IDEXX Summary #:5CJ

Title: FDA Approval for Colilert®, Colilert®-18 and Colisure® and Quanti-Tray®/ Quanti-Tray®/2000 for Bottled Water Source Water testing

Source: 21 Code of Federal Regulations Parts 129 and 165 as listed in the Federal Register / Vol. 74, No. 102 / Friday, May 29, 2009 / Rules and Regulations

Date: 29 May 2009

Highlights:

- The FDA amended its bottled water regulations to require manufacturers to test their source water for total coliform and to confirm any coliform positives for *E coli*, effective December 1, 2009
- Colilert®, Colilert®-18 and Colisure® and Quanti-Tray/ Quanti-Tray/2000 are approved analytical methods for quantifying both Total Coliforms and *E coli*, see comment 8 (attached), § 165.110 and § 129.35 and by inclusion in *Standard Methods for the Examination of Water and Wastewater*, see comment 6 (attached)
- 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 requires that bottled water manufacturers that obtain their source water from other than a public water system must *test their source water at least weekly for total coliform*, and that when source water is total coliform positive, that they conduct follow-up testing to determine whether any of the coliform organisms are *E. coli*
- After a positive has been detected in source water, a bottled water source water will be considered free from *E coli*, and acceptable for use in bottling, when 5 consecutive tests in a 24 hour period are negative for *E coli*
- This final rule will ensure that FDA's standards for the minimum quality of bottled water, as affected by fecal contamination, will be no less protective of the public health than those set by the Environmental Protection Agency (EPA) for public drinking water
- See yellow highlighted sections from the Federal Register Vol. 74, No. 102 / Friday, May 29, 2009

15 CFR CHAPTER IX

PART 902—NOAA INFORMATION COLLECTION REQUIREMENTS UNDER THE PAPERWORK REDUCTION ACT: OMB CONTROL NUMBERS

■ 1. The authority citation for part 902 continues to read as follows:

Authority: 44 U.S.C. 3501 *et seq.*

■ 2. In § 902.1, amend the table in paragraph (b), under the entry ''50 CFR'' by revising the entries for ''§ 665.13'', ''§ 665.14'', ''§ 665.16'' and ''§ 665.41'' to read as follows:

§ 902.1 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

* * * * *

(b) * * *

CFR part or section where the information collection requirement is located	Current OMB control number (all numbers begin with 0648–)
* * * * *	
50 CFR	.
* * * * *	
665.13	–0490, and 0586.
665.14	–0214, and 0586.
* * * * *	
665.16	–0360, and 0586.
* * * * *	
665.41	–0490, and 0586.
* * * * *	

[FR Doc. E9–12428 Filed 5–28–09; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 129 and 165

[Docket No. FDA–2008–N–0446]

Beverages: Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its bottled water regulations to require that bottled water manufacturers test source water for total coliform, as is required for finished bottled water products, and to require, if any coliform organisms are detected in source water, that bottled water manufacturers determine whether any of the coliform organisms are *Escherichia coli* (*E. coli*), an indicator of fecal contamination. FDA also is amending 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*. FDA also is amending the adulteration provision of the bottled water standard to reflect the possibility of adulteration caused by the presence of filth. 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 amending its bottled water regulations to require 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. This final rule will ensure that FDA's standards for the minimum quality of bottled water, as affected by fecal contamination, will be no less protective of the public health than those set by the Environmental Protection Agency (EPA) for public drinking water.

DATES: This rule is effective December 1, 2009. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of December 1, 2009.

FOR FURTHER INFORMATION CONTACT: Lauren Posnick Robin, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1639.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 17, 2008 (73 FR 53775), FDA published a proposed rule to amend its bottled water regulations in parts 129 and 165 (21 CFR parts 129 and 165) to provide increased protection against fecal contamination in water sources used for bottled water and in finished bottled water products (hereafter ''the proposed rule'' or ''the September 17, 2008 proposal''). FDA's current good manufacturing practice (CGMP) regulations for the processing and bottling of bottled water are contained in part 129. FDA's bottled water standard, contained in part 165, includes standard of identity regulations, which define different types of bottled water (§ 165.110(a)); standard of quality regulations, which establish allowable levels for contaminants in bottled water (§ 165.110(b)); required label statements for water of substandard quality (§ 165.110(c)); and an adulteration provision (§ 165.110(d)).

