. Water From a Municipal Supply

The agency proposed to require that the phrase ''from a municipal source'' appear on the principal display panel or panels as a part of the name of the food if the water is obtained from a municipal water supply, except if the water has been treated to meet the definitions of distilled water or purified water (58 FR 393 at 399). FDA also proposed to require that the statement appear on the principal display panel following the statement of identity in type at least one-half the size of the type in which the statement of identity appears but in no case less than one-sixteenth of an inch. The agency also proposed to require that the statement immediately and conspicuously precede or follow the name of the food without intervening written, printed, or graphic matter, other than statements required by proposed § 165.110(c).

72. Two comments suggested that FDA use the term ''public water supply'' as defined by EPA rather than use the term ''municipal supply.'' The comments noted that the use of the term ''public water supply'' would avoid confusion, as FDA would be using a term that is already defined and well understood. One comment stated that questions could arise about the definition of a ''municipal supply,'' such as how many people would a supply be required to serve to meet the definition of a ''municipal supply.'' Another comment stated that the term ''public water system'' is a more appropriate term because it would include the numerous water systems that are independent water purveyors not affiliated with specific municipalities.

The agency disagrees that the statement ''from a municipal source'' should be replaced with ''from a public water supply'' or ''from a public water system'' in § 165.110(a)(3)(ii). EPA defines a ''public water system'' as a system that provides piped water for human consumption and that: (1) Has at least 15 service connections, or (2) regularly serves at least 25 persons at least 60 days per year (40 CFR 141.2). Public water systems are split into two categories: Community and noncommunity water systems. Community water systems are systems that regularly serve 25 or more year-round residents (or have at least 15 service connections used by year-round residents) (40 CFR 141.2). Many factories, restaurants, schools, parks, and rest areas also operate their own supply of drinking water. However, these systems do not have the required residential community and are, thus, considered noncommunity systems.

There are two types of noncommunity water systems: Transient noncommunity or nontransient noncommunity (40 CFR 141.2).

Transient noncommunity systems serve travelers and other transients at locations such as highway rest stops, small restaurants, and public parks. The system serves at least 25 people a day for at least 60 days per year but typically not the same 25 people each day (40 CFR 141.2). On the other hand, nontransient noncommunity water systems do serve the same 25 persons for at least 6 months a year but not on a year-round residential basis (40 CFR 141.2). Schools and workplaces that have their own water supply and serve at least 25 of the same persons each day are examples of these systems.

The agency stated in the proposal (58 FR 393 at 399) that information about the actual source of a bottled water product is a material fact in light of either the explicit (e.g., use of terms such as ''spring'' or ''well'') or implied (the presentation of the product in the bottle) representation made by a bottled water product that the product is not tap water. Information about the source of the water is necessary to ensure that consumers do not incorrectly assume that because water is sold in a bottle it is not tap water.

According to 40 CFR 142.2, a ''municipality'' means a city, town, or other public body created by, or pursuant to, State law. Municipal water sources are systems that serve municipalities. Thus the term ''municipal source'' may be too narrow to encompass all types of tap water sources. Independent water purveyors and other community systems may operate similarly to municipal water sources, rely on the same types of water (e.g., surface water), use the same type of treatments of the water, and supply the water that flows from a tap. They may differ from a municipal source only in that they are not affiliated with a municipality.

Thus, FDA agrees that water from water systems that are independent water purveyors, but that are not affiliated with specific municipalities, should bear labeling that makes clear its source. Clearly, what would be considered a municipal source would be encompassed by the definition of a community water system because a source supplying an incorporated city or town would regularly serve 25 or more people on a year-round basis (or have the minimum 15 year-round service connections). The term ''community water system'' would encompass the independent water purveyors that the term ''municipal source'' would not.

Noncommunity water systems by definition would not serve a municipality. FDA notes that some bottled water firms may meet the definition of a nontransient noncommunity system if they employ at least 25 persons and use the source water as the workplace water supply. The intent of the labeling requirement was not to include these bottled water manufacturers. Their water is considered a public water system only because they choose to use their own water source and not pipe water in from another source for their workplace water supply.

Therefore, the agency concludes that bottled water from a community water system, as defined by EPA (40 CFR 141.2), must bear source labeling. FDA finds that including all community water system sources in § 165.110(a)(3)(ii) is the logical outgrowth of the January 5, 1993, proposal because the intent of the proposal, as explained above, was to cover all tap water. Thus, FDA is revising § 165.110(a)(3)(ii) to apply to bottled water coming from a community water system as defined in 40 CFR 141.2, rather than from a municipal source. Alternatively, manufacturers may label their product as ''from a municipal source'' if appropriate. (Moreover, as explained in comment 96 of this document, there may be some instances in which ''from a public water supply'' or ''from a public water system'' is appropriate.)

73. One comment disagreed with the provision that would exempt purified water from having to be labeled as from a municipal supply. It stated that the process does not change the source.

Although the agency acknowledges that purification does not change the source, FDA concludes that the exception for purified water is appropriate. As FDA stated in the proposal (58 FR 393 at 399), consumers purchase purified water because of its treatment and resultant purity rather than because of its source. In addition, because purified water and distilled water must meet the compositional requirements of the USP monograph for purified water, there are no significant compositional differences among purified and distilled waters, regardless of the source of the water. Source information for purified waters is not a material fact because the water may be significantly different in composition than other water from that particular source. Thus, the absence of source information for purified water is not misleading under section 403(a) of the act. The comment did not present any information other than the basic argument summarized above. Thus, FDA is not making any changes in response to this comment. However, manufacturers may optionally include source information on the label of purified water.

74. Several comments stated that proposed § 165.110(a)(3)(ii) implies that if bottled water from a municipal source has been treated to meet the definition of ''purified'' or ''distilled water,'' it may be exempt from the labeling declaration of ''from a municipal source,'' whether or not the product is labeled as ''purified water'' or ''distilled water.'' The comments stated that the circumstances in which the municipal source of the water need not be disclosed should be limited, as the agency apparently intended, to when the water is labeled as ''purified'' or ''distilled.'' To effect this limitation, the comments suggested that the agency add the words ''and is labeled as such'' to the regulation.

The agency agrees with the comments. In the preamble to the proposal, the agency stated that the exemption would apply only to purified water or distilled water that was labeled as such (58 FR 393 at 399). However, FDA failed to include the statement ''and is labeled as such'' in the regulation. Therefore, FDA is modifying § 165.110(a)(3)(ii) to include this requirement.

In addition, because FDA has included the alternative terms ''deionized water,'' ''demineralized water,'' ''purified drinking water,'' and ''reverse osmosis water'' in the definition of purified water, the agency is modifying § 165.110(a)(3)(ii) to include all of the terms that may be used under § 165.110(a)(2)(iv) in the exemption.

75. One comment requested that, if the source of bottled water labeled as ''sterilized water'' is a municipal source, the product be exempt from the labeling requirements in § 165.110(a)(3)(ii).

The agency agrees that use of the terms ''sterile'' or ''sterilized'' on the label of bottled water should exempt it from the requirements of § 165.110(a)(3)(ii). Sterile water has undergone a treatment to meet strict microbiological standards. Purified water is exempt from the requirements of § 165.110(a)(3)(ii) in part because the process of purification removes many substances that are typical of the source water, and also because there are no significant differences between purified waters even though the source waters may be very different. Consumers may purchase purified water and sterile water because of the specific treatment and not the source of the water. In addition, because sterile water must meet the microbiological requirements of the USP definition for ''sterile,'' there are no significant microbiological

differences among sterile waters, regardless of the source of the water. Source information for sterile waters is not a material fact because the water may be significantly different in microbiological content than water from that particular source. Thus, the absence of source information for sterile water is not misleading under section 403(a) of the act.

Therefore, the agency is modifying § 165.110(a)(3)(ii) to exempt sterile water and sterilized water that is from a community water system from the source labeling requirement.

76. One comment stated that FDA overlooked source labeling of partially purified water from a municipal source that is processed to remove some chemicals but does not meet the requirements of purified water.

FDA disagrees with the comment and affirms that water from a community water system that is partially purified (i.e., it does not meet the definition of purified water) does not qualify for an exemption from the requirements of § 165.110(a)(3)(ii). As discussed above under comment 74 of this document, there are no significant compositional differences between purified and distilled waters, regardless of the source of the water. Partially purified water, however, effectively continues to resemble the source water. Because partially purified water does not qualify for the exemption, it is covered by § 165.110(a)(3)(ii). Therefore, if the water is partially processed, and is from a community water source, the label must declare the latter fact.

77. One comment stated that it would be misleading if a country setting is shown on the label, including lakes or ponds, and the product is drinking water processed from municipal supplies via reverse osmosis systems.

FDA agrees that the use of certain graphics on a label of bottled water may be misleading to consumers if the source of the water is different than the source depicted or implied. For example, a country setting on a label may mislead consumers into believing that the product is spring water when it is not. Section 403(a) of the act specifically states that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. If a product is from a community water system, the label must clearly disclose this fact except as provided in § 165.110(a)(3)(ii).

78. Several comments stated that FDA has not provided, except in § 129.80(a), for the long-established industry practice of adding minerals to adjust the taste of water that has been previously treated to meet the definition of ''distilled'' or ''purified water.'' One comment stated that water that is purified to meet the definition for ''purified water,'' and subsequently has minerals added back to it, should be exempt from the source labeling requirement in § 165.110(a)(3)(ii) because it has a totally different composition than other water from the municipal source. It stated that the labeling could indicate that the water was purified or distilled, and that minerals had been added for flavor. Another comment stated that this approach would allow for flexibility in labeling while providing adequate information for the consumer.

FDA advises that water from a community water system that has been treated to meet the definition of ''purified water'' in § 165.110(a)(2)(iv), and is labeled as ''purified water'' or one of its alternative names, is exempt from the labeling requirements of § 165.110(a)(3)(ii). Water with minerals added for taste is considered a multi-component food, and the labeling ''from a municipal source'' describes only the water ingredient. Thus, if minerals are added to purified water for taste, and the label states that the product is ''purified water (or any of its alternative names) with minerals added for taste,'' the product is exempt from § 165.110(a)(3)(ii) because the water ingredient meets the criteria for the exemption.

79. Some comments agreed with the requirement in § 165.110(a)(3)(ii) but stated that the name of the source, be it a municipal source, water authority, or any other public water system, should be specifically included on the label so that the consumer may obtain water quality test results, such as those maintained by the public water system or the relevant regulatory agency. One comment stated that consumers may then compare water quality results of the bottler with those of the public water system selling the water to the bottler, and consumers could contact the municipal source and ascertain whether a bottler is using a municipal source that adds fluoride to its finished water.

Other comments requested that all bottlers of water list on the label the source of the product contained in the bottle. Comments asked that, for full disclosure, bottled water labels include the name of manufacturer, address of source, and well number or spring's legal name, so that consumers will know specifically from where the water comes. One comment noted that many States require the geographic source identity. Another comment added that many companies are misrepresenting their products to the consumer by vague labeling.

FDA does not object to the optional label declaration of more specific information concerning the water source because such information may be useful to some consumers. However, the agency does not agree that it should require specific water source labeling, or that the lack of such labeling means that the label is misleading and vague.

Under section 201(n) of the act, the agency must consider whether the information is a material fact whose nondisclosure will render the labeling misleading. Under this standard, it is difficult to see why the name of the specific source, be it a public water supply, spring, or well, would be a material fact. The agency requires that the product water supply for each bottled water plant be from a source that is inspected and approved by the government agency having jurisdiction (§ 129.3(a)). The product water supply must be properly located, protected, and operated, and must be easily accessible, adequate, and of a safe, sanitary quality that is in conformance at all times with the applicable laws and regulations of the government agency having jurisdiction (§ 129.35(a)(1)). Thus, the specific name of the source is not material to ensure the safety of the product.

In addition, the water must meet the requirements of the quality standard in § 165.110(b) or be labeled as substandard. Thus, the identity of the specific source is not material to ensure the quality of the product.

Finally, in this final rule FDA is providing for the use of alternative names that generally describe the source of the water (e.g., artesian, spring, and well). Thus, consumers can have confidence that bottled water labeled as being from a certain type of water source is from a source meeting an appropriate definition.

Therefore, the agency concludes that the absence of information concerning the exact water source (e.g., specific municipal source, the well number, spring's legal name, address of the source) is not a material omission that would render the labeling misleading because bottled water must meet FDA's requirements which provide the consumer with assurances as to the safety, quality, and type of source. While the agency recognizes that some States require the geographic source identity, FDA simply is not persuaded that the additional information is a material fact that must be disclosed.

The brand name and the name of the manufacturer distinguish bottled waters as much as specific source labeling

would. According to § 101.5(a), the label of a food in packaged form must specify conspicuously the name and place of business of the manufacturer, packer, or distributor. This labeling requirement provides consumers with the necessary information to contact the firm and obtain information (e.g., the name and location of the source, the well number, or the spring's legal name) that is not provided on the label if they are interested. Therefore, FDA concludes that there is no basis on which to require that information concerning the specific source of bottled water appear on the label.

3. Water for Infant Use

The agency proposed to require notice on the principal display panel of bottled water products that are promoted for infant use that such products are not sterile (if such is in fact the case), and that they should be used as directed by a physician or by infant formula preparation instructions (58 FR 393 at 400).

80. One comment stated that § 165.110(a)(3)(iii) should read: ''When the label or labeling characterizes the bottled water in any manner * * * as for feeding infants, and the product is not commercially sterile, within the meaning of the term at 21 CFR 113.3(e), the principal display panel shall bear conspicuously the phrase * * *.'' The comment stated that a qualification of the phrase ''not sterile'' to ''not commercially sterile'' would clarify that, by use of the term ''sterile,'' the agency does not intend to require that bottled water for infant food use meet the requirements of the USP monographs for sterile waters which are compendial pharmaceutical articles in themselves. It stated that there is no safety concern that necessitates that bottled water for infant use meet a different standard than the standard applicable to hermetically sealed low-acid foods, and none has been articulated by FDA in the proposal.

The agency agrees with the comment. As discussed previously, unless the label or labeling of a product that is labeled for use in feeding infants implies that the product meets USP requirements, FDA will not require that the product meet those requirements for sterility because commercial sterility is adequate. Canned infant formula is processed to be commercially sterile, as defined in § 113.3(e), and the agency sees no reason to subject bottled water for infants to stricter requirements. Therefore, the agency is modifying § 165.110(a)(3)(iii) to state that its provisions apply when the product is not commercially sterile under § 113.3(e)(3)(i).

81. A number of comments opposed the use of the phrase ''not sterile, use as directed by physician or by labeling directions for use of infant formula'' in § 165.110(a)(3)(iii). The comments stated that infants, and even adults, do not require sterile foods but need foods that are free of pathogens, and that many health care professionals do not recommend sterilizing infant formula. Some comments submitted scientific publications to support their position that infants do not need sterile foods. They pointed out that infant medicines, oral preparations (vitamins), and breast milk are not sterile.

Comments noted that it is difficult for parents to achieve and maintain sterility in infant preparations and stated that there is no difference between infant formulas prepared using a clean method and formulas prepared with sterile water. They stated that boiling bottled water that is not sterile may not be preferable to using water as it comes from the bottle because potentially harmful trace elements from the container used to boil the water may be concentrated during boiling. The comments maintained that, in some cases (e.g., areas not served by municipal supplies), bottled water may be a more reliable and superior source of water for infant use than other sources of water.

Some comments held that the requirement for the use of the phrase ''not sterile'' on infant formula or bottled water labeling is outdated, inappropriate, and may be unnecessarily alarming to consumers. They asserted that the phrase may have the unintended but harmful effect of giving a false sense of security to parents that would cause them, and perhaps cause the preparer of the infant formula, to ignore several important sources of bacterial risk.

Comments stated that the recommendations calling for sterilization were made in the 1940's and 1950's, before the widespread practice of chlorination of municipal water supplies, and that bottled water products being marketed today go through a rigorous quality control program to eliminate pathogens. They maintained that there already are adequate industry standards in place, and that the phrase ''not sterile'' is not necessary.

Some comments pointed out that all aqueous systems contain a normal, nonpathogenic microbial content, and that the absence of such a normal microbial content could in itself be indicative of the presence of a microbial antimetabolite in the water. Comments stated that a requirement for the label statement ''not sterile'' lacks technical merit and is contrary to FDA's position of not imposing plate count limitations on all food products. They stated that FDA provided no scientific rationale, hospital survey data, epidemiological health data, physician-use surveys, bottled water surveys, or any other reasonable, objective information to support this requirement. The comments held that sterilization does not provide a level of safety assurance equal to the assurance provided by the conjunction of protecting the aquifer from all risks of contamination and compliance with current good manufacturing practices (CGMP's), as demonstrated by the absence of microorganisms that are indicators of contamination (fecal bacteria).

Other comments stated that requiring a statement that the water is not sterile would serve only to eliminate certain products from the bottled water market. They held that it would be grossly misleading, unjustified, and discriminatory to the infant water industry.

Comments stated that the labeling recommended, but not required, by FDA for infant formula is to direct parents to consult with their physicians before using the product. The comments stated that this labeling of infant formula is to ensure that the parents are using the proper type and amount of formula for their babies, not because there was or should be concern about the water source used to mix the product. These comments recommended that FDA drop the requirement in § 165.110(a)(3)(iii) entirely because such labeling gives medical advice to parents. As an alternative, comments suggested that labeling could state that ''parents should consult their physician for infant use.''

