



Testimony of
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Hearing on
Regulation of Bottled Water

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Good morning Mr. Chairman and Members of the Subcommittee. I am Joshua Sharfstein, Principal Deputy Commissioner of Food and Drugs at the Food and Drug Administration, which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to discuss with you today the regulation of bottled water.

Bottled water is an increasingly popular beverage. According to the Beverage Marketing Corporation, the amount of bottled water consumed in the United States has doubled over the past 10 years. Specifically, between 1998 and 2008, the average per capita consumption of bottled water has increased from 14.7 to 28.5 gallons.

A possible indicator of bottled water's popularity is the volume of questions about bottled water coming into the Food and Drug Administration's (FDA or the Agency) regulatory and consumer information staff. People frequently contact us to ask questions such as: Who regulates bottled water? How is it regulated? Is bottled water tested and inspected? My testimony will summarize FDA's approach to regulating bottled water. I will cover such topics as our legal authority to regulate bottled water, what regulations and guidance are in place, and inspections.

FDA REGULATION OF BOTTLED WATER

In the United States, bottled water and tap water are regulated by two different agencies: FDA regulates bottled water and the Environmental Protection Agency (EPA) regulates tap water, also referred to as municipal water or public drinking water. EPA's Office of Ground Water and Drinking Water has issued extensive regulations on the production, distribution and quality of

public drinking water, including regulations on source water protection, operation of drinking water systems, contaminant levels, and reporting requirements.

Under our statutory authority, FDA regulates bottled water as a food. The Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) provides FDA with broad regulatory authority over food that is introduced or delivered into interstate commerce. Under the FD&C Act, manufacturers are responsible for producing safe, wholesome and truthfully labeled food products, including bottled water products. It is a violation of the law to introduce into interstate commerce adulterated or misbranded products that violate the various provisions of the Act.

FDA has established specific regulations for bottled water in Title 21 of the *Code of Federal Regulations* (21 CFR). These regulations include standard of identity regulations in 21 CFR § 165.110(a), that define different types of bottled water, such as spring water and mineral water, and standard of quality regulations in 21 CFR § 165.110(b), that establish allowable levels for chemical, physical, microbial and radiological contaminants in bottled water. FDA also has established current Good Manufacturing Practice (cGMP) regulations for the processing and bottling of bottled drinking water in 21 CFR part 129. Labeling regulations (21 CFR part 101) and cGMP regulations (21 CFR part 110) for foods in general also apply to bottled water.

Current Good Manufacturing Practice Regulations -- These regulations require that bottled water be safe and that it be processed, bottled, held and transported under sanitary conditions.

Processing practices addressed in the cGMP regulations include protection of the water source from contamination, sanitation at the bottling facility, quality control to ensure the

bacteriological and chemical safety of the water, and sampling and testing of source water and the final product for microbiological, chemical, and radiological contaminants. Bottlers are required to maintain source approval and testing records to show to government inspectors. Checking adherence to part 129 regulations is an important part of FDA inspections of bottled water plants.

Standard of Identity Regulations -- Under the standards of identity regulation at 21 CFR

165.110(a), FDA defines bottled water 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. Fluoride also may be added within the limits set by FDA. The name of the food is "bottled water" or "drinking water." FDA also has defined various other types of bottled water, such as "artesian water," "artesian well water," "ground water," "mineral water," "purified water," "sparkling bottled water," and "spring water."

Bottled water labeled with any of these terms must meet the appropriate definitions under the standard of identity or it will be considered misbranded under the FD&C Act. For example, a bottle labeled as containing "mineral water" must meet the following criteria, among others: the water must contain no less than 250 parts per million (ppm) total dissolved solids; it must come from a geologically and physically protected underground water source; and it must contain no added minerals. "Mineral water" also must have a constant level and relative proportions of minerals and trace elements at the point of emergence from the source, with due account being taken of natural fluctuation cycles. FDA established its definitions for different types of bottled water in 1995. These preempted state definitions existing at that time, some of which varied

from state to state. We have provided, in an appendix to our testimony, a table which provides several of these definitions.

Standard of Quality Regulations -- Under the standard of quality regulation at 21 CFR 165.110(b), FDA establishes allowable levels for contaminants in bottled water. There are microbiological standards that set allowable coliform levels; physical standards that set allowable levels for turbidity, color and odor; and radiological standards that set levels for radium-226 and radium-228 activity, alpha-particle activity, beta particle and photon radioactivity, and uranium. The standard of quality also includes allowable levels for more than 70 different chemical contaminants.