FDA proposed a number of changes to part 129. FDA proposed to amend § 129.35(a)(3)(i) to require that bottled water manufacturers that obtain their source water from other than a public water system (PWS) test their source water at least weekly for total coliform, and that when source water is total coliform positive, that they conduct follow-up[1] testing to determine whether any of the coliform organisms are *E. coli*. Further, FDA proposed to amend § 129.35(a)(3)(i) to indicate that if source water is found to contain *E. coli*, then the water would not be considered water of a safe, sanitary quality as required by § 129.35(a)(1). FDA also proposed in § 129.35(a)(3)(i) to require a bottler to rectify or otherwise eliminate the cause of the *E. coli* contamination. FDA also proposed that source water previously found to contain *E. coli* would be considered negative for *E. coli* after five samples collected from the source water supply over a 24-hour period are tested and found to be *E. coli* negative. FDA proposed in § 129.35(a)(3)(i) that bottlers maintain records of corrective measures taken to rectify or eliminate *E. coli* contamination in source water. FDA also proposed in § 129.80(g)(1) that if any coliform organisms are detected in weekly total coliform testing of finished bottled water, that bottlers must conduct follow-up testing to determine whether any of the coliform organisms are *E. coli*. Finally, FDA proposed revising § 129.35(a)(4)(iv) to include a reference to section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342(a)(3)) as a basis for adulteration, in addition to section 402(a)(1) of the act.

FDA proposed a number of changes to part 165. FDA proposed to add § 165.110(b)(2)(i)(B) to indicate that if *E. coli* is present in a sample of finished bottled water products, then the bottled water would be deemed adulterated

[1] In FDA's discussion, ''follow-up'' testing refers to testing to determine whether any of the coliform organisms detected in source water or finished bottled water products are *E. coli*.

under § 165.110(d). FDA also proposed to cite the multiple-tube fermentation (MTF) and membrane filter (MF) methods for both total coliform and *E. coli* testing in § 165.110(b)(2)(ii). Finally, FDA proposed to amend the adulteration provision of the bottled water standard in § 165.110(d) to reflect the possibility of adulteration caused by the presence of filth and to indicate that if *E. coli* is present in bottled water, then the bottled water will be deemed adulterated under section 402(a)(3) of the act.

FDA issued the proposed rule in response to EPA's issuance of a new National Primary Drinking Water Regulation (NPDWR), the Ground Water Rule (GWR), in the **Federal Register** of November 8, 2006 (71 FR 65574). The new NPDWR provides for increased protection against fecal microbial pathogens in PWSs that use ground water sources (also referred to as ground water systems (GWSs)). Under section 410(b)(1) of the act (21 U.S.C. 349(b)(1)), not later than 180 days before the effective date of an NPDWR issued by EPA for a contaminant under section 1412 of the Safe Drinking Water Act (SDWA) (42 U.S.C. 300g-1), FDA is required to issue a standard of quality regulation for that contaminant in bottled water, or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in PWSs but not in water used for bottled water. If FDA fails to take action within the prescribed time period in response to the NPDWR issued by EPA, section 410(b)(4)(A) of the act provides that EPA's NPDWR will apply to bottled water.

II. Summary of and Response to Comments

A. Summary of Comments

The agency received 19 responses, each containing one or more comments, to the September 17, 2008, proposal. The comments were from trade associations, industry, a law firm, an environmental advocacy organization, and consumers. The comments generally supported the proposed rule. Some comments addressed issues that are outside the scope of the proposed rule (e.g., testing of water in general; testing for agricultural chemicals, industrial chemicals, and parasites such as *Giardia*; public disclosure of test results for contaminants other than *E. coli*; and general labeling requirements) and thus will not be discussed here. A number of comments suggested certain modifications to the proposed rule. A summary of these comments and the agency's responses follow.