Conversely, several comments supported the proposal because: (1) Infants are a high-risk group in terms of susceptibility to infections, (2) consumers will interpret a label ''water for infant use'' as not requiring any preparation before use in infant formulas, and (3) the disclosure required for bottled water marketed for use with infants or children is consistent with the objectives of FDA in promulgating these regulations. One comment added that labeling that can mislead a consumer to use nonsterile water in the belief that it is sterile may cause needless illness and possibly deaths.

One comment stated that bottled water intended for the general population is used for a significant proportion of infants. It suggested a side

panel statement on all bottled water products such as: ''If using to prepare infant formula, follow the mixing instructions on the infant formula label.'' Another comment suggested that each label reference to use for infant formula preparation be accompanied by a statement referring the consumer to the side panel usage instructions.

However, another comment that supported the intent of the disclosure statement disagreed with the proposed labeling requirement for infant water. It stated that the proposed requirement in § 165.110(a)(3)(iii) is a backward approach to public health protection for infants. The comment stated that bottled water promoted for infant use should be required to meet strict sterility requirements.

FDA has considered these comments and, based on its consideration, concludes that labeling is necessary to inform consumers that bottled water labeled for infant use may not be sterile.

The agency generally agrees with the conclusions of the scientific publications that the commenters submitted. Although the conclusions of the articles demonstrated that infants generally do not need to consume a sterile product, one publication noted that ''it is safer to feed an infant an almost sterile formula, than to feed him a formula with an unknown amount of contamination'' (Ref. 18). Use of appropriate ingredients and procedures in the preparation of infant formula is key in providing a suitable product for infant consumption.

One study, concerning the inoculation of the digestive tracts of axenic mice with the autochthonous bacteria of mineral water, was conducted on 6-week-old mice and found that the autochthonous bacteria present in the mineral water from Vittel ''Grande Source'' were not able to establish themselves (i.e., to multiply and subsist in a great number) in the digestive tracts of axenic mice (Ref. 19). However, FDA questions whether these results apply to human infants because 6-week-old mice are past an infant stage. In addition, only one source of water was used in the study, and the results cannot be extrapolated to water from other sources.

The agency agrees with the comments that stated that nursing infants do not consume a sterile product, and that infants do not necessarily need to consume sterile products. However, although the heterotrophic bacteria present in water may not be harmful to the general population, high levels of some microorganisms, particularly opportunistic pathogens, may cause illness in some infants (Ref. 20). Parents need to be informed that bottled water labeled for infant use is not sterile because, without this statement, they may be led to believe that water labeled for infant use is sterile, and that its sterility is the characteristic that makes it appropriate for infant use. Thus, the agency concludes that bottled water intended for infant use should be at least commercially sterile or be labeled to inform consumers that it is not.

There are essentially two situations in which an infant may consume infant water: (1) When it is used to reconstitute powdered infant formula or dilute concentrated liquid formula; and (2) when it is not used as an ingredient of the infant formula but is otherwise fed to infants, especially when used directly for feeding infants. If infant water was used only in the first situation, the labeling statement on infant water to ''use as directed on the infant formula labeling'' would be sufficient (and indeed, the additional statement ''use as directed by a physician'' would be redundant, since this statement is also required on the formula label). Concerns of sterility are adequately addressed on the infant formula label because under § 107.20 (21 CFR 107.20), the product label must bear instructions for sterilization of water, bottles, and nipples when necessary for preparing infant formula for use. However, the second situation does not involve other appropriate labeling information. The second situation represents circumstances in which it would be appropriate to seek physician oversight, not only because of a potential concern about sterility, but also because of the concern about excessive feeding of water (and risk of hyponatremia) to infants.

FDA agrees that once a package has been opened, it is subject to contamination. The process of preparing infant formula may also introduce other sources of contamination. The contamination of these foods from environmental sources and during preparation may not be harmful to most infants. However, parents must be aware of the fact that bottled infant water is not sterile, so that they may take special precautions if needed. Parents may be purchasing bottled infant water rather than using other sources of water including tap water and other types of bottled water specifically because they assume that the infant water is sterile.

The agency is not advocating that parents boil bottled water that is not sterile and that is intended for infants. However, parents need to use infant water as directed by their physicians or by the labeling for infant formula. The agency stated in the final rule concerning labeling requirements for infant formula that ''potable,'' ''sterile,'' or ''pure drinking water'' must be used in preparing infant formula (50 FR 1833 at 1836, January 14, 1985). As stated previously in the response to this comment, under § 107.20(a)(3), infant formula labels must bear directions for sterilization of water, bottles, and nipples when necessary for preparing infant formula for use. In addition, § 107.20(b) requires that a pictogram appear on the label depicting the major steps for preparation of that infant formula. One of the steps in the example provided in the regulation includes an accompanying statement that sterilization is recommended, and that the infant's physician will decide if it is not required.

Thus, while it is true that recommendations for sterilization of water for infant use were made before the widespread practice of chlorination of municipal water supplies, FDA's regulations provide that sterilization should occur unless the physician decides otherwise. Parents need to consult with the infant's physician to determine whether sterilization is not necessary. The labeling requirement on bottled water is necessary to inform parents that the water is not sterile. Thus, if the physician says that sterilization of the infant's water is necessary, the parents will know that it is necessary to take appropriate steps to provide the infant with sterile water.

FDA agrees that bottled water ordinarily contains a normal microbial content unless treated. As some comments pointed out, the reason for the absence of microorganisms in bottled water may be from the presence of an antimetabolite (i.e., an antimicrobial agent) in the water. The bottled water standards allow for the optional addition of safe and suitable antimicrobial agents, and the lack of microorganisms may be the result of the addition or use of these agents. As defined in § 130.3(d), ''safe and suitable'' means that the ingredient performs an appropriate function in the food, is used at a level no higher than necessary to achieve its intended purpose, and is used in conformity with established regulations. Bottled water containing a substance, such as an antimetabolite, at a level considered injurious to health is deemed to be adulterated under section 402(a) of the act.

FDA disagrees that all bottled water labels need a side panel statement concerning infant use. Under section 201(n) of the act, in conjunction with section 701(a) of the act, the agency is authorized to require labeling if the

information is a material fact with respect to consequences that may result from the usual and customary use of the article. Because most bottled water is not consumed by infants, however, and thus, infant use is not the usual or customary use of bottled water, in the absence of other relevant statements in the labeling, only a mandatory statement on bottled water for infant use is necessary to disclose a material fact under section 201(n) of the act. Therefore, the agency concludes that the comment has not provided sufficient grounds to require that all bottled water bear this statement.

In regard to the comments stating that the labeling requirement is misleading, unjustified, and discriminatory to the infant water industry, the agency has found that this information is a material fact on infant water under section 201(n) of the act because the product is targeted for an infant subpopulation that has unique needs. Manufacturers are labeling their products with a special claim, and thus the agency is establishing a special requirement, the disclosure of a fact that is material in light of the claim, for the use of this claim.

Finally, the agency does not agree that all bottled water intended for use by infants should be sterile. As already discussed under this comment, infants do not always require sterile products. Thus, it is not necessary to require that bottled infant water be sterile.

Therefore, for the reasons discussed above, FDA concludes that the label statement, ''Not sterile. Use as directed by physician or by labeling directions for use of infant formula'' is appropriate for bottled water that is labeled for use in feeding infants if the product is not commercially sterile.

82. Three comments stated that the agency should consider limiting the sodium levels of infant waters to levels lower than those authorized for adults. They suggested limiting sodium levels to a maximum of 25 mg/L.

FDA disagrees with these comments. Sodium is an important nutrient for infants, and the agency has determined that it would not be prudent to take a regulatory approach that could cause bottlers to eliminate the sodium from their infant water products. However, FDA acknowledges that there is concern that, if sodium is consumed at high levels, infants may develop a taste for it that can have consequences later in life. The agency's infant formula regulations, in § 107.100(a) (21 CFR 107.100(a)), specify that for each 100 kilocalories of formula in the form prepared for consumption as directed on the container, the formula contain at least 20 mg, and not more than 60 mg, of sodium.

Bottled water is generally not a significant source of sodium. Data on the sodium content of the U.S. water supplies were reviewed and discussed in the April 18, 1984, final rule on the declaration of sodium content (49 FR 15510 at 15524). The data revealed that 50 percent of the water sources contain less than 3.0 mg sodium per 6 fluid ounces (oz), and that 95 percent contain less than 17.7 mg sodium per 6 fluid oz. Higher sodium levels, up to 52.9 mg per 6 fluid oz, occur in only 5 percent of the water sources.

Any bottled water, including bottled infant water, containing more than an insignificant amount of sodium (5 mg or more per 240 mL serving) must bear nutrition labeling that lists the number of mg of sodium per serving. The comment's recommended maximum level of 25 mg/L sodium is equivalent to 6 mg per 240 mL serving. Thus, any bottled water at or above the comment's recommended level will, in fact, be required to bear nutrition labeling.

Therefore, the agency concludes that no maximum level for sodium is warranted for bottled water labeled for infants because sodium is an important nutrient for infants, and bottled water generally does not contain more than an insignificant amount of sodium. Parents concerned about the amount of sodium in bottled water labeled for infant use will be alerted to the presence of more than an insignificant amount of sodium through nutrition labeling.

83. Three comments stated that the agency should consider limiting the nitrate levels of infant waters to levels lower than those authorized for adults. They suggested limiting nitrate levels to a maximum of 15 mg/L when expressed as nitrate (NO_3-) (3.4 mg/L when expressed as nitrogen (N)). The comments stated that infants are particularly at risk from ingestion of large amounts of nitrates which, at high doses, can result in cases of methemoglobinemia (blue baby syndrome).

In the Federal Register of December 1, 1994 (59 FR 61529) (hereinafter referred to as the December 1994 final rule), FDA established maximum levels of 10.0 ppm for nitrate (as N), 1 mg/L for nitrite (as N), and 10 mg/L (as N) for total nitrate and nitrite in bottled water (§ 165.110(b)(4)(iii)(A)). Bottled water exceeding these levels must be labeled as substandard under § 165.110(c)(3). FDA's maximum levels are based on maximum contaminant level goals (MCLG's) established by EPA in the Federal Register of January 30, 1991 (56 FR 3526). EPA based the MCLG's on the toxicity of nitrate in humans from the reduction of nitrate to nitrite in the human body. By reacting with hemoglobin, nitrite forms methemoglobin, which will not transport oxygen to the tissues and thus can lead to asphyxia (i.e., blue babies). If sufficiently severe, asphyxia can lead to death. Concern for adverse effects of nitrate and nitrite are primarily for infants and other special populations.

Therefore, because the toxicity of nitrate and nitrite in infants and other special populations was considered in establishing EPA's MCLG's, the agency concludes that there is no basis to establish a separate level for bottled water intended for infant use.

4. Method of Preparation of Purified Water

FDA did not propose to require that the method of preparation of purified water be stated on the label, although it stated that a manufacturer may include this information on the label if it desires. FDA requested comments from interested persons on the need to include this information on the label.

84. One comment stated that the specific purification process should be identified on the label because the public has a right to know what specific treatment the water receives.

FDA disagrees with the comment. Although the information may be useful for some consumers, the agency tentatively concluded in the proposal that there was no substantive basis on which to require that this information appear on the label. Under section 201(n) of the Act, the agency must determine, among other factors, whether the information is a material fact with respect to consequences that may result from use of the article, or in light of other representations made in the labeling, to require that information appear on the label. As discussed previously, purified water is defined compositionally, and there are no significant compositional differences among purified waters prepared through the different methods. Therefore, FDA finds that the comment has not provided an appropriate basis to justify a requirement that the specific purification process appear on the label, and it is not requiring that the method of preparation be stated on the label of purified water. However, a manufacturer may include this information on the label if it so desires.

5. Other Labeling

85. One comment asked that FDA reconsider IBWA's requested provision that any bottler whose corporate name, brand name, or trademark contains the

words ''spring,'' ''well,'' ''artesian,'' ''mineral,'' or any other derivation should be required to label each bottle with the type of bottled product in typeface at least equal to the size of the typeface of the corporate name, brand name, or trademark if the type of bottled water differs from that implied in the corporate name, brand name, or trademark. It stated that this requirement may eliminate some of the misconceptions consumers have about bottled water products on which the term ''spring water'' appears as part of the corporate name.

Another comment expressed concern about labels that use trade names or registered and unregistered trademarks on water that imply a geographic origin that is different from the actual source of the water.

The agency agrees that the use of certain corporate names, brand names, and trademarks may be misleading to consumers if the source of the water is different from the source stated or implied. Section 403(a) of the Act specifically states that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. Thus, the use of terms or vignettes that state or imply that the source of the water is different than the actual source would misbrand the food. In addition, section 403(f) of the Act states that a food is misbranded if any word, statement, or other information required by or under authority of the Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Thus, if required labeling describing the water is not appropriately conspicuous in relation to other label representations, the product is misbranded. Therefore, the agency concludes that it already has the authority to charge misbranding under the Act in the situations discussed by the comments, and that a specific regulation is not necessary. With the establishment of the standard of identity in § 165.110(a), FDA now has particular definitions of bottled water sources that will assist the agency in enforcing these misbranding provisions of the Act.

86. One comment stated that water can support the growth of bacteria, and that opening the bottle and pouring out the water exposes the remaining water to air and can constitute an ''inoculation'' with environmental bacteria. It stated that few consumers are aware that water is a suitable growth medium for bacteria, and that FDA may consider the advisability of a storage statement, such as ''refrigerate after opening,'' in the usage instructions for bottled water.

The agency does not agree that such labeling is necessary, although it would not object to manufacturers voluntarily including a statement such as ''refrigerate after opening'' on the label. The agency has established a microbiological quality standard in § 165.110(b)(2). In the Federal Register of October 6, 1993 (58 FR 52042), FDA proposed to amend the microbiological quality provision to require that bottled water be free of coliform bacteria. The agency expects to issue a final rule in that proceeding soon. Also in the October 6, 1993 proposal, FDA requested comments on other matters concerning the microbiological quality of bottled water. The agency will address these issues as appropriate.

FDA acknowledges that some bacteria can grow in bottled water, and that bottled water, unless treated in some manner, is not sterile. Innocuous bacteria are generally already present before the consumer's first use. Additional bacteria may enter a bottle of water with exposure to the air. However, the growth of bacteria is limited in bottled water because it is not a good source of nutrients for most microorganisms.

Therefore, the agency is not convinced that a statement such as ''refrigerate after opening'' is necessary on bottled water because water is not a good growth medium for microorganisms, and because the agency has already addressed microbiological standards in its quality standard.

III. Standard of Quality

FDA proposed to move the definition for bottled water from § 103.35(a)(1) to § 165.110(a)(1) and the standard of quality for bottled water from § 103.35 to § 165.110. The agency also proposed to include existing definitions for ''lot,'' ''sample,'' and ''analytical unit'' found in § 103.3 in part 165. Because FDA was proposing to remove the quality standard from § 103.35 and include it in § 165.110, FDA tentatively concluded that the definition of these terms should be moved as well.

87. One comment objected to a provision in § 165.3(b) that states that ''a sample consists of 10 subsamples (consumer units)'' because this amount of testing is too costly. It stated that a better procedure would be to analyze at least one sample for coliforms and heterotrophic plate count for each size of container and each type of product from one lot.

This comment falls outside the scope of this rulemaking. The agency did not propose to amend the current definitions but only to move these definitions to be in proximity with the bottled water standard in part 165. Therefore, FDA is not modifying the general definitions at this time. However, persons interested in an amendment of the definitions for ''lot,'' ''sample,'' and ''analytical unit'' may petition the agency, providing recommended definitions and justification for the recommendations.

A. Exemptions for Mineral Water

The agency tentatively concluded in the January 1993, proposal that certain aesthetically based allowable levels should not apply to waters with more than 500 ppm TDS. Accordingly, the agency proposed to add a footnote to the list of allowable levels in § 165.110(b)(4)(i)(A) to provide that when water is labeled as ''mineral water,'' it will be exempt from the allowable levels for color, odor, TDS, chloride, iron, manganese, sulfate, and zinc. However, FDA did not propose to include bottled waters that are not conspicuously identified with the term ''mineral'' or that are identified as ''mineral water, low mineral content'' in this exemption because consumers will not generally expect to encounter flavors affected by high mineral content in these bottled water products. In addition, the agency did not propose to exempt mineral water from the allowable levels for copper, fluoride, silver, and turbidity. The agency requested comment concerning the need to establish a separate turbidity level for mineral water.

The agency stated in the January 1993, proposal that, if it established an allowable level for aluminum, it would propose to exempt mineral water (except low-mineral-content type mineral waters) from that standard because the standard is intended to control the aesthetic properties of the water (turbidity) and not its effect on the body. In the December 1994 final rule, the agency established an allowable level of 0.2 mg/L for aluminum in bottled water. In a proposal published elsewhere in this issue of the Federal Register, the agency is proposing to exempt mineral water from the allowable level for aluminum.

88. Three comments stated that mineral water should be subject to all of the same regulations (including the TDS maximum allowable level) as bottled water with no exceptions. However, the comments provided nothing to support this position.

The agency disagrees with these comments. For the most part, mineral water is subject to the same requirements as bottled water. FDA is only exempting mineral water that contains more than 500 ppm TDS from the maximum level requirements for chloride, iron, manganese, sulfate, zinc, and total dissolved solids in § 165.110(b)(4) (see footnote 1 to § 165.110(b)(4)(i)(A)). The agency established these maximum levels based on aesthetic factors and not health or safety factors (27 FR 2152, March 6, 1962). Most mineral waters exceed the quality requirement of 500 mg/L for total dissolved solids because they contain higher levels of these minerals than other types of bottled water. The comments have not provided any basis for modifying the exemption for mineral water, only the general request that the agency do so. Given the nature of mineral water, and the fact that the exemption it is granting only has aesthetic significance, FDA finds no reason to make a change in § 165.110(b)(4) in response to these comments.

