International Bottled Water Association

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water
Docket No. FDA–2013–N–0333

Dear Sir or Madam:

The International Bottled Water Association (IBWA) is pleased to comment on the Food and Drug Administration (FDA) procedures that require domestic and foreign bottled water manufacturers that sell bottled water in the United States to maintain records of microbiological testing and corrective measures as described in 21 CFR 129.35(a)(3)(i), 129.80(g), and 129.80(h).

IBWA is the trade association representing all segments of the bottled water industry, including spring, artesian, mineral, sparkling, well, groundwater and purified bottled waters. Founded in 1958, IBWA member companies include domestic and international bottlers, distributors, and suppliers. IBWA's mission is to serve the members and the public, by championing bottled water as an important choice for healthy hydration and lifestyle, and promoting an environmentally responsible and sustainable industry.

Bottled Water Overview

Bottled water is comprehensively regulated by the FDA as a packaged food product and provides a consistently safe and reliable source of drinking water. By federal law, the FDA regulations governing the safety and quality of bottled water must be at least as stringent as the U.S. Environmental Protection Agency (EPA) regulations that govern public water systems. And in some very important cases like lead, coliform bacteria and *E. coli*, bottled water regulations are substantially more stringent.

All bottled water products, whether from groundwater or public water sources, are produced utilizing a multi-barrier approach. From source to finished product, a multi-barrier approach helps prevent possible harmful contamination to the finished product as well as storage, production, and transportation equipment. Measures in a multi-barrier approach may include one or more of the following: source protection, source monitoring, reverse osmosis, distillation, micro-filtration, carbon filtration, ozonation, and ultraviolet (UV) light.

Both EPA and FDA have substantial monitoring and testing requirements for drinking water. Additionally, FDA's current Good Manufacturing Practice (cGMP) regulations for bottled water (21 CFR Part 129) include requirements that:

- Are generally more frequent than public water systems on a per gallon basis;
- Do not allow for averaging of test results;
- Are consistent, regardless of number of consumers; and
- Are generally not subject to local monitoring waivers or reductions in test frequency.

Perhaps the most notable difference between tap water and bottled water is the method of delivery. Public water systems deliver water to consumers (businesses and private residences) through miles of underground iron (unlined and poly-lined), polyvinyl chloride and lead service lines that can be subject to leakage with age of the system and accidental failures, resulting in the risk of post-treatment contamination of the water that is delivered to consumers. Bottled water is delivered to consumers in sanitary, sealed containers that were filled in a bottling facility under controlled conditions in a fill room.

Bottled water is actually the only packaged food product currently regulated by FDA that is subject to both a dedicated set of cGMP regulations **and** an extensive set of testing standards under the standard of quality (SOQ) regulations. Furthermore, bottled water, as a packaged food product, is also now subject to an extensive set of new FDA requirements under the FDA Food Safety Modernization Act (FSMA) enacted in January 2011 and now being implemented. For bottlers/manufacturers, those new requirements will impact daily operations in terms of facility registrations, food safety plans and preventive controls, food defense plans, supply chain management and records maintenance. For FDA, those new requirements will allow for increased inspections, increased access to records, expanded administrative detention authority, new registration suspension authority, and new mandatory recall authority. IBWA supported the enactment of FSMA and is now fully engaged with FDA and other food industry stakeholders on its implementation.

History of the Updated FDA Bottled Water Microbial Rule

On November 8, 2006, the EPA promulgated a National Primary Drinking Water Regulation, referred to as the EPA Ground Water Rule.[1] The purpose of this rule was to ensure that the public health was adequately protected from fecally contaminated ground water. The EPA Ground Water Rule became effective December 1, 2009.

Under Section 410 of the Federal Food, Drug, and Cosmetic Act[2], FDA was required within 180 days of the effective date of the EPA Ground Water Rule to either promulgate a Standard of Quality for bottled water no less stringent and protective of the public health, or explain why the EPA rule was not relevant to bottled water. This law requires FDA to review all new EPA drinking water rules for applicability of standards and monitoring requirements to bottled water for the purpose of

[1] National Primary Drinking Water Regulations: Ground Water Rule, 71 Fed. Reg. 65574 (Nov. 8, 2006).
[2] FD&C Act, 21 U.S.C. § 349

assuring that bottled water regulations provide at least an equivalent level of public health protection. This is often referred to as "the hammer provision," and the requirements of the EPA Ground Water Rule would have become directly applicable to bottled water under the term of the "hammer provision" unless FDA acted on the rule by June 1, 2009.