B. Response to Comments

(Comment 1) One comment suggested FDA make clear that when a bottler conducts secondary[2] sampling of source water previously found to contain *E. coli*, the sampling should include the original site where the *E. coli* positive occurred, if there is more than one sampling site at the source.

(Response) FDA agrees that the sampling site where an *E. coli* positive occurred must be used in secondary testing to determine whether the source can now be considered negative for *E. coli*. Proposed § 129.35(a)(3)(i) provided that source water previously found to contain *E. coli* would be considered negative for *E. coli* after five samples collected from the source water supply over a 24-hour period are tested and found to be *E. coli* negative. To eliminate any possible ambiguity related to the phrases ''source water'' and ''source water supply'' and to make clear what is required before bottlers can use source water from a source that has tested positive for *E. coli*, FDA is revising proposed § 129.35(a)(3)(i), in pertinent part, as follows: ''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 otherwise eliminate the cause of *E. coli* contamination of that source in a manner sufficient to prevent its reoccurrence. 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 that originally tested positive for *E. coli* are tested and found to be *E. coli* negative.''

FDA notes that some manufacturers combine source waters from multiple sources. Weekly microbiological testing is required for each separate source in use by the plant. If *E. coli* is detected in one of these sources, secondary testing must be conducted at that same source and at the same sampling site that originally tested positive for *E. coli*.

(Comment 2) One comment stated that FDA should join EPA in mandating sanitary surveys as an effective measure of risk reduction. The comment also stated that sanitary surveys can identify and eliminate risks or weaknesses which weekly water testing cannot, such as cracks in sanitary seals around wells. Finally, the comment stated that if the lack of a primacy program arrangement with the States is the real reason for the lack of a sanitary survey requirement, FDA should look into establishing a primacy program arrangement, such as having the same State agencies and inspectors, which EPA trains and uses to conduct sanitary surveys of public water sources, also conduct sanitary surveys of bottled water sources.

(Response) FDA disagrees with this comment. Although FDA does not have a primacy program arrangement with States to conduct sanitary surveys, FDA believes that the requirement for weekly source water testing for total coliform (and for *E. coli*, should total coliform be detected) in this rule, combined with the existing requirement in the bottled water CGMP regulations for source inspection and approval, will ensure that FDA's standards for the minimum quality of bottled water, as affected by fecal contamination, will be no less protective of the public health than those set by EPA for public drinking water.

While sanitary surveys may help identify potential risks for fecal contamination in source water, such as cracks in sanitary seals, actual fecal contamination of source water is identified by source water testing. This rule requires weekly source water testing for total coliform, with *E. coli* testing in case of a total coliform positive. In addition, as FDA noted in the proposed rule, FDA's CGMP regulations for bottled water already require in § 129.35(a)(1) that product water be from an approved source, defined in § 129.3(a) as ''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 applicable laws and regulations of State and local government agencies having jurisdiction.'' Additionally, § 129.35(a)(1) specifies that the approved source be ''properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality* * *'' FDA also notes that certain elements of the GWR's sanitary survey, as outlined by EPA (71 FR 65574 at 65577 and 65586 through 65587), are not relevant to bottled water plants (e.g., distribution system surveys) or are relevant only to EPA's unique regulatory structure (e.g., operator compliance with State requirements), and therefore would not be appropriate for FDA to include in this rule.

[2] In FDA's discussion, ''secondary'' testing refers to testing to determine whether a source previously found to contain *E. coli* can now be considered negative for *E. coli*.

Therefore, FDA believes that the proposed requirement for weekly source water testing for total coliform (and for *E. coli*, should total coliform be detected), combined with the existing requirement in the bottled water CGMP regulations for source inspection and approval, will ensure that FDA's standards for the minimum quality of bottled water, as affected by fecal contamination, will be no less protective of the public health than those set by EPA for public drinking water.

(Comment 3) A number of comments questioned the proposed requirements for frequency of testing of source water and/or finished products in part 129. Some comments suggested that EPA requires more samples than FDA, while citing different numbers for how many samples EPA requires. Another comment stated that weekly testing would not detect intermittent contamination, and that daily testing would be more appropriate, as evidenced by FDA's proposal that a source previously found to contain *E. coli* will be considered negative for *E. coli* after five samples collected from the same source water supply over a 24-hour period are tested and found to be *E. coli* negative. Several comments made the point that the cost of testing would be low compared with the cost of a disease outbreak resulting from contaminated water.