89. Several comments supported the proposed exemption from secondary aesthetic-based maximum limits in the case of mineral water. However, they urged the agency not to limit the exemption only to mineral waters containing more than 500 mg/L. They requested that all mineral waters, regardless of their TDS content, be exempt from the secondary aesthetic-based maximum limits. The comments stated that given that there is no consumer safety concern for these secondary maximum levels, there is no reason to limit the exemption to mineral waters with a TDS above 500 mg/L. One comment noted that a mineral water with 490 ppm TDS, 0.4 mg/L iron, and 0.08 mg/L manganese and a mineral water with the same iron and manganese content but with 510 ppm TDS would be identical from an analytical perspective, but one would be substandard, and the other would not.

In the January 1993 proposal (58 FR 393 at 401), FDA stated that it did not include bottled waters that are not conspicuously identified with the term ''mineral,'' or that are identified as ''mineral water, low mineral content,'' in the exemption because consumers will not generally expect to encounter flavors affected by high mineral content in these bottled water products.

The agency agrees that there are no consumer safety concerns for these secondary maximum levels. The exemption from the quality standard for mineral water is based on allowable levels that were established for aesthetic reasons and not for consumer safety. The allowable levels from which mineral water is exempted are color and odor (physical quality) and chloride, iron, manganese, sulfate, total dissolved solids, and zinc (chemical quality). Water containing less than 500 ppm TDS will not exceed the allowable levels for chloride, sulfate, or total dissolved solids because of the high allowable levels in the standard. In addition, it is unlikely that water containing less than 500 ppm TDS would exceed the allowable levels from which mineral water is exempted.

The agency must consider whether consumers would expect products labeled as ''mineral water, low mineral content'' to contain objectionable aesthetic characteristics. Clearly, consumer expectations exist that products labeled as ''mineral water'' may contain unique aesthetic characteristics (Ref. 21). Because products containing less than 500 ppm TDS are labeled as ''mineral water,'' FDA finds that consumers will be informed that the product may contain objectionable aesthetic characteristics. Therefore, FDA concludes that the exception should also apply to ''mineral water, low mineral content.'' FDA is modifying the footnote to § 165.110(b)(3) and § 165.110(b)(4)(i)(A) to include all mineral water, including that containing less than 500 ppm TDS.

90. Some comments stated that it might be appropriate for the agency to clarify in the text of the regulation that the standards for which an exemption is provided for mineral water are aesthetically based and do not relate to a health concern.

FDA agrees that the exemptions from the allowable levels in the standard are for those that are based on EPA secondary maximum contaminant levels (SMCL's), which were established for aesthetic reasons and not for health or safety reasons, although the agency is not exempting mineral water from all of the allowable levels based on EPA's SMCL's. FDA finds that the requested modification in the footnote of the regulation would clarify the intent of the exemption. Therefore, the agency is modifying the footnote to § 165.110(b) to state that the exemptions are aesthetically based allowable levels and do not relate to a health concern.

91. Some comments urged the agency to exert caution concerning certain harmless, naturally occurring minerals that the agency characterizes as possibly causing negative aesthetic effects. They urged the agency to consider the rate of consumption by consumers of mineral waters containing these compounds before making any final decision.

The agency assures the commenters that, as it considers how EPA's SMCL's should apply to bottled water and to mineral water in particular, FDA has evaluated, and will continue to evaluate, whether the aesthetic effect of the substance will be of concern to consumers. This evaluation includes a consideration of the rate of consumption of mineral water. The agency is exempting mineral water from some but not all allowable levels that are based on EPA's SMCL's. As FDA explained in response to the previous comment, FDA has formulated the quality standards to protect consumers from any adverse effects on the body, even those that may be characterized as aesthetic.

92. One comment recommended that FDA reexamine the allowable levels for fluoride in the case of carbonated mineral water packaged in bottle sizes of 1.5 L or less because consumers will not use products packaged in these types of containers as a tap water alternative, and there will be a much lower average daily intake of these products. The comment stated that it would promote fairness towards existing mineral water bottlers by setting standards in a manner that is the same as that used for other food products. It suggested that the maximum allowable concentration of fluoride be no greater than 3.0 ppm for carbonated mineral waters, where the TDS is between 500 and 1000 ppm, and up to 6.0 ppm where the TDS is above 1000 ppm.

Another comment recommended that FDA set the fluoride limit for bottled waters at 2 ppm. The comment said that this limit is a feasible one for mineral water producers to meet. As an alternative, based on the theory that children rarely consume much of the high-mineral waters that are likely to have a high fluoride level, the comment suggested that FDA permit a fluoride content of more than 2 ppm in mineral waters, provided that the label bear this prominent warning: ''Not recommended for use by children; fluoride content can contribute to a significant risk of dental mottling.''

FDA disagrees that mineral water should be exempt from the maximum levels for fluoride for bottled water. Although mineral water may not be consumed in as great a quantity as other types of water, consumers may obtain fluoride from other sources, and thus, mineral water can contribute to excessive total consumption of this mineral.

The agency notes that the quality standard sets forth maximum levels for fluoride. FDA proposed a revised allowable level for fluoride of 2.0 ppm

for naturally occurring fluoride in bottled water (53 FR 36063 at 36067, September 16, 1988). The agency will be proceeding with that rulemaking now that EPA has published a notice of intent not to revise its fluoride drinking water standards (58 FR 68826, December 29, 1993). The label of bottled water, including mineral water, containing fluoride at levels greater than the maximum allowable levels of fluoride in § 165.110(b)(4)(ii) must bear the statement ''contains excessive fluoride'' in accordance with § 165.110(c)(3).

93. One comment stated that, if in the final rule FDA allows an exemption for sulfate in mineral water containing more than 500 ppm TDS, FDA should require that all bottled water containing sulfates display labels with language similar to the following: ''Warning, this product may contain high levels of sulfate which may cause diarrhea in sensitive population groups including infants, children, and pregnant women.'' It stated that this statement should be a minimum requirement because there is evidence that sensitive population groups are susceptible to harmful effects from products that contain sulfates.

The agency notes that in the Federal Register of December 20, 1994 (59 FR 65578), EPA proposed a MCLG and a National Primary Drinking Water Regulation (NPDWR) including a MCL of 500 ppm TDS for sulfate. EPA stated that sulfate is a unique contaminant because the health effect associated with the ingestion of relatively high levels of sulfate in drinking water (i.e., ranging from loose stools to diarrhea) is acute and temporary and is expected to last approximately 2 weeks. In addition, EPA stated that the health risk only applies to persons not already acclimated to high sulfate-containing water—infants, travelers, and new residents. EPA did not propose to amend the SMCL of 250 mg/L for sulfate that is based on aesthetic effects (i.e., taste and odor).

In the Memorandum of Understanding (MOU) concerning the control of drinking water, EPA and FDA agreed that the authority to control substances in drinking water should be vested with EPA to avoid duplicative and inconsistent regulation. Therefore, FDA is not establishing a maximum allowable level for sulfate in mineral water at this time. However, if EPA establishes an MCL for sulfate in public drinking water, in accordance with section 410 of the act (21 U.S.C. 349), FDA will consider amending the bottled water quality standard to establish a maximum allowable level for sulfate in mineral water.

The agency is exempting mineral water from the allowable level for sulfate of 250 ppm at this time because some mineral waters exceed this aesthetically determined level without causing any adverse effects (Ref. 22). However, if mineral water contains sulfate, or any other substance, at a level that is injurious to health, it is deemed to be adulterated and subject to regulatory action.

94. One comment stated that under the January 1993 proposal, bacteriologically and chemically pure artesian or mineral water, for example, that is safe for consumers would have to bear the label statement ''abnormal color and smell,'' even if the ''abnormal'' color and smell results from perfectly normal, naturally occurring dyes and gasses that are constituent to its source. The comment contended that these substances make the water unique by their individual combination and are often sought or favored by consumers, both domestically and internationally. It stated that the designation ''abnormal'' on unadulterated, uncontaminated water is an inappropriate requirement for labeling. It stated that it is especially inappropriate when the source waters are unique, identified as to their source, and otherwise pure, natural, and uncontaminated.

FDA established the physical quality standards concerning color and odor based on EPA SMCL's. These allowable levels were established for aesthetic reasons and not to ensure consumer safety. The primary purpose of a quality standard is to establish the minimum acceptable quality criteria for a product when it is offered to consumers. The quality standard for bottled water is based on the normal range of waters, and a consumer's expectation is also based on the normal range of waters. Thus, the label needs to respond to that expectation and not be tailored to individual situations. Because bottled water that does not meet the color and odor quality standard may be objectionable to consumers, the labeling requirements established in the standard continue to be appropriate for bottled water in general.

Therefore, bottled water (e.g., artesian water) that is not exempted from the quality standard and that exceeds the maximum allowable levels for color or odor must bear the label statements ''Abnormal Color'' or ''Abnormal Odor'' as required by § 165.110(c)(2). However, the agency points out that in the case of mineral water, products that do not meet the color and odor quality standard are exempted from the standard.

B. Substandard Chemical Quality Labeling

In the January 1993 proposal, FDA tentatively concluded that the general phrase, ''Contains Excessive Chemical Substances,'' may not be adequate for mineral water and proposed that the label or labeling of mineral water list the specific names of any substances present in amounts that exceed the allowable levels to which mineral water is subject (e.g., ''Contains Excessive Fluoride,'' ''Contains Excessive Trihalomethanes'').

95. Two comments objected to allowing bottlers to distribute a product that does not meet the water quality standards. One comment stated that the purpose of water quality standards is to prevent products that are below acceptable standards from being distributed to consumers. It noted that given the emphasis by the bottled water industry on the quality of bottled water versus tap water, it is quite doubtful that bottlers would print any substandard notice on the product label. Another comment questioned whether consumers would be able to interpret the significance of the phrase ''contains excessive chemical substances'' on a label. It requested that FDA require at a minimum that the specific chemical substances be listed similar to FDA's proposal for substandard mineral water.

One comment questioned whether bottled water exceeding the microbiological standards should be sold at all, regardless of how it is labeled.

FDA notes that under section 403(h)(1) of the act, a food is deemed to be misbranded if it is a food for which a standard of quality has been prescribed by regulation, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard. Bottled water may be sold even though it contains a substance at a level that exceeds the maximum allowable levels in the quality standard so long as that substance does not adulterate the food under section 402 of the act. However, the agency points out that most of the maximum allowable levels in the bottled water quality standard are identical to EPA MCL's, and EPA establishes its levels based on health considerations. Therefore, many substances, including microorganisms (e.g., coliforms), present in amounts exceeding FDA's maximum allowable levels could be present at levels that are injurious to health.

The agency disagrees with the request that it require, at a minimum, that the specific chemical substances that exceed the maximum allowable levels in § 165.110(b)(4) to be listed on the label instead of providing the exception in § 165.110(c)(3) if the bottled water is not mineral water. The chemical content of mineral waters generally exceeds one or more allowable levels in the bottled water standard, and thus, consumers would expect mineral water to normally contain excessive chemicals. As discussed above, the agency has exempted mineral water from certain allowable levels in the quality standard on this basis. Consumers would not expect bottled water that is not mineral water to contain any excessive chemicals because the quality standard is based on the normal range of waters.

Therefore, the agency concludes that the statement ''contains excess chemical substances'' is appropriate for bottled water other than mineral water, and that it is not necessary to require more specific labeling because consumers will be alerted to the presence of chemical substances in amounts that exceed the maximum allowable levels. However, the agency does not object to the labeling of bottled water that declares the substandard presence of specific chemicals in lieu of the more general statement ''contains excess chemical substances.''

FDA notes that it has made a number of editorial modifications in § 165.110(c), including deleting and renumbering several of the provisions that appeared in the proposal, for clarity.

IV. Current Good Manufacturing Practices

A. Product Water, Operations Water, and Compliance Procedures

On January 5, 1993, the agency proposed to update the references in § 129.35 and to delete the exclusion for mineral water from testing requirements in § 129.80(g). FDA also proposed to permit firms that use a municipal water system as the source of their water to substitute municipal testing results showing full compliance with the EPA primary and secondary drinking water regulations (or a certificate to this effect) for the source water chemical contaminant testing required in § 129.35(a)(3). In addition, the agency proposed to permit firms that use a nonmunicipal water source as the source of their water to reduce the frequency of testing and the number of chemical contaminants for which they test source water if they can document that such reduction is consistent with a waiver that the State has issued under EPA regulations (§ 129.35(a)(4)(ii)).

96. Several comments suggested that FDA use the term ''public water supply'' as defined by EPA rather than use the term ''municipal supply.'' (See previous discussion in comment 72.)

The agency notes that it used the term ''municipal water system'' in proposed source water testing exemptions in § 129.35(a)(4) (58 FR 393 at 407). However, FDA agrees that in the context of this section, the term ''public water system'' is more appropriate because it includes water that is covered by EPA's drinking water regulations and State programs established under EPA programs. The intent of FDA's testing exemptions was to apply to water based on whether or not the source was a public water system. Therefore, the agency is modifying § 129.35(a)(4)(i) to include firms that use a public water system for source water and § 129.35(a)(4)(ii) to include firms that do not use a public water system.

97. One comment requested that all types of nonmunicipal sources maintain documentation on file that establishes that the source has been evaluated and determined to meet the design, operation, and maintenance requirements of the government agency having jurisdiction.

The agency advises that firms must have source approval of their product water and must maintain records of the source approval. According to § 129.3(a), an ''approved source,'' when used in reference to a plant's product water or operations water, means a source of water and the water therefrom, whether it be from a spring, artesian well, drilled well, municipal water supply, or any other source, that has been inspected, and the water sampled, analyzed, and found to be of a safe and sanitary quality, according to the applicable laws and regulations of the State and local government agencies having jurisdiction. The presence in the plant of current certificates or notifications of approval from the government agency or agencies having jurisdiction constitutes approval of the source and the water supply. Therefore, no action is necessary in response to the comment.

98. Comments stated that no standards are set to protect a well or spring and its recharge area against the intrusion of contaminants. One comment stated that there should be very strict rules governing ownership, control, and protection of the recharge area of any well or spring.

FDA agrees that the recharge area of any well or spring is a critical area. However, the agency disagrees that it is necessary to establish requirements concerning ownership, control, and protection of the recharge area of any well or spring because it has already established requirements in parts 129 and 165 to guard against the presence of contaminants in bottled water, whether from the recharge area or any other source of contamination.

First of all, the source of the water must be an approved source, and the water found to be of a safe and sanitary quality by the government agency approving the source (§ 129.35(a)). Such source approval could include the source of recharge to determine whether the water will be of a safe and sanitary quality.

In addition to meeting the requirements of part 129, bottled water must meet the requirements of the quality standard in § 165.110(b) or be labeled as substandard in accordance with § 165.110(c). The quality standard lists allowable levels for many common contaminants of recharge areas (e.g., pesticides and nitrates).

Finally, as stated in § 165.110(d), 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 water bears a label statement of substandard quality. Therefore, the agency concludes that consumers are protected against problems that may occur in the recharge area of a spring or well used as a source for any bottled water product.

99. One comment stated that any water under the influence of surface water must be treated as surface water and should never be called ''spring water,'' ''well water,'' or ''natural water,'' regardless of whether it was collected from a spring or pumped from a well.

Another comment stated that, in general, the microbiological standards in the proposed regulation are weak and do not address the issue of ground water under the influence of surface water. The comment urged FDA to incorporate appropriate source approval standards similar to those of the State of North Carolina as a means to ensure safe bottled spring and well waters.

One comment requested that FDA state that spring water must not be under the direct influence of surface water. The comment stated that a requirement, such as an initial water particulate test during the rainy season, should be considered for spring water.

The agency agrees that any water under the direct influence of surface water is not ground water, regardless of whether it was collected from a spring or pumped from a well. EPA defines

''ground water under the direct influence of surface water'' in 40 CFR 141.2 as any water beneath the surface of the ground with significant occurrence of insects or other macroorganisms, algae, or large diameter pathogens such as *Giardia lamblia,* or significant and relatively rapid shifts in water characteristics such as turbidity, temperature, conductivity, or pH which closely correlates to climatological or surface water conditions. The manifestation of any of these factors evidences that the source is under the direct influence of surface water and is, therefore, not a ground water source. The definitions of ''spring water,'' ''artesian water,'' ''mineral water,'' and ''well water'' that FDA is adopting in this document require that the source be a ground water source.

EPA has published a *Consensus Method for Determining Groundwaters Under the Direct Influence of Surface Water Using Microscopic Particulate Analysis (MPA)* (Ref. 23). The consensus method is the result of a collaborative effort combining the experiences and knowledge of contributors from around the country into an acceptable consensus method. This guidance may be used to determine whether ground water is under the direct influence of surface water. This determination may be considered as part of the source approval conducted by the State or local agency having jurisdiction because, under § 129.3(a), source water must be found to be of a safe and sanitary quality.

FDA adds that it published a proposal, to amend the quality standard for bottled water to require that bottled water be free of coliform bacteria (58 FR 52042). In that proposed rule, FDA also addressed other matters concerning the microbiological quality of bottled water and requested comments on whether the agency should establish quality standard regulations for other microorganisms that may be present in bottled water and pose a health hazard. The agency will discuss the comments that it received in response to that proposal in that rulemaking.