Section 165.110(b) also lists methods that FDA will use to determine whether bottled water samples comply with the quality standard. Bottlers are not required to use these methods in their own facilities; alternate methods are acceptable. Whatever method they use, bottlers are responsible for ensuring that their bottled water can pass the tests used by FDA in its own laboratories, should testing be performed by FDA.

What happens if bottled water contains a substance at a level greater than that allowed under the quality standard? Section 165.110(c) states that when the microbiological, physical, chemical or radiological quality of bottled water is below that prescribed in the quality standard, the label of the bottled water bottle must contain a statement of substandard quality such as "Contains Excessive Bromate," "Contains Excessive Bacteria," or "Excessively Radioactive." Such labels solely indicate to the consumer that a quality standard has not been met. We are not aware of

firms that currently are availing themselves of their option to use such a disclaimer on the label. Even if such a labeling statement is used, labels cannot be used to ameliorate food safety deficiencies. Regardless of whether bottled water bears a statement of substandard quality, it is considered adulterated if it contains a substance at a level considered injurious to health under section 402(a)(1) of the FD&C Act.

Another noteworthy point about section 165.110 is that it allows for the use of safe and suitable antimicrobial agents such as ozone. FDA does not specifically require that bottlers use antimicrobial agents in bottled water as long as the water is safe for human consumption.

Inspection of Bottled Water Plants

FDA monitors and inspects bottled water products and processing plants as part of its general food safety program. Because FDA's experience over the years has shown that bottled water has a good safety record, bottled water plants generally are assigned a relatively low priority for inspection. The Agency, however, inspects violative firms more frequently, depending on the number, significance and recurrence of violations. In addition, FDA's field offices follow up on consumer and trade complaints and other leads, as appropriate, on potentially violative bottled water products.

In Fiscal Years (FY) 2007 and 2008, FDA and state agencies under contract to FDA conducted 412 and 468 inspections of bottled water facilities, respectively. In the first nine months of FY 2009, FDA and state contract agencies have conducted 253 inspections.

Information about what FDA inspectors look for during inspections generally is found in the Investigations Operations Manual published by FDA's Office of Regulatory Affairs (ORA), and more detailed information about inspections of bottled water facilities is found in the Guide to Inspections of Manufacturers of Miscellaneous Food Products, Volume II. Specific items mentioned in the inspection guide for bottled water establishments include: 1) verifying that the plant's product water and operational water supply are obtained from an approved source; 2) checking whether any source claims on the label comply with the definitions in 21 CFR 165.110(a); 3) inspecting washing and sanitizing procedures; 4) inspecting the filling, capping, and sealing operations; and 5) determining whether the firms analyze their source water and product water for the chemical and microbiological contaminants listed in 21 CFR 165.110(b), according to the required schedules.

Sampling and Testing

As with other types of food, FDA periodically collects and analyzes samples of bottled water. Samples come from several different sources. Some samples are collected during inspections if the inspector's observations warrant collection to test for contaminants or if the bottled water facility has a previous history of contamination. Other samples are collected in response to trade or consumer complaints. Finally, samples of foreign bottled water products offered for entry into the United States may be collected and tested to determine if they are in compliance with all applicable U.S. laws and FDA regulations.

FDA laboratories may test the water for microbiological, radiological or chemical contamination. Individual samples are not tested for all possible contaminants cited in the quality standard, but

for selected contaminants, depending on the reason for the sampling. For example, suspected microbiological contamination may result in microbiological analysis. (However, as noted, bottlers are required to maintain testing records to show to government inspectors for all the contaminants in the quality standard.) FDA also may review the labeling on bottled water samples.

State and Local Regulations

In addition to FDA, state and local governments also regulate bottled water. FDA relies on state and local government agencies to approve water sources for safety and sanitary quality, as specified in part 129.3(a). The International Bottled Water Association (IBWA) also has developed a model code of regulations that its members must follow.

Developing New FDA Regulations

It is important to note that under section 410 of the FD&C Act, FDA must follow specific instructions on establishing quality standard regulations for bottled water in response to regulatory developments at EPA concerning public drinking water.