(Response) FDA disagrees with these comments on the proposed requirements for the frequency of testing of source water and finished products. FDA does not believe that it is appropriate to compare the number of tests required by EPA for total coliform in PWSs to the number of tests required by FDA for total coliform in source and finished bottled water. To monitor the microbiological safety of their distribution systems, PWSs must take samples throughout their distribution systems and in a pattern that is representative of the distribution system. Bottled water plants do not have distribution systems and monitor finished bottled water products from a filling line. Therefore, FDA does not believe that the number of tests required for a PWS distribution system serving a large geographical area is comparable to the monitoring required for a bottled water manufacturing plant.

In this rule FDA is amending its bottled water regulations to require that bottled water manufacturers test source water at least weekly for total coliform, as is required for finished bottled water products, and to require, if any coliform organisms are detected in source water, that bottled water manufacturers determine whether any of the coliform organisms are *E. coli*, an indicator of fecal contamination (§ 129.35(a)(3)(i)). By contrast, EPA requires testing of source water for *E. coli* only when triggered by a coliform positive in the distribution system. FDA also is amending its bottled water regulations to require that 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* (§ 129.80(g)(1)). (FDA notes that weekly sampling is the minimum required under the CGMP regulations for bottled water, and that manufacturers should test as frequently as needed to ensure the safety of their products.)

Also, FDA previously established additional microbiological testing requirements to help ensure the safety of finished bottled water products. The CGMP regulations for bottled water in § 129.80(a) state that product water samples shall be taken after processing and prior to bottling by the plant and analyzed as often as is necessary to assure uniformity and effectiveness of the processes performed by the plant. FDA also requires in § 129.80(f) that at least once each 3 months, a bacteriological swab and/or rinse count should be made from at least four containers and closures selected just prior to filling and sealing. All of the samples are required to be free of coliforms, and no more than one of the four samples may exceed more than one bacteria per milliliter of capacity or one colony per square centimeter of surface area.

For these reasons, FDA believes that the frequency of testing of source water and finished products, as set forth in the new and revised requirements under part 129, will ensure that FDA's standards for the minimum quality of bottled water, as affected by fecal contamination, will be no less protective of the public health than those set by EPA for public drinking water.

(Comment 4) One comment stated that the requirement that bottled water manufacturers ''take and analyze at least once a week a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production'' in § 129.80(g)(1) fails to specify that the day's production that is to be sampled must have been produced during the week in question.

(Response) FDA believes that § 129.80(g)(1) requires that the sample mandated to be taken ''at least once a week'' must be taken from bottled water produced during the week it is sampled. It would not make sense to interpret this provision to allow otherwise in light of the clear intent to mandate regular, timely testing. Further, FDA is not aware of any bottlers who have understood the provision as not requiring the sample to have been produced during the week in question. Therefore, FDA does not believe it is necessary to make any changes to § 129.80(g)(1) based on this comment.

(Comment 5) One comment suggested that FDA establish specific requirements, like the EPA GWR, as to how bottlers should correct *E. coli* contamination. The comment also stated that the FDA should consider employing EPA's various treatment options in order to ensure that bottlers are using methods that are known to be effective.

(Response) FDA does not agree that it is necessary to include specific requirements in its regulations for rectifying or eliminating the cause of *E. coli* contamination. Bottled water manufacturers are responsible for ensuring that their manufacturing operations comply with all applicable provisions of the act and FDA's regulations for bottled water, including the new provision providing that source water found to contain *E. coli* is not considered water of a safe, sanitary quality as required for use in bottled water. As noted in the proposed rule (73 FR 53775 at 53780), bottlers may wish to consult with States or with EPA, or review EPA guidance (*http://www.epa.gov/safewater/disinfection/gwr/compliancehelp.html*), for advice on how to eliminate causes of contamination. FDA notes that, under § 129.35(a)(1), bottled water manufacturers are responsible for using water from sources that have been approved by the government agency or agencies (e.g., State or local agencies) having jurisdiction. These government agencies may have helpful advice on rectifying or eliminating the cause of *E. coli* contamination at a specific source based on local conditions, since the cause of contamination may vary from site to site.