100. One comment recommended added testing for bacteriological contaminants, trihalomethanes, lead, and copper in those situations where the bottled water manufacturers will be permitted to substitute municipal test results for the testing requirements of § 129.35(a)(3). It stated that additional testing is necessary for these contaminants because of contamination that could occur in the water distribution system.

One comment stated that allowing bottled water producers that use a municipal water source to substitute municipal testing results for the source testing requirements is reasonable only if the final product testing requirements are retained.

FDA disagrees that it should require additional testing by bottled water manufacturers who substitute public water system test results for source water testing. However, the agency agrees with the comment that stated that the substitution of public water system test results for source water testing is appropriate only if the final product is tested according to the requirements in § 129.80(g). The testing exemptions for microbiological contaminants that FDA established previously (§ 129.35(a)(3)(i)) and for chemical contaminants that FDA is establishing in this rulemaking (§ 129.35(a)(4)(i)) apply to the source water testing requirement only. Part 129 also requires testing of product water (i.e., after processing but prior to packaging) and finished product. Under § 129.80(a), product water samples must be taken after processing and before bottling by the plant and analyzed as often as is necessary to ensure uniformity and the effectiveness of the processes performed by the plant. In addition, under § 129.80(g)(1) and (g)(2), a bottled water plant must analyze a representative sample of the finished product of each type of bottled drinking water at least once a week for the presence of bacteria and at least annually for chemical contaminants.

The agency concludes that no additional chemical or microbiological testing requirements are necessary for bottled water manufacturers who use public water systems and who substitute testing results from the public water system for source water testing requirements in part 129 because FDA requires that product water and finished product water be regularly tested, and if any contaminant is contributed by the water distribution system it will be detected by the required testing. The testing requirements in § 129.80 have functioned satisfactorily since FDA adopted them in 1979 (44 FR 12173, March 6, 1979), and the agency finds no reason to amend them. FDA points out that its adoption of the source water testing exemptions in § 129.35(a)(4) in no way changes how product water and finished product water are to be tested.

101. Two comments objected to § 129.35(a)(4)(ii) regarding a waiver for nonmunicipal water used by firms for the purposes of manufacturing bottled water. They stated that under proposed § 129.35(a)(4)(ii), a firm could reduce the number of contaminants for which it tests, and the frequency with which it performs testing, if it can document that such reduction is consistent with a waiver that the State has issued under EPA regulations. The comments stated that FDA should not allow a manufacturer to establish that such a waiver exists but should require the governmental entity regulating the source to make such a determination.

The agency disagrees with the comments. Firms may reduce the frequency of testing and the number of chemical contaminants for which they test source water if they can document that such reduction is consistent with a State-issued waiver under EPA regulations for public water systems. State waivers may either eliminate the requirement for a 3-year compliance period (e.g., pesticides/polychlorinated biphenyl's (PCB's)) or reduce the frequency of testing (e.g., inorganics and volatile organic chemicals). Waivers are either based on a review of established criteria (''a waiver by rule'') or on a vulnerability assessment. In the Federal Register of January 30, 1991 (56 FR 3526 at 3562), EPA discussed the criteria for waivers by ''rule'' and ''vulnerability assessment.''

EPA may rescind waivers issued by a State where EPA determines that the State has issued a significant number of inappropriate waivers. If a waiver is rescinded, the firm must monitor in accordance with the requirements in § 129.35.

States develop their own specific vulnerability assessment procedures that use the general guidelines established by EPA. If a State chooses not to develop these procedures, firms cannot receive waivers and must monitor the source water in accordance with § 129.35.

Therefore, firms cannot decrease the amount of testing that they perform unless the State has issued a waiver to them. The presence of a current State-issued document in the plant will certify that testing of source water may be reduced. The reduction in testing is only for those contaminants covered by the waiver. If the State has not issued such a waiver, the firm must annually test for all contaminants.

FDA points out that the State-issued waiver from chemical testing requirements in § 129.35(a)(4) applies only to source water testing, and that the product water must be tested in accordance with § 129.80(a). Moreover, the finished product must be tested for all substances in accordance with § 129.80(g). Thus, FDA concludes that no modification of § 129.35(a)(4)(ii) is warranted.

102. One comment recommended that § 129.35(a)(4)(ii) be modified to require that at least two complete samples for

all contaminants be made before any reduction in testing is allowed, even when the State has issued a waiver. It stated that there can be great variation in contaminant levels in both surface and ground water sources, even with withdrawal points that are in close proximity. The comment claimed that a requirement for initial sampling is the only way to ensure that waivers are appropriate, and that, where firms make use of this testing exception, they should be required to maintain the data from initial sampling and support documentation on State waivers indefinitely rather than for the 2-year period typically required for test data.

The agency disagrees with the comment. As EPA explained in the Federal Register of January 30, 1991 (56 FR 3526 at 3562), waivers are granted on a contaminant-by-contaminant basis. Waivers for pesticides/PCB's and volatile organic chemicals (VOC's) may be granted after the firm conducts a vulnerability assessment, and the State determines that the source is not vulnerable based on that assessment. A waiver must be renewed every 3 years (*id.*). Waivers for inorganic contaminants (except nitrate/nitrite) may be granted for up to 9 years. If a firm does not receive a waiver, it must comply with the requirements in § 129.35.

The vulnerability assessment is based on a two-step waiver procedure. Step 1 determines whether the contaminant was used, manufactured, stored, transported, or disposed of in the area. In the case of some contaminants, an assessment of the contaminant's use in the treatment or distribution of water may also be required. ''Area'' is defined as the watershed area for a surface water system or the zone of influence for a ground water system and includes effects in the distribution system. If the State determines that the contaminant was not used, manufactured, stored, transported, or disposed of in the area, then the system may obtain a ''use'' waiver. Systems receiving a ''use'' waiver are not required to continue on to Step 2 to determine susceptibility. EPA anticipated that most ''use'' waivers will be for pesticides/PCB's, the use of which can be determined more easily than for VOC's. Obtaining a use waiver for the VOC's will be limited because VOC's are ubiquitous in the United States (56 FR 3526 at 3562).

If a use waiver cannot be given, that is, if the State cannot make a determination that the contaminant was not used, manufactured, stored, transported, or disposed of in the area, a system may conduct an assessment to determine susceptibility (Step 2). Susceptibility considers prior occurrence or vulnerability assessment results, environmental persistence and transport of the chemical, the extent of source protection, and EPA Wellhead Protection Program reports. Systems with no known ''susceptibility'' to contamination based upon an assessment of the above criteria may be granted a waiver by the State. If ''susceptibility'' cannot be determined, a system is not eligible for a waiver (56 FR 3526 at 3563).

EPA also established guidelines for decreased monitoring of inorganic chemicals (56 FR 3526 at 3564). States may decide, based on prior analytical results, variation in analytical results, and system changes such as pumping rates or stream flows/characteristics, to allow firms to reduce the monitoring frequency to no less than 9 years. To qualify for this waiver, at a minimum, three previous compliance samples must have been reliably and consistently less than the MCL.

The above minimum guidelines, along with any additional State requirements, provide adequate consumer protection because a firm must perform appropriate testing before a waiver will be issued. In addition, the use or susceptibility requirements of the program provide assurances that a contaminant is not present in the area. Finally, the waiver does not extend to testing of the product water and the finished product. Thus, FDA concludes that the requirements for obtaining the waiver adequately address consumer safety concerns.

Firms must document that they have a current State-issued waiver, and that the waiver complies with State requirements even though the waiver may have been issued prior to the 2-year record retention time period required by § 129.80(h). Records of the waiver must be retained for not less than 2 years after the waiver expires to meet the requirements of § 129.80(h). This retention requirement ensures that all testing records, exemptions from testing, and source approval requirements are documented for the same production batch of bottled water. However, the agency sees no need for manufacturers to maintain these records indefinitely, and the comment has not provided grounds for such a requirement.

103. One comment asked whether FDA is requiring the same sampling frequency as is required for public systems under EPA's Phase II rules (56 FR 3526) by including the waiver process in this regulation. The comment stated that, for example, inorganics could be tested at a frequency of once every 9 years according to EPA regulations. It asked whether FDA feels that such a frequency of testing provides adequate protection of source water.

The agency notes that manufacturers must comply with all the source testing requirements in § 129.35(a)(3) unless they have received a State-issued waiver for specific contaminants. As discussed above, under EPA's Phase II rules (56 FR 3526), States may issue waivers only if circumstances affecting the source and the area surrounding the source make it unlikely that the contaminant will be present. Based on its review of the evidence on these factors, the State may issue a waiver decreasing the frequency of testing from 3 to 9 years depending on the contaminant.

FDA believes that the use of a State-issued waiver is an appropriate substitute for source water testing because a State must require that the water be tested before issuing the waiver, and that the conditions relevant to the occurrence of the contaminant confirm that it is unlikely that the contaminant will be present. Again, FDA affirms that the finished bottled water must be tested at least annually for chemical contaminants and comply with FDA regulations.

104. One comment stated that, because the source has no bearing on the final product for purified or distilled water, there was reason to question whether it was necessary for a bottler that bottles only purified water to have annual chemical and radiological tests of its source water.

FDA disagrees with the comment. Source testing is important to ensure the purity of the source water. The source water must be of reasonable quality to ensure that the finished product complies with the quality requirements. If a source contains excessively high levels of some contaminants, these contaminants may not be adequately removed in the purification process. Therefore, the agency concludes that the source water for purified water should not be exempt from all the requirements of part 129. However, the agency notes that there are source water testing exemptions in § 129.35(a)(4) that may apply to the source water for purified water. If applicable, these exemptions could replace or reduce the source testing requirements for chemical contaminants.

105. One comment expressed concern about FDA regulating the testing of source water if FDA would preempt State agencies from setting standards for source water that are equivalent to State Drinking Water Standards. The comment held that the State should have the authority to set more stringent standards for source water when there is

a safety issue. It noted that water bottled in a State should have at least the same health-based quality standards as public drinking water in that State. The comment questioned whether FDA has jurisdiction over source water and was opposed to FDA regulating the water quality standards for source water, which are under the jurisdiction of the States or EPA.

The agency notes that it is not amending its regulations with respect to the testing of source water except to provide that bottlers using a public water supply may substitute certificates showing compliance with EPA's requirements for chemical contaminants for testing results, and that bottlers may use a State-issued waiver for some chemical contaminants. Section 129.35(a)(3) specifies the frequency of testing of source water for chemical, radiological, and microbiological contaminants. This sampling is in addition to any that is performed by government agencies having jurisdiction. The source is approved by the State or local government agency having jurisdiction and must comply with the applicable laws of that agency, even though those laws are more stringent than FDA requirements. FDA has traditionally relied on the laws of the State or locality having jurisdiction. Therefore, FDA concludes that there is no basis for the concern expressed by the comment.

B. Additional Definitions

Although the agency did not propose definitions for ''bottled water plant,'' ''plant operator,'' or ''water dealer,'' or to revise the definition for ''bottled drinking water,'' as IBWA requested, FDA requested comment from interested persons on the need to define or amend the definitions of these terms.

106. One comment recommended that FDA define ''bottled water plant.'' It stated that such a definition would enable States that have bottled water regulations to adopt a uniform definition.

The agency has decided that it is not necessary to adopt a definition for ''bottled water plant.'' Part 110, concerning CGMP in manufacturing, packing, and holding human food, applies to bottled water along with part 129. Under § 110.3(k), ''plant'' means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food. Thus, ''bottled water plant'' can be fairly interpreted, under FDA's regulations, to mean the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of bottled water. In its petition, IBWA defined ''bottled water plant'' as any place or establishment in which bottled water is prepared for sale. The State of California defines ''water-bottling plant'' as any facility in which bottled water is produced (Ref. 2). Thus, FDA concludes that the definition in § 110.3(k) is adequate because it is consistent with the common definition of a bottled water plant, and that a specific definition for this term in part 129 is not necessary.

C. Unregulated Contaminants

IBWA requested revision of part 129 to provide for additional source and final product testing requirements in § 129.35 to detect and control specific unregulated contaminants. The agency did not propose to require such testing because firms are free to test for contaminants not listed in the quality standard, and they must employ appropriate quality control procedures to ensure that food is suitable for human consumption (§ 110.80). In addition, bottled water that contains a poisonous or deleterious substance is subject to regulatory action under the adulteration provisions of the act. Producers that knowingly produce and distribute adulterated bottled water may be subject to the criminal penalties of the act.

107. One comment requested that FDA amend § 129.35 to require testing of bottled water products (on at least an annual basis) for those substances listed in EPA's requirements for monitoring of unregulated contaminants. It stated that this requirement should be made immediately applicable to all bottled water producers.

The agency disagrees with the comment. Under section 1445(a) of the SDWA, EPA was required to promulgate monitoring requirements for unregulated contaminants. EPA established monitoring requirements for 51 synthetic organic chemicals in the Federal Register of July 8, 1987 (52 FR 25690), and promulgated monitoring requirements for an additional 30 synthetic organic chemicals and inorganic chemicals in the Federal Register of January 30, 1991 (56 FR 3526), that were not regulated by NPDWR's to assist EPA in establishing future NPDWR's. EPA did not establish regulations that would set forth maximum levels of these contaminants, only the requirement that public water systems monitor for them.

FDA does not believe that it is necessary to mandate testing for unregulated contaminants in bottled water because such testing is for EPA monitoring and information purposes only. As EPA identifies the need to regulate a substance from its monitoring activities, and subsequently adopts MCL's for them, FDA will promulgate applicable regulations for bottled water under section 410 of the act (21 U.S.C. 349). The comment did not provide a basis to establish a requirement for additional testing. It only requested that FDA do so. Therefore, the agency concludes that amending § 129.35 in the manner suggested by the comment is not warranted.

108. One comment stated that additional final product testing should be required for any contaminants that can enter the water through the water system or through the bottles. It stated that these contaminants, given their low levels, may not be poisonous or immediately deleterious but should not be in bottled water. The comment stated that several years ago, a California firm used a new clear resin that was subsequently found to be leaching cyclohexanes, among other things. It stated that at least one consumer injury was reported when a particularly bad batch of resin was used. The comment cited another instance of chemicals entering the water from improperly cured new piping. It stated that in these instances, the required source water monitoring for additional contaminants would not have uncovered the problem in the finished product.

FDA disagrees that it should establish additional finished product testing requirements for chemical contaminants derived from processing equipment or packaging. Substances that get into the product from product contact surfaces can vary from manufacturer to manufacturer and from lot to lot. The agency considers these substances to be indirect food additives. Thus, any product that contains such a substance whose use has not been regulated by FDA will be deemed to be adulterated under section 402(a)(2)(C) of the act (21 U.S.C. 342(a)(2)(C)) in that it contains an unsafe food additive.

Under § 129.40(a), all plant equipment and utensils must be suitable for their intended use. Included under the coverage of this section are all collection and storage tanks, piping, fittings, connections, bottle washers, fillers, cappers, and other equipment that may be used to store, handle, process, package, or transport product water. All product water contact surfaces must be constructed of nontoxic and nonabsorbent material that can be adequately cleaned and sanitized and that is in compliance with section 409 of the act (21 U.S.C. 348). Furthermore, § 129.80(f) requires that only nontoxic containers and closures be used. ''Nontoxic materials'' is

defined in § 129.3(e) as materials for product water contact surfaces, used in the transporting, processing, storing, and packaging of bottled drinking water, that are free of substances that may render the water injurious to health or that may adversely affect the flavor, color, odor, or bacteriological quality of the water. Therefore, the agency concludes that there are already adequate provisions in part 129 to address the comment's concern, and that no modifications are necessary.

D. Microbiological Control Standards

IBWA requested revision of § 129.40 to include microbiological control standards that included prohibitions from processing and bottling water with equipment that has been used to produce milk, fruit juice, or any other food product likely to contribute nutrients for microbiological growth. FDA was not persuaded by the information that IBWA submitted that the revision was needed.

109. A number of comments stated that FDA did not provide a sufficient rationale for not requiring that firms use dedicated equipment (i.e., equipment used solely for one product) for processing bottled water. One comment stated that dedicated equipment, with the exception of fillers, is an important precaution to maintain the quality of bottled water.

One comment stated that FDA should prohibit equipment used for milk production from being also used for bottled water production to protect consumers from potential health hazards. It stated that there is a greater potential of microbiological contamination of bottled water if it is produced using equipment that is also used for milk production. Another comment stated that high coliform and other bacteria counts from either inadequate cleaning or inadequately trained personnel improperly maintaining or operating the equipment has been a problem with at least one California dairy that also bottles water.

Several comments were concerned that FDA proposed no restriction on the use by water bottlers of: (1) Equipment used to transport, store, process, or bottle nonfood products (e.g., pesticides, toxic chemicals); and (2) equipment used to transport, store, process, or bottle food products likely to contaminate bottled water with nutrients for microbial growth. The comments stated that these equipment use restrictions are important public health safeguards.

Conversely, other comments supported FDA's position that dedicated lines for bottled water should not be a requirement. The comments noted that only good sanitation will ensure a low probability of microbiological contamination. One comment stated that the rationale used by the agency is supportable based on the performance history of the dairies and soft drink manufacturers that also produce bottled water.

One comment stated that certified results confirmed that bottled water produced by dairy plants equalled or exceeded the bacterial quality of that produced by dedicated water bottlers. It stated that all bottlers should be subject to the same quality and testing regulations.

One comment from a dairy stated that a requirement for dedicated equipment would eliminate that dairy from the bottled water market. The comment stated that, because the firm is experienced in high quality sanitation practices from bottling fluid milk products, it is confident of its ability to meet regulatory product standards for consumer safety.