Under section 410, when EPA establishes new maximum contaminant levels (MCL) or treatment techniques for contaminants in public drinking water as part of a National Primary Drinking Water Regulation (NPDWR), FDA is required to establish a standard of quality regulation for the same contaminants in bottled water, or to make a finding that such a regulation is not necessary to protect the public health because the contaminant is not present in water used for bottled drinking water. For treatment techniques, section 410 requires that bottled water be

subject to requirements no less protective of the public health than those applicable to water from public water systems using the techniques required by EPA's NPDWRs. If FDA adopts an allowable level under the quality standard regulations, the level in bottled water must be no less stringent than EPA's MCL for drinking water; FDA's regulation must have the same effective date as EPA's regulation and be published no later than 180 days before the effective date.

FDA has generally adopted EPA's MCLs for contaminants in public drinking water as allowable levels for the same contaminants in the quality standard regulations for bottled water. However, in some cases, FDA standards for bottled water differ from EPA standards for public drinking water. Lead is an example. In 1991, EPA adopted a requirement that public water systems treat their water to reduce lead when lead levels consistently exceed 15 parts per billion (ppb). The 15 ppb level took into account the fact that lead appears in public drinking water from corrosion of public water distribution systems and residential plumbing. However, leaching of lead from distribution systems is not a factor for bottled water and, based on its survey data, FDA concluded that bottlers can readily produce bottled water products with lead levels below 5 ppb. In 1994, FDA adopted an allowable level for lead at 5 ppb as a bottled water quality standard regulation. This action was consistent with FDA's goal of reducing consumers' exposure to lead in drinking water to the extent practicable.

Recent Regulatory Activities

In recent years, FDA has promulgated a number of quality standard regulations for bottled water in response to EPA regulatory activity. In March 2001, FDA adopted EPA's MCLs and maximum residual disinfectant levels (MRDL) for four disinfection byproducts (bromate,

chlorite, haloacetic acids and total trihalomethanes) and for three disinfectants (chloramine, chlorine and chlorine dioxide), respectively, as allowable levels in its standard of quality regulations for bottled water, with the same effective date as that for EPA's regulations for the same contaminants in public drinking water.

In March 2003, FDA issued a final rule that amended its quality standard for bottled water by adopting EPA's MCL for uranium public drinking water as the allowable level for the same contaminant in bottled water.

In June 2005, FDA issued a final rule that amended its bottled water quality standard regulations by revising the existing allowable level for the contaminant arsenic. The revised allowable level for arsenic in bottled water is the same as EPA's MCL for arsenic in public drinking water.

This year, on May 29, 2009, FDA published a final rule in the *Federal Register* (74 FR 25664), to require that bottled water manufacturers test source water for total coliform, and to require, if any coliform organisms are detected, that bottled water manufacturers determine whether any of the coliform organisms are *Escherichia coli* (*E. coli*), an indicator of fecal contamination.

FDA's final rule also amends its bottled water regulations to require, if any coliform organisms are detected in finished bottled water products, that bottled water manufacturers determine whether any of the coliform organisms are *E. coli*.

Bottled water containing *E. coli* will be considered adulterated, and source water containing *E. coli* will not be considered to be of a safe, sanitary quality and will be prohibited from use in the

production of bottled water. FDA is also requiring that, before a bottler can use source water from a source that has tested positive for *E. coli*, the bottler must take appropriate measures to rectify or eliminate the cause of *E. coli* contamination of that source, and that the bottler must keep records of such actions. Existing regulatory provisions require bottled water manufacturers to keep records of new testing required by this rule. The rule is effective on December 1 of this year.

ISSUES REGARDING FDA’S REGULATION OF BOTTLED WATER

General Accountability Office (GAO) Report

FDA has worked with GAO to provide information and assist with their investigation into bottled water regulation, and we have provided responses to their draft report. FDA is aware that the forthcoming GAO report highlights a number of challenges that the Agency faces in regulating bottled water.

While FDA has not seen the final version of the report, we understand that key concerns include that FDA currently does not have the ability to require the submission to the Agency of results from the testing conducted by and on behalf of bottled water manufacturers, and that FDA does not have specific authority to mandate the use of certified laboratories. These concerns are at least partially addressed by recent and pending legislation, as we discuss later below.

While GAO found FDA’s standard of quality regulations generally equivalent to EPA regulations, it noted that FDA has not yet set a standard for di(2-ethylhexyl)phthalate (DEHP).

GAO also found that FDA labeling regulations for bottled water provided for less information about the sources and quality of water than that required by EPA for municipal systems. On these two issues, we understand that GAO will recommend that the Secretary of HHS direct the Commissioner of FDA to:

- Issue a standard of quality regulation for DEHP or publish in the *Federal Register* the Agency's reasons for not doing so within 180 days of the conclusion of its task force study on the issue.
- Implement FDA's findings on methods that are feasible for conveying information about bottled water to customers, such as, at a minimum, requiring that companies provide on the label contact information directing customers how to obtain comprehensive information. Should FDA determine it lacks the necessary authority to implement its findings, it should seek legislation to obtain such authority.