(Comment 6) One comment suggested that FDA update the reference in proposed § 165.110(b)(2)(ii) to the most current version of ''Standard Methods for the Examination of Water and Wastewater.''

(Response) FDA agrees that the most current edition should be cited in the final rule. In the proposed rule, FDA cited the 20th Edition of ''Standard Methods for the Examination of Water and Wastewater.'' However, there is a 21st Edition of ''Standard Methods for the Examination of Water and

Wastewater.'' Therefore, FDA is revising § 165.110(b)(2)(ii) to incorporate by reference the 21st Edition (2005) of ''Standard Methods for the Examination of Water and Wastewater.''

(Comment 7) One comment suggested the need for guidance on demonstrating comparable results when labs are comparing other methods to the MTF and MF methods. The comment further recommended that an established or pre-agreed-upon protocol should be used to prove comparability.

(Response) FDA does not believe that such guidance is necessary. As stated in the proposed rule (73 FR 53775 at 53782), bottlers can use different methods approved by the government agency or agencies having jurisdiction as long as their methods give comparable results to the methods used by FDA. Laboratories routinely adopt new analytical methods and have standard practices to follow for validating the performance of these methods and for comparing the sensitivity, accuracy, and precision of the new methods to currently used methods. These practices, along with the information provided by FDA on allowable levels of *E. coli* and total coliform (revised § 165.110(b)(2)(i)), sampling (§ 165.3(b)), and methodology (revised § 165.110(b)(2)(ii)), should provide laboratories with sufficient information to compare different methods to those used by FDA.

(Comment 8) Several comments recommended that FDA consider a test result for *E. coli* to be a valid ''positive'' only if it has been confirmed.

(Response) FDA agrees that a presumed positive test result for *E. coli* should be confirmed. This rule cites the MTF and MF methods, which incorporate confirmation steps for *E. coli* including streaking presumptive *E. coli* positive cultures on eosin methylene blue (EMB) agar, selecting colonies with the typical appearance of *E. coli*, and using a series of biochemical assays or rapid identification tests to identify *E. coli* isolates (Ref. 1).

As noted in the proposed rule, bottlers can use methods other than the MTF and MF methods to analyze water for total coliform and *E. coli*. However, FDA will use the MTF and MF methods when it tests source water or finished bottled water products. Bottlers that want to use different methods must ensure that their methods give comparable results. FDA notes that alternate methods must be capable of quantifying total coliform, if coliform is present, to meet the standard in § 165.110(b)(2)(i)(A). Furthermore, all methods, including those used to confirm presumed positive *E. coli*, must be methods approved by the government agency or agencies having jurisdiction, as required under § 129.35(a)(3)(ii).

(Comment 9) One comment stated that not all strains of *E. coli* bacteria are pathogenic, and therefore, water with *E. coli* in it is also not necessarily contaminated. The comment added that testing for specific pathogenic strains of *E. coli* and other intestinal parasites would prove more effective than general *E. coli* tests in determining whether water is contaminated.

(Response) FDA agrees that not all strains of *E. coli* are pathogenic. However, FDA disagrees that water with *E. coli* in it is not contaminated and that testing bottled water products for specific pathogenic strains would be more effective than testing for generic *E. coli*. In the GWR, EPA stated that ground water is fecally contaminated when fecal indicators such as *E. coli* are present. Because *E. coli* is indicative of fecal contamination, FDA provided in the proposed rule that bottled water containing *E. coli* would be considered adulterated under section 402(a)(3) of the act, in that it ''consists in whole or in part of any filthy, putrid, or decomposed substance, or * * * is otherwise unfit for food.'' Because testing for generic *E. coli* is sufficient to determine whether bottled water is fecally contaminated, it is not necessary to require testing for specific strains.