One comment stated that, although milk, fruit juice, and other food processing operations should not be prohibited from processing bottled water, additional operational requirements should be imposed on these types of processing plants because of the likelihood of mineral deposits building up inside feed lines. The comment stated that these mineral deposits tend to shield bacteria and other pathogens from disinfection if standard disinfection practices are used.

FDA disagrees with the comments that stated that it should require dedicated equipment for processing bottled water. Under § 129.37(a), the product water-contact surfaces of all multiservice containers, utensils, pipes, and equipment used in the transportation, processing, handling, and storage of product water must be clean and adequately sanitized. All product water-contact surfaces must be inspected by plant personnel as often as necessary to maintain the sanitary condition of such surfaces and to ensure that they are free of scale, oxidation, and other residues. The presence of any unsanitary condition, scale, residue, or oxidation must be immediately remedied by adequate cleaning and sanitizing of that product water-contact surface before it is used again.

Section 129.40(a)(2) requires that all product water contact surfaces be constructed of nontoxic and nonabsorbent material that can be adequately cleaned and sanitized and that is in compliance with section 409 of the act. Furthermore, § 129.80(d) states that sanitizing operations must be adequate to effect sanitization of the intended product water-contact surfaces and any other critical area. Therefore, the agency concludes that there already are appropriate regulations in part 129 that adequately address the concerns of the comments.

As FDA stated in the proposal (58 FR 393 at 403), dedicated equipment will not ensure that the goal of production of foods with a low probability of microbiological contamination will be met. Only good sanitation will ensure that this goal is achieved. FDA does not require dedicated equipment for any other food and is not persuaded that dedicated equipment is necessary for bottled water. Bottled water containing any substance considered injurious to health is adulterated under section 402(a)(1) of the act.

Microbiological standards exist for bottled water in § 165.110(b)(2). Manufacturers must ensure that bottled water meets the microbiological quality standards in § 165.110(b)(2) or label the product as substandard. If the product is deemed to be adulterated, it cannot be sold at all.

In the Federal Register of October 6, 1993 (58 FR 52042), the agency proposed to amend the quality standard to require that bottled water be free of coliform bacteria. In addition, FDA addressed other matters concerning the microbiological quality of bottled water and requested comments on whether it should establish quality standard regulations for other microorganisms that may be present in bottled water and may pose a health risk. The agency intends to discuss the comments that it received in response to that proposal in that rulemaking.

E. Processes and Controls

IBWA requested revision of certain requirements in part 129 pertaining to filtration and germicidal treatment. FDA did not propose the requested revisions but stated that it would consider adopting them in other rulemakings. As stated above, the agency has proposed to amend the quality standard for bottled water to require that bottled water be free of coliform bacteria (58 FR 52042). In that proposal, FDA also addressed other matters concerning the microbiological quality of bottled water and requested comments on whether the agency should establish quality standard regulations for other microorganisms that may be present in bottled water and may pose a health risk. The agency will discuss the comments that it received in response to that proposal in that rulemaking.

110. Several comments urged FDA to require mandatory disinfection of

bottled water with ozone or an equivalent disinfection process. Two comments stated that failure to require treatment of mineral water with ozone or an equivalent disinfectant process would reduce the level of public health protection now provided.

However, some comments stated that bottled water need not be disinfected if it meets the standards of the European Economic Community Directive 80/777/EEC for Natural Mineral Water, July 15, 1980 (European Community), which mandates that numerous and frequent microbiological analyses of the water be done to ensure its potability in lieu of disinfection. One comment stated that mandatory disinfection of mineral water that includes bottled water products covered by the ERCS for ''natural mineral waters'' would constitute interstate commerce restraints and inappropriate regulations.

The agency does not consider it necessary at this time to require disinfection of bottled water. FDA acknowledges the strict standards for bottling water that have been adopted by the European Community and by other countries, and that, when water from protected sources is bottled under strict hygienic conditions, disinfection may not be necessary. However, the agency has established microbiological quality standards in § 165.110(b)(2), and bottled water that does not comply with the microbiological quality standard must be labeled with a statement of substandard quality, in accordance with § 165.110(c)(1). In addition, any bottled water containing a substance at a level considered injurious to health is deemed to be adulterated regardless of whether or not the label bears a statement of substandard quality. FDA has authority to take regulatory action against such product under section 402(a)(1) of the act.

Under the SDWA, EPA monitors drinking water and establishes regulations to protect the public from the adverse health effects of contaminants in public drinking water. FDA's microbiological standard, like other bottled water standards, follows EPA's requirements for drinking water. Thus, even though the microbiological standard was established for quality purposes and not safety, FDA concludes that it is adequate to protect the public health. The agency points out that should EPA require disinfection of drinking water, FDA will consider mandatory disinfection of bottled water.

F. Laboratory and Personnel Approval

IBWA requested that the CGMP regulations be revised to include requirements for certification of laboratories that analyze water and of supervisory personnel. The agency stated in the proposal that the act did not provide authority to the agency to require such approval, and that even if such authority were provided by the act, the agency lacked the resources to monitor analytical laboratories and personnel in the absence of a significant public health problem. Under § 129.35(a)(3)(iii), analysis of samples may be performed for the plant by competent commercial laboratories. The agency did not receive comments concerning laboratory personnel.

111. A number of comments urged FDA to require the use of certified laboratories to test bottled water. Comments stated that laboratories performing analyses should be validated in some manner to ensure their competency, although FDA need not be the validator. One comment stated that the public is better and more consistently protected by requiring that certified laboratories conduct the required analyses.

One comment stated that the compliance of bottled water with quality standards is directly related to the competence and reliability of the laboratories that perform the analysis for contaminants. It stated that it is not clear what FDA means by ''competent commercial laboratories.'' It asked, concerning the criteria that would be used to determine whether a laboratory is competent, who would determine whether a laboratory meets these criteria, and how would a bottler be able to determine that a laboratory is able to provide valid test results. The comment stated that the term ''competent'' is too vague and will not promote uniformity. Another comment stated that the use of uncertified, ''competent'' laboratories provides little assurance that contaminants, even when present, will be detected.

Comments stated that, because EPA requires that determinations of compliance with its MCL's be based on data generated by a certified drinking water laboratory, it would be consistent with the spirit of the MOU between FDA and EPA for FDA also to require the use of certified laboratories. The comments stated that FDA would not have to expend resources because certification programs are in place and administered by the States, with laboratories bearing the cost. They added that FDA's adoption of a laboratory certification requirement would be consistent with its stated intent of incorporating EPA drinking water analytical methods for determining compliance with bottled water quality standards.

Comments stated that bottled water laboratory testing certification is a major problem that must be addressed by FDA. They stated that, currently, a number of State regulatory agencies require that bottled water sold in their States be tested in one of their State-certified laboratories, and that this issue causes undue replication expenses for multiple State licensing and hinders free interstate commerce.

One comment stated that water bottlers should be encouraged to perform laboratory tests on site. It stated that transportation to a certified laboratory can require considerable time and can delay results. The comment stated that while it is important for a certified laboratory to serve as a reference, water bottlers would best serve the public by performing analyses on site.

The agency disagrees that it should require the use of certified laboratories to test bottled water. Under § 129.35(a)(3)(iii), analysis of the water samples may be performed for the plant by competent commercial laboratories. Thus, laboratories used to analyze bottled water must be competent whether or not they have been certified competent. A competent laboratory is one that is capable of performing the required analyses and of obtaining valid and accurate results from its analyses. Any laboratory that has been certified by EPA or a State to test drinking water is deemed to be a competent laboratory. EPA- and State-certified laboratories may be used for comparative purposes against other commercial laboratories or a plant's own laboratory. To clarify that the agency believes that EPA- and State-certified laboratories are appropriate to perform water analyses to demonstrate compliance with parts 129 and 165, FDA is amending § 129.35(a)(3)(iii) to specifically cite EPA- and State-certified laboratories as examples of competent laboratories. Failure to have been certified will not preclude a laboratory from being considered competent, but the existence of such certification will eliminate any doubt about the laboratory's competency.

FDA agrees with the comment that stated that water bottlers should be encouraged to perform laboratory tests on site. Manufacturers of many types of foods effectively perform their own routine laboratory tests on their products. To the extent possible, bottled water manufacturers should perform routine tests on bottled water. For example, testing for microbiological quality must be conducted at least once a week for source water (§ 129.35(a)(3)), as often as necessary for product water (§ 129.80(a)), and at least once a week

for the finished product (§ 129.80(g)(1)). Manufacturers can obtain quick, reliable results using their own laboratories versus the time it would take to send the samples to a commercial laboratory. However, firms must ensure the competency of their labs.

The comments have not convinced the agency that the public health will be better protected by requiring the use of certified laboratories. Regardless of the laboratory used for testing, water containing any substance at a level considered injurious to health is deemed to be adulterated (see section 402(a)(1) of the act and § 165.110(d)). Thus, the agency concludes that the public health is already protected.

The MOU between FDA and EPA delineates jurisdiction over types of drinking water but does not consider the issue of certified laboratories. Although FDA incorporates EPA methods into the quality standard, FDA has yet to be convinced that only EPA- or State-certified laboratories are capable of using EPA methods.

In response to the comment concerning States requiring additional testing in laboratories certified in their own States, the agency points out that regardless of whether it required the use of certified labs, the CGMP regulations are not preemptive and does not preclude States from establishing stricter requirements for bottled water sold in their States.

G. Annual Plant Inspection

IBWA requested that FDA revise the CGMP regulations to include a requirement for annual plant inspections to ensure compliance with the regulations. FDA stated in the January 1993, proposal that without a clear indication of a significant public health problem that could not be corrected by other means, there is no basis for FDA to adopt such a requirement for bottled water. FDA recognized, however, that IBWA requires third party inspection of its member firms, and FDA encourages such self-regulated programs within industry.

112. A number of comments stated that FDA did not provide sufficient rationale for not imposing annual plant inspection requirements on the growing bottled water industry. Several comments stated that annual inspections would reduce the likelihood that bottlers would be out of compliance for extended periods of time. One comment stated that, irrespective of who performs the inspection, FDA should require inspections at least biannually for bottled water plants. It added that FDA could contract with State regulatory agencies to accomplish these inspections.

Some comments encouraged FDA to consider third party inspections because third party inspections would ensure compliance with the regulations without requiring FDA to increase resource requirements. One comment urged FDA to modify § 129.80(g) to include a requirement for annual inspections by a qualified third party organization because it would address expressed State government concerns. It stated that some State governments require that companies submit a report issued by a recognized organization that inspects bottled water systems for compliance with part 129 (i.e., NSF International or other organization, State, or country with an inspection protocol as stringent as NSF's).

The agency disagrees with the comments and affirms that, in the absence of a significant public health problem, the hazards from bottled water do not warrant this requirement.

The monitoring/inspectional aspect of FDA's program is carried out by its field force. The agency monitors and inspects bottled water products and processing plants as part of its compliance programs for foods. There are roughly 30 compliance programs for foods covering the full range of potential food safety problems, including chemical contaminants, pesticides, filth, and food additives. About one-half of the programs are for imported foods. They provide broad guidance to the field on the agency's inspectional priorities. The agency's work plan further specifies the number of inspections, sample collections, wharf exams, analyses, and other activities in each program by district. The districts have considerable latitude as to the establishments that they inspect and the products that they examine to allow for adequate coverage of local problems and regionalized industry.

Bottled water establishments are covered under the general food safety program. Bottled water plants, along with carbonated beverage bottling plants and warehouses, generally are assigned low priority for inspection. Priorities are based on factors such as the potential for a public health problem and the violation rate of the industry. When compared to products such as low-acid canned foods and products in which *Listeria* or *Salmonella* have a significant potential to develop, bottled water products are a relatively low public health problem.

FDA's experience over the years has supported that ranking (Ref. 24). Studies of bottled water products have generally not found significant problems in these products (*id*). Consequently, bottled water plants shipping in interstate commerce are inspected about once every 4 years, unless the firm is violative. The frequency of inspection of violative firms is accelerated depending on the number, significance, and recurrence of violations. Furthermore, the districts follow up on consumer and trade complaints and other leads, as appropriate, on potentially violative bottled water products.

FDA also contracts with the States to perform some bottled water plant inspections. The FDA district offices are generally in contact with their State counterparts to exchange information about compliance problems, inspectional coverage, and new food establishments. In addition to FDA inspection, the State and local governments have their own inspection and licensing programs. Therefore, FDA concludes that it need not mandate annual plant inspections for bottled water.

113. One comment suggested that FDA consider establishing specific criteria for the operation of a bottled water plant to ensure that there is compliance with CGMP's for bottled water manufacturing. It stated that it is a lot easier for an inexperienced person to establish a bottling facility for water, capable of producing high volumes of product, than it is to start up with other food products. The comment held that an effective licensing program is needed far more for this type of product than for other foods and beverages because of a greater risk to the public.

Another comment suggested that FDA establish for its quality standards some type of monitoring timeframes along with deadlines for submission of monitoring results from State-approved drinking water laboratories.

FDA notes that it has established a CGMP regulation in part 129 for the processing and bottling of drinking water. Thus, FDA has established regulations on how to operate a bottled water plant. Bottled water produced in violation of part 129 is adulterated under section 402(a)(4) of the act in that the food has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

Part 129 requires monitoring of the source water, product water, and finished product. According to § 129.35(a)(3), samples of source water must be taken and analyzed at a minimum frequency of once each year for chemical contaminants and once every 4 years for radiological

contaminants. Additionally, source water obtained from somewhere other than a public water system is to be sampled and analyzed for microbiological contaminants at least once each week. Test and sample methods must be consistent with the minimum requirements set forth in § 165.110(b).

Product water samples must be taken after processing and before bottling, and analyzed as often as is necessary to assure the uniformity and the effectiveness of the processes performed by the plant (§ 129.80(a)).

The compliance procedures for the finished product are set forth in § 129.80(g). A firm must test a representative sample of each product for bacteriological contamination at least once a week. To ensure chemical, physical, and radiological quality, a manufacturer must take and analyze at least annually a representative sample of each product. The finished bottled water must comply with the quality standard in § 165.110(b).

Plants must retain all records required by part 129 for not less than 2 years, and these documents must be available for official review at reasonable times (§ 129.80(h)). These records must be available for FDA plant inspections. The agency notes that it does not have the resources to review bottled water test results except during FDA plant inspections.

Thus, while FDA has not established a licensing requirement for water bottlers, it has established a regulatory regime to ensure the safety and quality of bottled water products.

H. Recall Procedures

IBWA requested that FDA establish specific recall procedures for bottlers and dealers in the CGMP regulations. In the January 1993 proposal FDA found no basis for this requested revision.

114. A number of comments stated that FDA did not provide sufficient rationale in the proposal for not establishing specific recall procedures for bottlers and dealers in the growing bottled water industry.

One comment stated that, although there should not be specific recall procedures in the regulations, language that requires that a written recall plan or document be maintained by the bottler should be included in the FDA regulations. It stated that the existence of such a plan would ensure a quick response by a bottler in the event that a recall is necessary.

The agency notes that part 7 (21 CFR part 7), subpart C provides guidelines on policy, procedures, and industry responsibilities for recalls. In § 7.59, FDA advises firms to: (1) Prepare and maintain a current written contingency plan for use in initiating and effecting a recall; (2) use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots; and (3) maintain such product distribution records as are necessary to facilitate locating of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and the expected use of the product.

The agency notes that recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and from products that present risks of injury or gross deception or are otherwise defective. Recall is an alternative to an FDA court action for removing distributed products from interstate commerce.

FDA is not aware of any circumstances that establish that there is a unique problem with recalls of bottled water. Therefore, FDA concludes that the guidelines for recall procedures for foods are adequate. If a firm refuses to undertake a recall that is requested by FDA, or where FDA has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing, it may initiate seizure, multiple seizure, or other court action.

V. Other Matters

A. Ozone

The agency proposed to specify in § 184.1563(d) that the term ''bottled water,'' for purposes of this section, does not include mineral water with TDS greater than 500 ppm. The agency stated that this action is necessary to ensure that FDA's rulemaking on the definition of bottled water in § 165.110 does not inadvertently have the effect of expanding the permitted uses of ozone.

115. Two comments objected to the exclusion of mineral water from ozonation. One of the comments stated that this exclusion conflicts with other FDA proposals to include mineral water as a bottled water. It stated that California has permitted the ozonation of mineral water for many years, and that ozonation is by far the most common means of germicidal water treatment that California mineral water firms use.

Another comment stated that there is no known reason to preclude ozonation as the antimicrobial agent for mineral water with TDS's greater than 500 ppm, provided that the maximum residual level requirements are met. It stated that the difference between mineral water and bottled water is only how much ozonation is required, at what temperature, and for how long a period of time.

The agency has reconsidered its January 1993, proposal in light of these comments and of its original decision to affirm the use of ozone in bottled water as generally recognized as safe (GRAS). In that decision (47 FR 50209, November 5, 1982), FDA noted its 1968 opinion that ozone used to disinfect potable water is GRAS if it is used in accordance with CGMP and with the recommendations of the U.S. Public Health Service. The only restriction was that the water must be potable. FDA also noted the continuous use of ozone in Europe for disinfecting municipal water for nearly 70 years without any evidence of toxicity. To ensure that the levels of any oxidation products formed are low and safe, the agency included a requirement in the GRAS affirmation regulation that the starting water, before ozonation, meet the microbiological, physical, chemical, and radiological quality standards for bottled water specified in § 103.35 (b) through (e). FDA considers this requirement to be a clarification of what it considered to be CGMP, namely, that ozone would not be used to disinfect polluted water.