On September 17, 2008, FDA published in the *Federal Register* a proposed rule to amend its bottled water regulations to incorporate a new standard of quality for *Escherichia coli* (*E. coli*) and to modify their current good manufacturing practice (cGMP) regulations for bottled water in order to satisfy the requirements of Section 410 of the Federal Food, Drug, and Cosmetic Act. On May 29, 2009, FDA published a final rule in the *Federal Register*, establishing a zero tolerance for *E.coli* for bottled water in both source water and finished product, thereby providing public health protection that is at least equivalent to the level of protection provided by the EPA Ground Water Rule. The current FDA Bottled Water Microbial Rule became effective December 1, 2009.

Requirements of the Current FDA Bottled Water Microbial Rule

Under the current Bottled Water Microbial Rule, the bottled water regulations in parts 129 and 165 (21 CFR parts 129 and 165) require that if any coliform organisms are detected in weekly total coliform testing of finished bottled water, follow-up testing must be conducted to determine whether any of the coliform organisms are *Escherichia coli*. The adulteration provision of the bottled water standard (§ 165.110(d)) provides that a finished product that tests positive for *E. coli* will be deemed adulterated under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(3)) and would be subject to recall.

Under the current Bottled Water Microbial Rule, the current good manufacturing practice (cGMP) regulations for bottled water in part 129 also require that source water from other than a public water system be tested at least weekly for total coliform. If any coliform organisms are detected in the source water, the bottled water manufacturers are required to determine whether any of the coliform organisms are *E. coli*. Source water found to contain *E. coli* is not considered to be water of a safe, sanitary quality and would be unsuitable for bottled water production. Before a bottler may use source water from a source that has tested positive for *E. coli*, a bottler must take appropriate measures to rectify or otherwise eliminate the cause of the contamination. A source previously found to contain *E. coli* will be considered negative for *E. coli* after five samples collected over a 24-hour period from the same sampling site are tested and found to be negative for *E. coli*. Bottlers must maintain records of corrective measures taken to rectify or eliminate *E. coli* contamination.

IBWA agrees with FDA's assessment that because current cGMP regulations for bottled water already reflect the time and associated recordkeeping costs for those bottlers that are required to conduct microbiological testing of their source water, as well as total coliform testing of their finished bottled water products, any additional burden and costs in recordkeeping based on follow-up testing that is required if any coliform organisms detected in the source water and finished bottled water products test positive for *E. coli* will not be significant.

IBWA strongly supported promulgation of the updated Bottled Water Microbial Rule that in reality set a higher *E. Coli* standard for bottled water than the EPA Ground Water Rule does for public water systems. EPA currently has no enforceable standard for either total coliform or *E. coli* in public source waters. Under the EPA Ground Water Rule, groundwater-sourced public water systems must engage in additional source water testing and implement a sanitary survey, specified levels of treatment, and other corrective actions. Public water systems are required to collect a specified number of samples per month, and the current EPA Total Coliform Rule (TCR) maximum contaminant level (MCL) for total coliform is "no more than 5% of monthly samples are valid for total coliform."

For example, if a small groundwater sourced public water system collects only the required minimum of 25 samples per month, one or more of those samples may test positive for total coliform, but the system would still be in compliance with the EPA's TCR. The TCR requires positive test results for total coliform to be confirmed for presence of *E. coli*. If any of the coliform samples are positive for *E. coli*, a public notification, usually with a boil water order, is issued to consumers. But the public water source is not removed from service. The same cannot be said for finished bottled water products that if found to test positive for *E. coli* will be deemed adulterated and subject to recall.

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Thank you for the opportunity to provide these comments, and please do not hesitate to contact us if you have any related concerns or questions.

Sincerely yours,

Daniel Felton
Vice President, Government Relations
International Bottled Water Association