In addition, as noted in the GWR, while fecal indicators typically are not harmful when ingested, their presence demonstrates that there is a pathway for pathogenic viruses and bacteria to enter ground water sources (71 FR 65574 at 65576). Therefore, it is not necessary to test for specific pathogenic strains to demonstrate that there is a pathway for pathogenic viruses and bacteria to enter ground water sources. Confining testing to a few specific pathogenic strains would be less effective at detecting fecal contamination than the broader *E. coli* testing required by this rule. Therefore, FDA is not making changes in the final rule to require testing only for pathogenic strains of *E. coli*.

(Comment 10) One comment suggested that FDA adopt EPA's maximum contaminant level goals (MCLGs) as enforceable standards for chemical and microbiological contaminants in bottled water.

(Response) FDA notes that with the exception of fecal contaminants, this comment is outside of the scope of this rulemaking. MCLGs are unenforceable health goals established by EPA. EPA establishes enforceable standards for contaminants in drinking water in the form of maximum contaminant levels (MCLs) or treatment techniques (TTs). The SDWA (section 1412(b)(4) (42 U.S.C. 300g-1(b)(4))) requires EPA to set MCLs and TTs as close to the MCLGs as is feasible, with feasibility including technical and economic considerations. Section 410(b)(3)(A) of the act provides that an FDA regulation issued in response to an EPA MCL shall establish an MCL for the contaminant in bottled water which is no less stringent than the MCL provided in EPA's NPDWR. Likewise, section 410(b)(3)(B) of the act provides that an FDA regulation issued in response to an EPA TT shall be no less protective of the public health than the TT required by EPA's NPDWR. Therefore, FDA's response to NPDWRs is based on the legally enforceable MCLs and TTs, as provided for in the act.

(Comment 11) Several comments suggested that FDA require companies to disclose source information on bottled water labels. One comment said that there are ground water sources and surface water sources that are fouled by fecal pollution or other contaminants, and that public disclosure, on the bottle label, of the precise location of the water withdrawal site, of potential contamination of source water, or of pollutants in bottled waters will provide consumers with the evidence on which to make the decisions to purchase the product that would best suit their needs and the needs of their families.

(Response) FDA disagrees that it should require disclosure of source information as part of this rulemaking. FDA addressed the issue of source disclosure in the final rulemaking establishing a standard of identity for bottled water (§ 165.110(a)) (60 FR 57076 at 57104, November 13, 1995). FDA noted that under section 201(n) of the act (21 U.S.C. 321(n)), the agency must consider whether specific water source labeling information is a material fact whose nondisclosure will render the labeling misleading. FDA concluded that the specific name of the source is not material to ensure the safety of the product, given the requirements for source approval and operation in §§ 129.3(a) and 129.35(a)(1). FDA believes that the specific name of the source is not material to ensure the safety of the product from fecal contamination, in light of the requirements cited above and those added by this rule.

For this reason, FDA is not making any changes in response to these comments.

(Comment 12) Several comments suggested that FDA require bottled water companies to disclose test results for *E. coli* in source water and/or finished bottled water products to the

public. One comment stated that the FDA rule should include a provision for public notification as found in EPA tap water regulations, which require PWSs that use ground water to notify the public if monitoring samples test positive for a fecal indicator or if the appropriate water protection measures have not been taken in a timely manner.

(Response) FDA disagrees that it should require companies to routinely disclose test results for *E. coli* in source water and finished products to the public. Routine public disclosure of source water testing results is not necessary because source water containing *E. coli* will not be considered to be of a safe, sanitary quality under revised § 129.35(a)(3)(i) and thus will be prohibited from use in the production of bottled water under § 129.35(a)(1).

Likewise, routine public disclosure of test results for *E. coli* in finished bottled water products is not necessary because bottled water products that test positive for the fecal indicator *E. coli* are deemed adulterated under new § 165.110(b)(2)(i)(B) and revised § 165.110(d). Adulterated products cannot be introduced or delivered for introduction into interstate commerce under section 301 of the act (21 U.S.C. 331), and FDA may take enforcement action against adulterated products, including pursuing product seizure (section 304 of the act (21 U.S.C. 334)). In addition, FDA notes that its recall guidance in 21 CFR part 7 includes recommendations for public communication of recalls. Therefore, the new regulations are sufficient to ensure the safety of bottled water products, with regard to the presence of fecal contamination, without requiring routine public disclosure of testing results. Accordingly, FDA is not making any changes in response to this comment to require routine public disclosure of monitoring results.