A restriction on the use of ozone in mineral water with TDS greater than 500 ppm does not specifically address the goal of the proposal which was to ensure that the level of oxidation products do not exceed the levels anticipated when the GRAS affirmation regulation was issued. The oxidation products of concern from the use of ozone that were considered in establishing the GRAS regulation were those from dissolved organic material, whereas the increased solids content of mineral water consists primarily of minerals (inorganic material). Moreover, the restriction in the GRAS affirmation regulation that the use of ozone in disinfecting water be in accordance with CGMP means that only water that meets the new standard in § 165.110(b), which limits the amount of dissolved organic material that may be present, will be processed with ozone. Therefore, FDA has decided that there is no need to include the restriction limiting the TDS to 500 ppm for mineral water in the GRAS affirmation regulation for ozone.

Of relevance in this regard is the fact that bromate can be formed when ozone is used on waters that contain sufficient levels of bromide (a mineral component). EPA has conducted an evaluation of bromate and classified it as a probable human carcinogen because bromate administered to rodents in their

drinking water has been shown to produce several types of tumors in both sexes. EPA has proposed an MCLG for bromate of zero and an MCL of 10 micrograms (µg)/L (59 FR 38668, July 29, 1994). In the event EPA establishes an MCL for bromate in drinking water, then in accordance with section 410 of the Act FDA will propose to establish an allowable level for bromate in bottled water in § 165.110(b). The agency further emphasizes that water that is treated with ozone that results in bromate levels that may be injurious to health is adulterated under section 402(a)(1) of the Act.

B. Nutrition Labeling

116. One comment stated that it was concerned with the level of sodium that is allowed under the current regulations, while still allowing the label to claim that the food is ''sodium free'' or ''salt free.'' It stated that FDA permits the label to claim ''sodium free'' up to 21.1 ppm in bottled water. The comment noted that bottlers who use ion exchange in their treatment process can actually add sodium to the bottled water. The comment expressed concern about any regulation that permits advertising of ''sodium free'' when there actually is sodium in the bottled water.

The agency discussed this aspect of its ''sodium-free'' regulation in the Federal Register of January 6, 1993 (58 FR 2302 at 2321) and stated that it believes that it is appropriate to apply the term ''free'' to a nutrient when a food contains that nutrient in a dietetically trivial or physiologically inconsequential amount, even though the nutrient is present at a level at or near its reliable limit of quantitation. With modern analytical methods, the level at which the presence of a nutrient may be quantified is becoming increasingly smaller.

For example, there are almost no foods that can be said to be truly sodium free, yet the level of sodium present in some foods has no impact on the diet. The Daily Recommended Value for sodium is 2,400 mg. Thus, the agency concluded that a food containing less than 5 mg per reference amount customarily consumed (reference amount) could be considered sodium free because 5 mg is a dietarily insignificant fraction of 2,400 mg. The reference amount for bottled water is 240 mL. Therefore, the claim ''sodium free'' may be used on a bottled water label if the sodium content is less than 5 mg per 240 mL serving (21 ppm). If a ''sodium free'' claim is made, the bottled water must bear nutrition labeling in accordance with § 101.9.

The agency points out that although the term ''salt'' is not synonymous with ''sodium,'' salt refers to sodium chloride. Under § 101.61(c)(1), the term ''salt free'' may be used on the label or in labeling of foods only if the food is ''sodium free.''

FDA recognizes that some sodium may be added to water during ion exchange treatment. The label of the bottled water product treated in this manner could still qualify to bear the statement ''sodium free'' if the sodium content of the final product is less than 5 mg per 240 mL serving. However, if the sodium content is 5 mg or greater per 240 mL serving, the bottled water must bear nutrition labeling and could not be labeled as ''sodium free.''

117. One comment asked that bottled water have a qualified exception from the nutrition labeling regulations except when a claim is made that the water contains a significant level of a nutrient or nutrients. It stated that in that event, nutrition labeling for the nutrient for which the claim is made would be required. The comment stated that, for example, if a bottled water bore a claim of ''no sodium'' or ''no calories,'' it could be accompanied, on the information panel, by a statement, ''not a significant source of _____'' with the blank filled in with the items claimed in the statement. Another comment questioned why the declaration ''sodium free'' would trigger a nutritional panel for information on fat and calories when it is common knowledge that water does not contain these nutrients.

One comment requested that FDA exempt bottled water products other than mineral water from nutrition labeling. It stated that consumers do not expect any nutrition from bottled water, except perhaps for some minerals in mineral water. It suggested that bottled water with less than 250 ppm TDS (i.e., bottled water that is not mineral water) be exempted from nutrition labeling, even if fluoride is added. It stated that label space was a problem.

FDA notes that the requested exemptions and modifications for nutrition labeling fall outside the scope of this rulemaking. However, FDA discussed these issues in the final rule on nutrition labeling of January 6, 1993 (58 FR 2079 at 2149), and stated that:

> A recent IOM [Institute of Medicine] report, ''Food Labeling: Toward National Uniformity'' (Ref. 25), noted that many States have expressed concern about the heightened potential for consumer confusion because of the increased number of bottled water products on the market and the aggressive marketing and advertising claims of superiority made for them. Thus, FDA maintains its position that nutrition information relating to food must be provided for all products, including bottled and mineral water, that contain more than insignificant amounts of any of the nutrients or food components that are required to be listed, or whose label, labeling, or advertising contains a nutrient content claim or any other nutrition information in any context. For products that qualify for the simplified format, if manufacturers voluntarily declare nutrients allowable under § 101.9(c) that are not among the 14 required nutrients (e.g., potassium), the required statement ''Not a significant source of _____,'' must be used, with the blank filled in with the name of any of the 14 required nutrients or food components that are not present or are present in insignificant amounts. Moreover, if a product is voluntarily enriched or fortified with added vitamins or minerals, any such nutrients must be declared using the simplified format and followed by the above statement. Thus, a product labeled as ''bottled water, minerals added'' will have to bear nutrition labeling.
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> Bottled water products containing juice or other flavors are subject to the same nutrition labeling requirements as any other food. If a product meets the criteria for no nutritional significance, and no claims are made, then nutrition labeling is not required. A ''sodium free'' declaration on bottled water or on any other food label will trigger nutrition labeling, because such a claim promotes the nutritional properties of the product.

As discussed previously under comment 92 of this document, if fluoride is added to bottled water, and the label bears a statement to indicate this addition, other than in the ingredient statement, the label must bear nutrition labeling that complies with the simplified format.

C. Preemption

118. Comments from several States objected to the Federal standards of identity for bottled water preempting any State standards that are not identical to it, as some States have established regulations for bottled water that are more stringent than the FDA standard. One comment stated that it is a fundamental right of a State to make regulations and standards that are at least as stringent as or more stringent than Federal regulations and standards. It contended that FDA's role is more appropriately to establish Federal rules that will protect the public health and prevent fraudulent claims from being made that might mislead consumers of bottled water products. Another State held that it has made great efforts to ensure that bottled water meets standards at least as stringent as those set forth in EPA's primary drinking water regulations.

A number of comments requested that FDA more clearly explain the scope of

the preemption provision, and that it specifically address whether the agency interprets Federal preemption to apply to certain State requirements (i.e., labeling restrictions, laboratory certification, and certain testing requirements).

Comments asserted that many State regulations are costly and do not provide consumers with any more protection than is likely to be provided by those proposed by FDA. One comment stated that FDA should emphasize that a given State should not be allowed to place an undue burden on interstate commerce by requiring that analyses be performed only in laboratories that are certified by that State, or that analyses be performed according to an unduly restrictive frequency unrelated to public health protection. The comment added that regulatory activity by the States in areas such as standards and environmental protection is causing difficulties for those seeking to import goods into the United States.

FDA notes that, under section 403A(a)(1) of the act (21 U.S.C. 343–1(a)(1)), a State may not establish or continue in effect a standard of identity for a food that is the subject of a standard of identity under section 401 of the act if the State standard is not identical to the Federal standard. Section 403A(a)(1) of the act only effects preemption with respect to matters on which a Federal requirement exists. If there is no Federal requirement to be given preemptive effect, preemption does not occur.

Under § 100.1(c)(4), if the State requirement is identical to the Federal law, there is no issue of preemption. In addition, if the State requirement does the same thing that the Federal law does, even if the words are not exactly the same, then it is effectively the same requirement as the Federal requirement. FDA's view, as embodied in § 100.1(c)(4), is that such a State or local requirement is consistent with the Federal requirement. Therefore, the only State requirements that are subject to preemption are those that are affirmatively different from the Federal requirements on matters that are covered by section 403A(a) of the act.

FDA acknowledges that some stringent State laws will be preempted by less restrictive Federal regulations. However, one of the goals of the national uniformity provisions of the 1990 amendments was to give industry some relief from some types of State requirements that interfere with their ability to market products in all 50 States in an efficient and cost-effective manner (Statement of Rep. Madigan, 136 Congressional Record H12954 (October 26, 1990)). Thus, in enacting the 1990 amendments, Congress apparently decided that even though Federal requirements may preempt more restrictive State requirements in certain instances, the net benefits from national uniformity in these aspects outweigh the loss in consumer protection that may occur as a result.

The agency notes that certain State laws and regulations will not be preempted because FDA's requirements have not been given preemptive effect. Therefore, a State will not be precluded from enforcing its provisions in such circumstances. The agency points out, for example, that FDA has not sought to give preemptive effect to part 129. Therefore, if a State has stricter requirements than those in part 129, the State standard is not preempted by the Federal requirement.

The agency advises that, in those instances where a State requirement is preempted and the State believes that there are significant protections of the public that will be lost as a result, the State may petition the agency to modify the standard in question. FDA intends to give careful consideration to any such petitions that it receives.

119. Some comments contended that many States have bottlers whose products do not cross State lines, thereby avoiding compliance with FDA regulations. They suggested that the regulation should include all bottlers regardless of intrastate/interstate sales.

One comment from a State contended that by proposing to apply these standards only to interstate manufacturers, FDA establishes an undue logistical burden on regulatory agencies, as they would have to establish two levels of regulation. The comment argued that more consistent regulation is possible by applying the same standards to all bottled water firms that desire to sell their products in a particular State.

The agency advises that the act only applies to food that is in, or is intended to be shipped in, interstate commerce. Sections 301 and 304 of the act (21 U.S.C. 331 and 334) specifically describe prohibited acts and liability for seizure of food that is held for sale in, is in, or has been shipped in interstate commerce. FDA encourages States to apply the Federal standard to both interstate and intrastate commerce to eliminate two levels of regulation and to avoid undue logistical burdens.

VI. Conclusions

After review and consideration of the comments received in response to the January 1993 proposal, FDA concludes that it should amend part 129 and establish part 165 as set forth in the proposal but with the specific modifications to the proposed regulation discussed in this document. For the purposes of this final rule, certain changes, in addition to those discussed in this document, were made for editorial purposes, clarity, and consistency only. These changes do not modify any matter of substance.

VII. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (58 FR 393, January 5, 1993). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VIII. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is ''economically significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affect in a material way a sector of the economy, competition, or jobs. A regulation is considered ''significant'' under Executive Order 12866 if it raises novel legal or policy issues.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. In compliance with the Regulatory Flexibility Act, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

In the economic assessment to the proposal in this rulemaking (58 FR 393), FDA considered the costs and benefits of taking this action. FDA estimated compliance costs to be between $18 million and $21 million and benefits to be approximately $35 million plus the value of any increase in interstate

commerce that might occur because of the elimination of conflicting State regulations. Thus, benefits were estimated to exceed costs by from $14 million to $17 million, plus the value of any increase in interstate commerce in bottled water.

The comments to the proposal discussed three issues relevant to the economic assessment. The first issue involves the ability of the product definitions adopted in this final rule to communicate information about bottled water products to consumers. The second issue involves the cost of label changes. The third issue involves the economic consequences of the definitions and labeling requirements adopted in this final rule for particular bottled water manufacturers.

A. Ability of Definitions To Communicate Information to Consumers

Some comments suggested or provided data indicating that some of the definitions for particular types of bottled water adopted in this final rule may not correspond to some consumers' current ideas about the essential features of various types of bottled water. The implication of these comments is that the definitions adopted in this final rule will generate confusion over the characteristics of these products.

Although FDA acknowledges that some of the definitions may not correspond to some consumers' current ideas about the essential features of some types of bottled water, this phenomenon does not necessarily imply that confusion over these products will be increased by this final rule. In States in which these products are not currently defined, the terms currently used to refer to various bottled water products may also not correspond to some consumers' current ideas about the essential features of those types of bottled water. Similarly, in States in which these products are already defined, the State definitions may also not correspond to some consumers' current ideas about the essential features of those types of bottled water.

Other comments suggested that alternative definitions could be adopted that would be more consistent with most consumers' current ideas about the essential features of various types of bottled water than the definitions adopted in this final rule. These comments imply confusion will be greater under the definitions adopted in this final rule than under the alternative definitions. Similarly, some comments suggested definitions already adopted by particular States are more consistent with consumers' current ideas about the essential features of various types of bottled water than the definitions adopted in this final rule. These comments imply confusion will be increased if existing state definitions are superseded by the definitions adopted in this final rule.

For example, a number of comments suggested that most consumers believe ''spring water'' must be extracted from the natural orifice of a spring and not from a bore hole. This final rule defines ''spring water'' to include water extracted from both the natural orifice of a spring and from a bore hole tapping the underground formation feeding the spring. The comments imply the definition of ''spring water'' adopted in this final rule will generate greater confusion over the characteristics of this product than would a definition specifying that ''spring water'' be extracted from the natural orifice of a spring. As discussed in the preamble to this document, FDA believes that these comments are in error, and that most consumers do not believe ''spring water'' must be extracted from the natural orifice of a spring.

Another comment discussed the results of a survey in which the majority of respondents thought ''artesian well water'' flowed to the surface due to natural pressure. In contrast, the geological definition of an artesian well does not imply water from this type of well flows to the surface due to natural pressure. The definition of ''artesian well water'' adopted in this final rule is consistent with the geological definition of an artesian well and does not require that this type of water flow to the surface due to natural pressure. The comment suggested the definition adopted in this final rule will create more confusion over the characteristics of this product than would a definition specifying that ''artesian well water'' flows to the surface due to natural pressure.

FDA acknowledges that many consumers may be unaware of the geological definition of an ''artesian well,'' and that, in the short run, the definition of ''artesian well water'' adopted in this final rule may lead some consumers to be confused over the characteristics of this product. However, in the long run, this confusion will be less than the confusion that would be generated if FDA failed to adopt a definition for this term or adopted a definition that failed to correspond to the accepted geological definition of an artesian well. Adopting a standardized definition for this term will increase the ability of interested consumers to interpret this term. Adopting a standardized definition consistent with accepted geological terminology will increase the ability of interested consumers to attain information on this type of water.

Comments also discussed a number of other elements of the definitions adopted in this final rule. These comments are addressed in the preamble to this document. These comments do not provide sufficient information to establish that alternative definitions would be more consistent with most consumers' current ideas about the essential features of various types of bottled water than the definitions adopted in this final rule.

B. The Cost of Label Changes

Comments provided a wide range of estimates of the cost of relabeling bottled water products to conform to the proposed definitions and labeling requirements. One comment suggested label changes will cost $2,000 per product, per location, not including the cost of the actual label. Another comment suggested the cost of each label plate change alone will be $200. Another comment suggested it will cost a single firm ''hundreds of thousands of dollars'' to change their labels.

In the economic assessment of the proposal in this rulemaking, FDA used an average relabeling cost of $45,000 per label change. This cost estimate was based on information previously provided by a bottled water manufacturer. Although the comments suggest the cost of relabeling may be highly variable across firms, and that the cost of relabeling may be lower than $45,000 per label for many firms, the comments do not provide sufficient information to determine an appropriate adjustment in the average cost of relabeling.

Some comments implied that changes in advertising would also be required to accommodate the product definitions established under this final rule. In the economic assessment to the proposal in this rulemaking, FDA did not consider these costs because FDA believed the proposed definitions were sufficiently broad that no firm legally selling a given type of bottled water would be unable to do so because of the proposed regulation.

One comment suggested 44 brands of bottled water currently marketed as mineral water in the United States would no longer be able to be marketed as mineral water under this final rule. However, the only brands listed in this comment were Mountain Valley, Volvic, and Poland Spring. Based on the information available to the agency, this comment is in error. It appears that no

mineral water is actually being marketed under these brand names.

Another comment suggested most of the mineral water sold in the world, including the U.S. market, is produced in Europe, and that these products currently exhibit a wide range of total dissolved solids (TDS) levels, from under 100 mg/L to over 1,000 mg/L. The implication of this comment is that some mineral water produced in Europe with less than 250 ppm TDS is currently being marketed as mineral water in the United States and would no longer be able to be marketed as mineral water under this final rule. However, this comment did not identify any European brands that would actually be affected in this manner, and FDA is not aware of any such brands.

FDA, therefore, has no information that this final rule will require extensive modification of existing advertising.

C. Economic Consequences of Definitions and Other Labeling Requirements on Particular Bottled Water Manufacturers

A number of comments suggested that the definitions and the labeling requirements in this final rule will have a negative impact on the sales of some bottled water products and thus a negative impact on some bottled water manufacturers.

Two comments suggested that some water currently sold as mineral water would no longer be able to be sold as mineral water under this final rule, and that this would have a negative impact on the sales of those products. This issue is different from the advertising cost issue, which is the context in which these same comments were discussed in the preceding section. However, FDA's response to these comments is the same in this context as in the context of advertising costs. FDA is not aware of any brand of mineral water that will no longer be able to be marketed as mineral water under this final rule.