DEHP

In the case of DEHP, FDA proposed in a 1993 *Federal Register* notice to adopt EPA's maximum contaminant level for this chemical in tap water as the allowable level in the bottled water quality standard regulations. A comment to this proposal pointed out that this chemical is permitted under the FD&C Act for use in certain types of food containers and closures. The comment raised the concern that lawful uses might result in levels of DEHP that would exceed the allowable level. Therefore, FDA's final rule published on March 26, 1996, stated that the Agency was deferring final action on the proposed allowable level for DEHP in bottled water.

FDA agrees with GAO that it should make a decision regarding establishing a level for DEHP in bottled water. At this time, therefore, FDA has decided to move forward on making such a decision and has begun the decision making process.

Bottled Water Feasibility Study on Additional Disclosures to Consumers

Under the Safe Drinking Water Act Amendments of 1996, section 114(b), FDA was required to publish for notice and comment a study on the feasibility of appropriate methods of informing consumers about the contents of bottled water. FDA published a notice requesting comments on this issue in November 1997 and a draft feasibility study in February 2000. Based on these comments, FDA published a final study report on August 25, 2000 (65 FR 51833). The final study report evaluates information received from the comments and identifies appropriate and feasible methods for conveying information about the contents of bottled water to consumers. FDA believes it is feasible for bottled water manufacturers to provide consumers with additional information on bottled water comparable to the data provided by municipal water systems. However, the FD&C Act does not provide FDA with the authority to require bottled water manufactures to disclose such information.

Food Safety Enhancement Act (FSEA)

FDA believes that the legislation currently being developed by the Energy and Commerce Committee takes some positive steps in providing additional authority that will help to fill some of the gaps identified by GAO. Specifically, section 102 provides for food safety plans, hazard analyses and preventative controls that will complement FDA's cGMPs for bottled water facilities. For foreign-produced bottled water, FSEA requires importers to register with FDA

and to comply with good importer practices, and gives FDA the authority to require certification as a condition of importation, in certain instances.

FSEA also provides FDA with the authority to establish science-based performance standards in section 103, routine access to records (section 106), and stronger criminal and civil penalties for violations of the FD&C Act (sections 134 and 135).

Finally, we note that upon implementation of the Reportable Food Registry provisions of the Food and Drug Administration Amendments Act of 2007 (PL 110-85), which FDA anticipates in early fall, bottlers will be required to report the results of tests showing that products in commerce pose a threat of serious adverse health consequences or death.

CONCLUSION

FDA regulates bottled water as a food under the FD&C Act and is responsible for ensuring that bottled water is safe and truthfully labeled. Specific FDA regulations for bottled water cover cGMPs for bottled water production and standards of identity and quality. Recent regulatory activity includes adoption of maximum allowable levels for critical contaminants, including certain disinfectants and disinfection byproducts, uranium, arsenic, and the adoption of testing and remediation requirements for the prevention of *E.coli* contamination.

FDA will carefully consider the conclusions of the GAO report and factor their findings into our future regulatory decisions. We will also continue to work with the Committee in your efforts to craft a bill that enhances food safety.

Thank you for the opportunity to testify.

APPENDIX

Table 1. Various types of bottled water.	
TYPE	DEFINITION
Artesian Water	Water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer.
Mineral Water	Water containing not less than 250 ppm total dissolved solids that originates from a geologically and physically protected underground water source. Mineral water is characterized by constant levels and relative proportions of minerals and trace elements at the source. No minerals may be added to mineral water.
Purified Water	Water that is produced by distillation, deionization, reverse osmosis or other suitable processes and that meets the definition of "purified water" in the U.S. Pharmacopeia, 23d Revision, Jan. 1, 1995. As appropriate, also may be called "demineralized water," "deionized water," "distilled water," and "reverse osmosis water."
Sparkling Bottled Water	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.
Spring Water	Water derived from an underground formation from which water flows naturally to the surface of the earth at an identified location. Spring water may be collected at the spring or through a bore hole tapping the underground formation feeding the spring, but there are additional requirements for use of a bore hole.
(FOR COMPLETE REGULATORY DEFINITIONS, SEE 21 CFR 165.110(A)(2).)	