(Comment 13) One comment requested that FDA limit the applicability of the proposed rule to bottled water manufacturers that use ground water, noting that FDA modeled its proposed rule after the EPA GWR, which expressly limits its application to PWSs that use ground water. The comment also states that if FDA intends to regulate manufacturers that use surface water, it should adopt the analogous provisions of EPA's regulations in 40 CFR part 141, subparts C and H, which were designed specifically for surface water PWSs, and which are based on filtration and disinfection requirements rather than FDA's proposed requirements for an *E. coli*-free source and regular source testing. This comment also stated that source testing and corrective action should not be required for manufacturers that use surface water, since EPA does not impose these requirements on surface water PWSs. As further support for its position, the comment argued that these requirements are not necessary for manufacturers that use surface water because *E. coli* are removed during treatment processes such that the amount of coliform in the source has no bearing on the final product. The comment also stated that the imposition of the corrective action requirements in this rule on any ''source,'' regardless of origin, would unfairly force manufacturers that use surface water to either shut down their intakes and undertake the impossible task of eliminating *E. coli* that is going to be eliminated anyway during treatment or, alternatively, purchase water from PWSs.

(Response) FDA disagrees with the comment that it should apply this rule specifically to bottled water manufacturers that use ground water, that any FDA requirements for bottled water manufacturers that use surface water should be modeled after EPA's regulations for surface water PWSs, and that FDA should not adopt its own source and testing requirements for bottled water because EPA has different requirements for surface water PWSs. The application of this rule to all bottled water manufacturers is consistent with the adulteration provisions in section 402(a)(3) and (a)(4) of the act and with FDA's obligations under section 410 of the act. Specifically, under section 410(b)(1) of the act, FDA is required to respond to EPA's issuance of an NPDWR for a contaminant in drinking water by issuing a standard of quality regulation for that contaminant in bottled water, or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in PWSs but not in water used for bottled water. Section 410(a)(b)(2) of the act also provides that a standard of quality regulation issued by FDA shall include monitoring requirements that the agency determines to be appropriate for bottled water.

In this rule, FDA is responding to an EPA NPDWR on fecal contamination in ground water. Fecal contamination can be found in surface water as well as ground water. Therefore, FDA believes that it is appropriate for it to respond to EPA's issuance of a NPDWR on fecal contamination in GWSs by establishing a regulation that will apply to all manufacturers of bottled water. As FDA explained in the proposed rule, ''[T]he potential for fecal contamination addressed in the EPA GWR also exists for ground water sources used for bottled water. The potential also exists for bottled water products from ground water sources to be contaminated during processing and for bottled water products from other sources to be contaminated from source water or during processing. Therefore, FDA is proposing to require that source water currently subject to weekly microbiological testing be analyzed specifically for total coliform * * *.'' (73 FR 53775 at 53779 through 53780). FDA notes that this rule is consistent with its regulatory approach, which has not been to establish separate regulations for ground water and surface water sources under parts 129 and 165.

In response to the comment's contention that the microbiological source testing and rectification requirements of this rule are not necessary for manufacturers that use surface water because microbiological contaminants are removed during treatment processes, FDA emphasizes that all bottled water products are subject to existing requirements related to the water supply. FDA's CGMP regulations for bottled water define ''an approved source'' as ''a source of water and the water therefrom * * * that has been inspected and the water sampled, analyzed, and found to be of a safe and sanitary quality according to applicable laws and regulations of State and local government agencies having jurisdiction'' (§ 129.3(a)). The CGMP regulations require that the product water supply be of a ''safe, sanitary quality'' (§ 129.35(a)(1)). FDA does not consider source water containing *E. coli* to be of a safe and sanitary quality. The CGMP regulations also require at least weekly microbiological testing under § 129.35(a)(3)(i) for source water obtained from other than a PWS. Therefore, sources other than PWSs that have not been sampled and analyzed for microbiological contaminants are not in compliance with FDA's CGMP regulations for source water.