Another comment noted the definition of ''bottled water'' does not allow for the addition of ingredients such as minerals for flavor, sodium fluoride, flavors which comprise less than one percent by weight, and carbon dioxide. According to this comment, many products currently sold simply as ''bottled water'' contain these ingredients, and that by causing these products to be labeled differently, this final rule will generate a tremendous adverse economic impact on the firms producing these products. FDA believes this comment is in error because it is currently illegal to sell water containing these ingredients as simply ''bottled water,'' and FDA is not aware of any products that are labeled in this manner.

Another comment suggested that if drinking water is not recognized by FDA as a specific type of bottled water, severe economic repercussions would occur for companies that currently sell bottled drinking water. This final rule does not define ''drinking water'' as a specific type of bottled water, although it does allow for the use of the term ''drinking water'' as a synonym for ''bottled water.'' However, this comment provided no information to support the claim that consumers believe drinking water is a specific type of bottled water. In addition, nearly all bottled water sold in the United States meets the conditions suggested in this comment as being peculiar to drinking water. Therefore, FDA does not believe the sales of drinking water will be significantly affected by this final rule.

Another comment suggested that the additional labeling requirements for bottled water marketed for use in infant formula will cause a negative impact on the sales of these products and will effectively destroy this product line. However, the comment provided no information to support this claim. Therefore, there is no basis for FDA to take any action in reliance on this comment.

D. Conclusions

The economic assessment to the proposal in this rulemaking (58 FR 393) estimated net benefits of $14 million to $17 million plus the value of any increase in interstate commerce that might occur because of the elimination of conflicting State regulations.

The previous economic assessment did not consider the potential effect of the definitions and labeling requirements on the level of consumer confusion over bottled water products. Accounting for this effect will probably increase estimated net benefits. However, FDA has insufficient information to estimate this increase in net benefits.

In addition, the definitions and labeling requirements adopted in this final rule may result in a decrease in the sales of some products and an increase in the sales of other products. However, FDA has insufficient information to determine the size or significance of these effects.

Therefore, FDA estimates that the benefits of this final rule will exceed the costs by $14 million to $17 million, plus the value of any increase in interstate commerce which might occur because of the elimination of conflicting State regulations and the value of any reduction in consumer confusion over these products.

IX. Effective Date

FDA proposed that any final rule that was issued based upon the proposal would become effective 180 days following issuance of the final rule.

120. One comment asked FDA to consider the cost and phase- in considerations for bottled water companies whose main business involves 3-, 5-, or 6-gallon reusable polycarbonate silk-screened bottles. The comment stated that these bottles, which are generally recycled when no longer fit for use, cost approximately $4 to $5 each and have a normal life span of 5 to 7 years, although they can last 10 years or longer. It stated that a company with about $6 million in sales has an inventory of about 200,000 bottles or a bottle investment of $800,000 to $1,000,000. The comment maintained that any change in labeling requirements has major potential expense implications for bottlers using 3-, 5-, or 6-gallon polycarbonate silk screened bottles. It held that any relabeling of these bottles with adhesive labels can be costly and presents potential problems in the washing process. It asked that consideration be given to extended phase-in periods for reusable bottles where a change in labels is required because of the new regulations.

Under section 403(g) of the act, a food is deemed to be misbranded if it purports to be, or is represented as, a food for which a definition and standard of identity has been prescribed by regulation unless it conforms to such definition and standard, and its label bears the name of the food specified in the definition and standard. Thus, all bottled water labels must bear appropriate labeling in conformance with an effective standard of identity.

FDA recognizes that some bottled water labels will have to be modified to comply with the standard of identity for bottled water, even though the definitions are based on current meanings of terms. The agency has provided for additional nomenclature (e.g., ''drinking water'') in this final rule, and as a result, many label changes that the comment may have anticipated will not be required.

However, FDA realizes that it may be a hardship for some firms to make required label changes on reusable polycarbonate silk-screened bottles because these bottles are used for years before replacement, and replacement of an entire stock would be burdensome by the effective date of this final rule. Therefore, the agency is allowing an

alternative means of compliance whereby the labeling information required by the standard of identity that is otherwise required on reusable polycarbonate silk- screened bottles may be placed on the customer invoice or bill of lading that is provided with each delivery. This alternative means of compliance is provided in lieu of having the labeling information required by the standard of identity permanently affixed to an existing bottle as otherwise required by section 201(k) of the act. This alternative means of compliance only applies to information on the polycarbonate silk-screened bottles and does not apply to information on the bottle cap.

The special labeling provision is provided for currently existing containers. As a firm replaces the polycarbonate silk-screened bottles presently in use with new ones, the required information must be permanently affixed to the new bottles. To fulfill the intent of the act, all labeling on the invoice or bill of lading must be in compliance with FDA requirements. The agency notes that this alternative means of compliance is consistent with that established for nutrition labeling under § 101.9(g)(9).

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. Codex Alimentarius, vol. XII, ''Codex Standards for Natural Mineral Waters and Edible Ices and Ice Mixes,'' Food and Agriculture Organization of the United Nations, World Health Organization, Rome, 1982.

2. State of California, Chapter 639, Assembly Bill No. 170, September 15, 1987.

3. ''The Surgeon General's Report on Nutrition and Health,'' DHHS, Public Health Service Publication No. 88–50210 (Government Printing Office Stock No. 017–001–00465–1), U.S. Government Printing Office, Washington, DC, 1988.

4. Barness, Lewis A., Nutrition and Oral Health, ''Pediatric Nutrition Handbook,'' 3d Ed., American Academy of Pediatrics, Elk Grove Village, IL, 1993.

5. Heath, R.C., United States Geological Survey, ''Basic Ground-Water Hydrology,'' Water-Supply Paper 2220, United States Government Printing Office, 1989.

6. The United States Pharmacopeia, 23d Revision, United States Pharmacopeial Convention, Inc., Rockville, MD, 1995.

7. Association of Food and Drug Officials, ''AFDO Model Bottled Water Regulation,'' 1986.

8. Davis, S.A., memorandum to file, ''A Comparison of Definitions for Mineral Water,'' May 11, 1995.

9. Freeze, R.A. and J.A. Cherry, ''Groundwater,'' Prentice-Hall Inc., 1979.

10. Sax, N.I., and R.J. Lewis, Sr., ''Hawley's Condensed Chemical Dictionary,'' Van Nostrand Reinhold Company, 1987.

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25. Committee on State Food Labeling, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, ''Food Labeling: Toward National Uniformity,'' National Academy Press, Washington DC, 1992.

List of Subjects

21 CFR Part 103

Beverages, Bottled water, Food grades and standards.

21 CFR Part 129

Beverages, Bottled water, Food packaging, Reporting and recordkeeping requirements.

21 CFR Part 165

Beverages, Bottled water, Food grades and standards, Incorporation by reference.

21 CFR Part 184

Food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR Chapter I is amended as follows:

PART 103—QUALITY STANDARDS FOR FOODS WITH NO IDENTITY STANDARDS

1. The authority citation for 21 CFR part 103 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 410, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 349, 371, 379e).

Subpart B—[Reserved]

2. Subpart B, consisting of § 103.35 *Bottled water*, is removed and reserved.

PART 129—PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

3. The authority citation for 21 CFR part 129 continues to read as follows:

Authority: Secs. 402, 409, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 348, 371, 374); sec. 361 of the Public Health Service Act (42 U.S.C. 264).

4. Section 129.35 is amended by revising paragraphs (a)(3)(ii) and (a)(3)(iii) and by adding new paragraph (a)(4) to read as follows:

§ 129.35 Sanitary facilities.

* * * * *

(a) * * *

(3) * * *

(ii) Test and sample methods shall be those recognized and approved by the government agency or agencies having jurisdiction over the approval of the water source, and shall be consistent with the minimum requirements set forth in § 165.110(b) of this chapter.

(iii) Analysis of the sample may be performed for the plant by competent commercial laboratories (e.g., Environmental Protection Agency (EPA) and State-certified laboratories).

(4) *Source water testing exemptions.* (i) Firms that use a public water system for source water may substitute public water system testing results, or certificates showing full compliance with all provisions of EPA National Primary and Secondary Drinking Water Regulations pertaining to chemical contaminants (40 CFR parts 141 and 143), for the testing requirements of § 129.35(a)(3).

(ii) Firms that do not use a public water system as the source of their water may reduce the frequency of their testing of that source, as well as the number of chemical contaminants for which they test the source water, if they can document that such reduction is consistent with a State-issued waiver under EPA regulations (40 CFR parts 141 and 143).

(iii) The finished bottled water must comply with bottled water quality standards (21 CFR 165.110(b)) and section 402(a)(1) of the act dealing with adulterated foods.

* * * * *

5. Section 129.80 is amended by revising the introductory text of paragraph (g) to read as follows:

§ 129.80 Processes and controls.

* * * * *

(g) *Compliance procedures.* A quality standard for bottled drinking water is established in § 165.110(b) of this chapter. To assure that the plant's production of bottled drinking water complies with the applicable standards, laws, and regulations of the government agency or agencies having jurisdiction, the plant will analyze product samples as follows:

* * * * *

6. New part 165 is added to read as follows:

PART 165—BEVERAGES

Subpart A—General Provisions

Subpart B—Requirements for Specific Standardized Beverages

Authority: Secs. 201, 401, 403, 403A, 409, 410, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 343A, 348, 349, 371, 379e).

Subpart A—General Provisions

§ 165.3 Definitions.

(a) A *lot* is:

(1) For purposes of determining quality factors related to manufacture, processing, or packing, 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.

(2) For purposes of determining quality factors related to distribution and storage, a collection of primary containers or units transported, stored, or held under conditions as nearly uniform as possible.

(b) A *sample* consists of 10 subsamples (consumer units), one taken from each of 10 different randomly chosen shipping cases to be representative of a given lot, unless otherwise specified in a specific standard in this part.

(c) An *analytical unit* is the portion(s) of food taken from a subsample of a sample for the purpose of analysis.

Subpart B—Requirements for Specific Standardized Beverages

§ 165.110 Bottled water.

(a) *Identity*—(1) *Description.* Bottled water is water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents. Fluoride may be optionally added within the limitations established in § 165.110(b)(4)(ii). Bottled water may be used as an ingredient in beverages (e.g., diluted juices, flavored bottled waters). It does not include those food ingredients that are declared in ingredient labeling as ''water,'' ''carbonated water,'' ''disinfected water,'' ''filtered water,'' ''seltzer water,'' ''soda water,'' ''sparkling water,'' and ''tonic water.'' The processing and bottling of bottled water shall comply with applicable regulations in part 129 of this chapter.

(2) *Nomenclature.* The name of the food is ''bottled water,'' ''drinking water,'' or alternatively one or more of the following terms as appropriate:

(i) The name of water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer is ''artesian water'' or ''artesian well water.'' Artesian water may be collected with the assistance of external force to enhance the natural underground pressure. On request, plants shall demonstrate to appropriate regulatory officials that the water level stands at some height above the top of the aquifer.

(ii) The name of water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure is ''ground water.'' Ground water must not be under the direct influence of surface water as defined in 40 CFR 141.2.

(iii) The name of water containing not less than 250 parts per million (ppm) total dissolved solids (TDS), coming from a source tapped at one or more bore holes or springs, originating from a geologically and physically protected underground water source, may be ''mineral water.'' Mineral water shall be distinguished from other types of water by its constant level and relative proportions of minerals and trace elements at the point of emergence from the source, due account being taken of the cycles of natural fluctuations. No minerals may be added to this water.

(iv) The name of water that has been produced by distillation, deionization, reverse osmosis, or other suitable processes and that meets the definition of ''purified water'' in the United States Pharmacopeia, 23d Revision, January 1, 1995, which is incorporated by reference in accordance with 5 U.S.C. 551(a) and 1 CFR part 51. (Copies may be obtained from the United States Pharmacopial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852 and may be examined at the Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC), may be ''purified water'' or ''demineralized water.'' Alternatively, the water may be called ''deionized water'' if the water has been processed by deionization, ''distilled water'' if it is produced by distillation, ''reverse osmosis water'' if the water has been processed by reverse osmosis, and ''_____ drinking water'' with the blank being filled in with one of the defined terms describing the water in this paragraph (e.g., ''purified drinking water'' or ''deionized drinking water'').

(v) The name of water that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide that it had at emergence from the source may be ''sparkling bottled water.''

(vi) The name of water derived from an underground formation from which water flows naturally to the surface of the earth may be ''spring water.'' Spring water shall be collected only at the spring or through a bore hole tapping the underground formation feeding the spring. There shall be a natural force causing the water to flow to the surface through a natural orifice. The location of the spring shall be identified. Spring water collected with the use of an external force shall be from the same underground stratum as the spring, as shown by a measurable hydraulic connection using a hydrogeologically

valid method between the bore hole and the natural spring, and shall have all the physical properties, before treatment, and be of the same composition and quality, as the water that flows naturally to the surface of the earth. If spring water is collected with the use of an external force, water must continue to flow naturally to the surface of the earth through the spring's natural orifice. Plants shall demonstrate, on request, to appropriate regulatory officials, using a hydrogeologically valid method, that an appropriate hydraulic connection exists between the natural orifice of the spring and the bore hole.

(vii) The name of water that meets the requirements under ''Sterility Tests'' <71> in the United States Pharmacopeia, 23d Revision, January 1, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR 51. (Copies may be obtained from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852 and may be examined at the Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC), may be ''sterile water.'' Alternatively, the water may be called ''sterilized water.''

(viii) The name of water from a hole bored, drilled, or otherwise constructed in the ground which taps the water of an aquifer may be ''well water.''

(3) *Other label statements.* (i) If the TDS content of mineral water is below 500 ppm, or if it is greater than 1,500 ppm, the statement ''low mineral content'' or the statement ''high mineral content'', respectively, shall appear on the principal display panel following the statement of identity in type size at least one-half the size of the statement of identity but in no case of less than one-sixteenth of an inch. If the TDS of mineral water is between 500 and 1,500 ppm, no additional statement need appear.

(ii) When bottled water comes from a community water system, as defined in 40 CFR 141.2, except when it has been treated to meet the definitions in paragraphs (a)(2)(iv) and (a)(2)(vii) of this section and is labeled as such, the label shall state ''from a community water system'' or, alternatively, ''from a municipal source'' as appropriate, on the principal display panel or panels. This statement shall immediately and conspicuously precede or follow the name of the food without intervening written, printed, or graphic matter, other than statements required by paragraph (c) of this section, in type size at least one-half the size of the statement of identity but in no case of less than one-sixteenth of an inch.

(iii) When the label or labeling of a bottled water product states or implies (e.g., through label statements or vignettes with references to infants) that the bottled water is for use in feeding infants, and the product is not commercially sterile under § 113.3(e)(3)(i) of this chapter, the product's label shall bear conspicuously and on the principal display panel the statement ''Not sterile. Use as directed by physician or by labeling directions for use of infant formula.''

(4) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) *Quality.* The standard of quality for bottled water, including water for use as an ingredient in beverages (except those described in the labeling as ''water,'' ''carbonated water,'' ''disinfected water,'' ''filtered water,'' ''seltzer water,'' ''soda water,'' ''sparkling water,'' and ''tonic water''), is as follows:

(1) *Definitions.* (i) *Trihalomethane* (THM) means one of the family of organic compounds, named as derivatives of methane, wherein three of the four hydrogen atoms in methane are each substituted by a halogen atom in the molecular structure.

(ii) *Total trihalomethane* (TTHM) means the sum of the concentration in milligrams per liter of the trihalomethane compounds (trichloromethane, dibromochloromethane, bromodichloromethane and tribromomethane), rounded to two significant figures.

(2) *Microbiological quality.* Bottled water shall, when a sample consisting of analytical units of equal volume is examined by the methods described in applicable sections of ''Standard Methods for the Examination of Water and Wastewater,'' 15th Ed. (1980), American Public Health Association, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (copies may be obtained from the American Public Health Association, 1015 15th St., NW., Washington, DC 20005, or a copy may be examined at the Office of the Federal Register, 800 North Capitol St., NW., suite 700, Washington, DC, or at the Center for Food Safety and Applied Nutrition, 200 C St., SW., Washington, DC), meet the following standards of microbiological quality:

(i) *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 an MPN of 9.2 or more coliform organisms per 100 milliliters; or

(ii) *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.

(3) *Physical quality.* Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the method described in applicable sections of ''Standard Methods for the Examination of Water and Wastewater,'' 15th Ed. (1980), which is incorporated by reference (the availability of this incorporation by reference is given in paragraph (b)(2) of this section), meet the following standards of physical quality:

(i) The turbidity shall not exceed 5 units.

(ii) The color shall not exceed 15 units.[1]

(iii) The odor shall not exceed threshold odor No. 3.[1]

(4) *Chemical quality.* (i)(A) Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (b)(4)(i)(B) of this section, 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
Chloride[1]	250.0
Iron[1]	0.3
Manganese[1]	0.05
Phenols	0.001
Sulfate[1]	250.0
Total dissolved solids[1]	500.0
Zinc[1]	5.0
Organics:	
Endrin (1,2,3,4,10,10-hexachloro-6,7-epoxy 1, 4, 4a, 5, 6, 7, 8, 8a-octa-hydro-1,4-endo, endo-5,8-dimethane naph-thalene)	0.0002
Total Trihalomethanes	0.10

[1] Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

(B) Analyses conducted to determine compliance with paragraph (b)(4)(i)(A) of this section shall be made in accordance with the methods described in the applicable sections of ''Standard Methods for the Examination of Water

and Wastewater,'' 15th Ed. (1980), or ''Methods for Chemical Analysis of Water and Wastes,'' Environmental Monitoring and Support Laboratory (EMSL), EPA–600/4–79–020, March 1983, U.S. Environmental Protection Agency (EPA), both of which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(C) Analyses for organic substances shall be determined by the appropriate methods set forth below. The methods in paragraphs (b)(4)(i)(C)(*1*) and (C)(*2*) of this section are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and are described in ''Standard Methods for Examination of Water and Wastewater,'' 15th Ed. (1980). Copies may be obtained from the American Public Health Association, 1015 Fifteenth St., NW., Washington DC 20005, and examined at the Office of the Federal Register, 800 North Capitol St., NW., suite 700, Washington DC, or the Center for Food Safety and Applied Nutrition, 200 C St. NW., Washington DC. The methods in paragraphs (b)(4)(i)(C)(*3*) and (C)(*4*) are cross-referenced in 40 CFR part 141, subpart C, Appendix C.

(*1*) ''Methods for Organochlorine Pesticides in Industrial Effluents;''

(*2*) ''Methods for Chlorinated Phenoxy Acid Herbicides in Industrial Effluents,'' November 28, 1973;

(*3*) ''Part I: The Analysis of Trihalomethanes in Finished Waters by the Purge and Trap Method;'' which is cross-referenced in 40 CFR part 141, subpart C, appendix C;

(*4*) ''Part II: The Analysis of Trihalomethanes in Drinking Water by Liquid/Liquid Extraction,'' Method 501.2 which is cross-referenced in 40 CFR part 141, subpart C, appendix C;

(ii)(A) 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 (°F)	Fluoride concentration in milligrams per liter
53.7 and below	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

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

(C) 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 (°F)	Fluoride concentration in milligrams per liter
53.7 and below	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

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

(iii) Having consulted with EPA as required by section 410 of the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration has determined that bottled water, when a composite of analytical units of equal volume from a sample is examined by the methods listed in paragraphs (b)(4)(iii)(E) through (b)(4)(iii)(F), and (b)(4)(iii)(G) of this section, shall not contain the following chemical contaminants in excess of the concentrations specified in paragraphs (b)(4)(iii)(A) through (b)(4)(iii)(D) of this section.

(A) The allowable levels for inorganic substances are as follows:

Contaminant	Concentration in milligrams per liter (or as specified)
Barium	2.
Cadmium	0.005.
Chromium	0.1.
Copper	1.0.
Lead	0.005.
Mercury	0.002.
Nitrate	10 (as nitrogen).
Nitrite	1 (as nitrogen).
Total Nitrate and Nitrite.	10 (as nitrogen).
Selenium	0.05.

(B) The allowable levels for volatile organic chemicals (VOC's) are as follows:

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
Benzene (71–43–2)	0.005
Carbon tetrachloride (56–23–5)	0.005
o-Dichlorobenzene (95–50–1)	0.6
p-Dichlorobenzene (106–46–7)	0.075
1,2-Dichloroethane (107–06–2)	0.005
1,1-Dichloroethylene (75–35–4)	0.007
cis-1,2-Dichloroethylene (156–59–2)	0.07
trans-1,2-Dichloroethylene (156–60–5)	0.1
1,2-Dichloropropane (78–87–5)	0.005
Ethylbenzene (100–41–4)	0.7
Monochlorobenzene (108–90–7)	0.1
Styrene (100–42–5)	0.1
Tetrachloroethylene (127–18–4)	0.005
Toluene (108–88–3)	1
1,1,1-Trichloroethane (71–55–6)	0.20
Trichloroethylene (79–01–6)	0.005
Vinyl chloride (75–01–4)	0.002
Xylenes (1330–20–7)	10

(C) The allowable levels for pesticides and other synthetic organic chemicals (SOC's) are as follows:

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
Alachlor (15972–60–8)	0.002
Atrazine (1912–24–9)	0.003
Carbofuran (1563–66–2)	0.04
Chlordane (57–74–9)	0.002
1,2-Dibromo-3-chloropropane (96–12–8)	0.0002
2,4-D (94–75–7)	0.07
Ethylene dibromide (106–93–4)	0.00005
Heptachlor (76–44–8)	0.0004
Heptachlor epoxide (1024–57–3)	0.0002
Lindane (58–89–9)	0.0002
Methoxychlor (72–43–5)	0.04
Pentachlorophenol (87–86–5)	0.001
PCB's (as decachlorobiphenyl) (1336–36–3)	0.0005
Toxaphene (8001–35–2)	0.003
2,4,5-TP (Silvex) (93–72–1)	0.05

(D) The allowable levels for certain chemicals for which EPA has established secondary maximum contaminant levels in its drinking water regulations (40 CFR part 143) are as follows:

Contaminant	Concentration in milligrams per liter
Aluminum	0.2
Silver	0.1

(E) Analyses to determine compliance with the requirements of paragraph (b)(4)(iii)(A) of this section shall be conducted in accordance with an applicable method and applicable revisions to the methods listed in paragraphs (b)(4)(iii)(E)(*1*) through (b)(4)(iii)(E)(*13*) of this section and described, unless otherwise noted, in ''Methods for Chemical Analysis of Water and Wastes,'' U.S. EPA, Environmental Monitoring and Support Laboratory (EPA–600/4–79–020), March 1983, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service, U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161, or may be examined at the Office of Plant and Dairy Foods and Beverages (HFS–305), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St., SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(*1*) [Reserved]

(*2*) Barium shall be measured using the following methods:

(*i*) Method 208.2—''Atomic Absorption; furnace technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*ii*) Method 208.1—''Atomic Absorption; direct aspiration,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(A) of this section.

(*iii*) Method 200.7—''Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,'' Rev. 3.3, April 1991. The revision is contained in the manual entitled ''Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, Washington, DC 20460, (EPA/600/4–91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service, U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161, or may be examined at the Office of Plant and Dairy Foods and Beverages (HFS–305), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St., SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(*3*) [Reserved]

(*4*) Cadmium shall be measured using the following methods:

(*i*) Method 213.2—''Atomic Absorption; furnace technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*ii*) Method 200.7—''Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,'' Rev. 3.3, April 1991. The revision is contained in the manual entitled ''Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development,(EPA/600/4–91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*2*)(*iii*) of this section.

(*5*) Chromium shall be measured using the following methods:

(*i*) Method 218.2—''Atomic Absorption; furnace technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*ii*) Method 200.7—''Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,'' Rev. 3.3, April 1991. The revision is contained in the manual entitled ''Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, (EPA/600/4–91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*iii*) of this section.

(*6*) Copper shall be measured as total recoverable metal without filtration using the following methods:

(*i*) Method 220.2—Atomic Absorption; furnace technique, in ''Methods for Chemical Analysis of Water and Wastes,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*ii*) Method 220.1—Atomic Absorption; direct aspiration, in ''Methods for Chemical Analysis of Water and Wastes,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*iii*) Method 200.7—''Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,'' Rev. 3.3, April 1991. The revision is contained in the manual entitled ''Methods for the Determination of Metals in Environmental Samples,'' Office of Research and Development, (EPA/600/4–91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service, U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161, or may be examined at the Office of Plant and Dairy Foods and Beverages (HFS–305), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(*iv*) Method 200.8—''Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991. The revision is contained in the manual entitled ''Methods for the Determination of Metals in Environmental Samples,'' June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*7*)(*iii*) of this section.

(*v*) Method 200.9—''Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,'' Revision 1.2, April 1991. The revision is contained in the manual entitled ''Methods for the Determination of Metals in Environmental Samples,'' June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*2*)(*iii*) of this section.

(*7*) [Reserved]

(8) Lead shall be measured as total recoverable metal without filtration using the following methods:

(*i*) Method 239.2—Atomic Absorption; furnace technique, in ''Methods for Chemical Analysis of Water and Wastes,'' which is incorporated by reference in accordance

with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*2*)(*iii*) of this section.

(*ii*) Method 200.8—''Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Revision 4.4, April 1991. The revision is contained in the manual entitled ''Methods for the Determination of Metals in Environmental Samples,'' June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*7*)(*iii*) of this section.

(*iii*) Method 200.9—''Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,'' Rev. 1.2, April 1991. The revision is contained in the manual entitled ''Methods for the Determination of Metals in Environmental Samples,'' June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*2*)(*iii*) of this section.

(*9*) Mercury shall be measured using the following methods:

(*i*) Method 245.1—''Manual cold vapor technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*ii*) Method 245.2—''Automated cold vapor technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*10*) [Reserved]

(*11*) Nitrate and/or nitrite shall be measured using the following methods:

(*i*) Method 353.3—''Spectrophotometric cadmium reduction,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*ii*) Method 353.2—''Colorimetric, automated, cadmium reduction,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(*iii*) Method 300.0—''The Determination of Inorganic Anions in Water by Ion chromatography,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service, Port Royal Rd., Springfield, VA 22161, or may be examined at the Office of Plant and Dairy Foods and Beverages (HFS–305), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC.

(*iv*) Method 353.1—''Colorimetric, automated, hydrazine reduction,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*12*) Selenium shall be measured using the following methods:

(*i*) Method 270.2—''Atomic Absorption; furnace technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*ii*) Method 270.3—''Atomic Absorption; gaseous hydride,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*13*) [Reserved]

(F) Analyses to determine compliance with the requirements of paragraphs (b)(4)(iii)(B) and (b)(4)(iii)(C) of this section shall be conducted in accordance with an applicable method or applicable revisions to the methods listed in paragraphs (b)(4)(iii)(F)(*1*) through (b)(4)(iii)(F)(*20*) of this section and described, unless otherwise noted, in ''Methods for the Determination of Organic Compounds in Drinking Water,'' Office of Research and Development, Environmental Monitoring Systems Laboratory EPA/600/4–88/039, December 1988, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, or may be examined at the Office of Plant and Dairy Foods and Beverages (HFS–305), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(*1*) Method 502.1—''Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography,'' Rev. 2.0, 1989, (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*2*) Method 502.2—''Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series,'' Rev. 2.0, 1989 (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*3*) Method 503.1—''Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography,'' Rev. 2.0, 1989 (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*4*) Method 524.1—''Measurement of Purgeable Organic Compounds in Water by Packed Column Gas Chromatography/Mass Spectrometry,'' Rev. 3.0, 1989 (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*5*) Method 524.2—''Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry,'' Rev. 3.0, 1989 (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*6*) Method 504—''1,2-Dibromoethane (EDB) and 1,2-Dibromo-3-Chloropropane (DBCP) in Water by Microextraction and Gas Chromatography,'' Rev. 2.0, 1989 (applicable to dibromochloropropane (DBCP) and ethylene dibromide (EDB)), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*7*) Method 505—''Analysis of Organohalide Pesticides and Commercial Polychlorinated Biphenyl (PCB) Products in Water by Micro-Extraction and Gas Chromatography,'' Rev. 2.0, 1989 (applicable to alachlor, atrazine, chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, toxaphene and as a screen for polychlorinated biphenyl's (PCB's)), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*8*) [Reserved]

(*9*) Method 507—''Determination of Nitrogen- and Phosphorus-Containing Pesticides in Water by Gas Chromatography with a Nitrogen-Phosphorus Detector,'' Rev. 2.0, 1989 (applicable to alachlor and atrazine), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*10*) Method 508—''Determination of Chlorinated Pesticides in Water by Gas Chromatography with an Electron Capture Detector,'' Rev. 3.0, 1989 (applicable to chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, toxaphene, and as a screen for PCB's), which is incorporated

by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*11*) Method 508A—''Screening for Polychlorinated Biphenyls by Perchlorination and Gas Chromatography,'' Rev. 1.0, 1989 (used to quantitate PCB's as decachlorobiphenyl if detected in methods 505 or 508) in paragraph (b)(4)(iii)(F)(*7*) or (b)(4)(iii)(F)(*9*) of this section, respectively), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*12*) Method 515.1—''Determination of Chlorinated Acids in Water by Gas Chromatography with an Electron Capture Detector,'' Rev. 5.0, May 1991 (applicable to 2,4-D, 2,4,5–TP (Silvex) and pentachlorophenol), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*13*) Method 525.1—''Determination of Organic Compounds in Drinking Water by Liquid-Solid Extraction and Capillary Column Gas Chromatography/Mass Spectrometry,'' Rev. 2.2, May 1991 (applicable to alachlor, atrazine, chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, and pentachlorophenol), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*14*) Method 531.1—''Measurement of N-Methylcarbamoyloximes and N-Methylcarbamates in Water by Direct Aqueous Injection HPLC with Post Column Derivatization,'' Rev. 3.0, 1989 (applicable to carbofuran), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(*F*) of this section.

(*15*) [Reserved]

(G) Analyses to determine compliance with the requirements of paragraph (b)(4)(iii)(D) of this section shall be conducted in accordance with an applicable method and applicable revisions to the methods listed in paragraphs (b)(4)(iii)(G)(*1*) and (b)(4)(iii)(G)(*2*) of this section and described, unless otherwise noted, in ''Methods of Chemical Analysis of Water and Wastes,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*1*) Aluminum shall be measured using the following methods:

(*i*) Method 202.1—''Atomic Absorption; direct aspiration technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(*ii*) Method 202.2—''Atomic Absorption; furnace technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*iii*) Method 200.7—''Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,'' Rev. 3.3, April 1991. The revision is contained in ''Methods for the Determination of Metals in Environmental Samples,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of the incorporation by reference is given in paragraph (b)(4)(iii)(E)(*2*)(*iii*) of this section.

(*iv*) Method 200.8—''Determination of Trace Elements in Waters and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991. The revision is contained in ''Methods for the Determination of Metals in Environmental Samples,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*iii*) of this section.

(*v*) Method 200.9—''Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption, Spectrometry,'' Rev. 1.2, April 1991. The revision is contained in ''Methods for the Determination of Metals in Environmental Samples,'' June 1991, which is incorporated by reference in accordance with 5. U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*7*)(*iii*) of this section.

(*2*) Silver shall be measured using the following methods:

(*i*) Method 272.1—''Atomic Absorption, direct aspiration,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*ii*) Method 272.2—''Atomic Absorption, furnace technique,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*iii*) Method 200.7—''Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,'' Rev. 3.3, April 1991. The revision is contained in ''Methods for the Determination of Metals in Environmental Samples,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*iii*) of this section.

(*iv*) Method 200.8—''Determination of Trace Elements in Waters and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Rev. 4.4, April 1991. The revision is contained in ''Methods for the Determination of Metals in Environmental Samples,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*iii*) of this section.

(*v*) Method 200.9—''Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption, Spectrometry,'' Rev. 1.2, April 1991, in ''Methods for the Determination of Metals in Environmental Samples,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*iii*) of this section.

(*3*) and (*4*) [Reserved]

(*5*) *Radiological quality.* (i) Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (b)(5)(ii) of this section, meet standards of radiological quality as follows:

(A) The bottled water shall not contain a combined radium-226 and radium-228 activity in excess of 5 picocuries per liter of water.

(B) The bottled water shall not contain a gross alpha particle activity (including radium-226, but excluding radon and uranium) in excess of 15 picocuries per liter of water.

(C) The bottled water shall not contain beta particle and photon radioactivity from manmade radionuclides in excess of that which would produce an annual dose equivalent to the total body or any internal organ of 4 millirems per year calculated on the basis of an intake of 2 liters of the water per day. If two or more beta or photon-emitting radionuclides are present, the sum of their annual dose equivalent to the total body or to any internal organ shall not exceed 4 millirems per year.

(ii) Analyses conducted to determine compliance with paragraph (b)(5)(i) of this section shall be made in accordance with the methods described in the applicable sections of ''Standard Methods for the Examination of Water and Wastewater,'' 15th Ed. (1980), and ''Interim Radiochemical Methodology for Drinking Water,'' U.S. EPA, EMSL,

EPA–600/4–75–008 (Revised), March 1976, both of which are incorporated by reference. The availability of these incorporations by reference is given in paragraph (b)(2) of this section.

(c) *Label statements.* When the microbiological, physical, chemical, or radiological quality of bottled water is below that prescribed by paragraphs (b)(2) through (b)(5), of this section, the label shall bear the statement of substandard quality specified in § 130.14(a) of this chapter except that, as appropriate, instead of or in addition to the statement specified in § 130.14(a) the following statement(s) shall be used:

(1) ''Contains Excessive Bacteria'' if the bottled water fails to meet the requirements of paragraph (b)(2) of this section.

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

(3) ''Contains Excessive _____,'' with the blank filled in with the name of the chemical for which a maximum contaminant level in paragraph (b)(4) of this section is exceeded (e.g., ''Contains Excessive Arsenic,'' ''Contains Excessive Trihalomethanes'') except that ''Contains Excessive Chemical Substances'' may be used if the bottled water is not mineral water.

(4) ''Excessively Radioactive'' if the bottled water fails to meet the requirements of paragraph (b)(5) of this section.

(d) *Adulteration.* 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 water bears a label statement of substandard quality prescribed by paragraph (c) of this section.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

7. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

8. Section 184.1563 is amended by revising paragraph (c) to read as follows:

§ 184.1563 Ozone.

* * * * *

(c) In accordance with § 184.1(b)(2), the ingredient is used to treat food only within the following specific limitations:

Category of food	Maximum treatment level in food	Functional use
Bottled water that prior to ozonation meets the microbiological, physical, chemical, and radiological quality standards of § 165.110 (b)(2) through (b)(5) of this chapter.	Not to exceed current good manufacturing practice. Current good manufacturing practice results in a maximum residual level at the time of bottling of 0.4 milligram of ozone per liter of bottled water.	Antimicrobial agent, § 170.3 (o)(2) of this chapter.

Dated: November 3, 1995.

William K. Hubbard,

Acting Duputy Commissioner for Policy.

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