One existing exemption to the microbiological testing requirement is for source water from PWSs. As explained in the final rule establishing this exemption, PWSs are subject to EPA regulations to ensure the safety of public drinking water, including water from surface sources (60 FR 57076 at 57111). In this case, FDA considers the source water for bottling to be the treated water from the PWS, not the original surface water source from which the PWS drew its water. Therefore, this rule's requirement for coliform and, potentially, *E. coli* testing

of source water does not apply to manufacturers that obtain their source water from PWSs that use surface water.

In response to concerns regarding the rule's impact on manufacturers that use surface water, FDA noted in the proposed rule that 70 to 75 percent of bottled water manufacturers use ground water (73 FR 53775 at 53779). FDA believes that the vast majority of the remaining manufacturers obtain their source water from PWSs, rather than from surface water sources, based on information provided by industry (66 FR 35439 at 35440 through 35441, July 5, 2001). FDA also notes that this comment did not provide any specific information identifying manufacturers using surface water that might be affected by the rule. For these reasons, FDA is unaware of evidence of any bottled water manufacturers using surface water directly from a surface water source that would be negatively affected by this rule, e.g., manufacturers using sources that are potentially contaminated with *E. coli*.

For the reasons summarized above, FDA is not making changes to the final rule in response to this comment.

III. Conclusion

The comments to the September 17, 2008, proposal (73 FR 53775) supported most of the provisions that FDA is adopting in this final rule. After review and consideration of the comments received in response to the September 17, 2008, proposal, FDA concludes that it should amend part 129 and part 165 as set forth in the proposed rule 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.

Therefore, FDA is amending parts 129 and 165 to provide the following:

- Bottled water manufacturers that obtain their source water from other than a PWS must test their source water at least weekly for total coliform, and if that source water is total coliform positive, must conduct follow-up testing to determine whether any of the coliform organisms are *E. coli* (§ 129.35(a)(3)(i));
- Source water found to contain *E. coli* will not be considered water of a safe, sanitary quality as required for use in bottled water by § 129.35(a)(1) (§ 129.35(a)(3)(i));
- 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 otherwise eliminate the cause of *E. coli* contamination of that source in a manner sufficient to prevent its reoccurrence. 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 that originally tested positive for *E. coli* are tested and found to be *E. coli* negative (§ 129.35(a)(3)(i));
- Bottlers must maintain records of corrective measures taken to rectify or eliminate *E. coli* contamination (§ 129.35(a)(3)(i));
- 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 *E. coli* (§ 129.80(g)(1));
- Section 402(a)(3) of the act, in addition to section 402(a)(1), may apply as a basis for adulteration (§ 129.35(a)(4)(iv));
- Analyses conducted to determine compliance with the standards for microbiological quality for total coliform and *E. coli* must be made in accordance with the MTF and MF methods (§ 165.110(b)(2)(ii)); and
- If *E. coli* is present in bottled water, then the bottled water is deemed to be adulterated under section 402(a)(3) of the act (§ 165.110(b)(2)(i)(B); § 165.110(d)).

As a result of these amendments to parts 129 and 165, upon the effective date of this final rule, December 1, 2009, any source water containing *E. coli* will not be considered water of a safe, sanitary quality and cannot be used for the production of bottled water. Also, any finished bottled water product that contains *E. coli* is deemed to be adulterated under section 402(a)(3) of the act.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule. 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.

V. Analysis of Impacts

A. Executive Order 12866 and Regulatory Flexibility Act

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the costs per entity of this rule are small, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

This final economic impact analysis revises the analysis set forth in the proposed rule (73 FR 53775) in response to comments received. Except as indicated below, the analysis in this final rule is the same as the analysis of the proposed rule.

1. Need for Regulation

FDA did not receive any comments on the need for regulation in the analysis of the proposed rule. Under section 410 of the act, FDA is required to respond to the GWR published by EPA by issuing its own standard of quality regulation for bottled water that is no less protective of the public health than the treatment techniques adopted by EPA in the GWR, unless it makes a finding that such additional regulations are not necessary to protect the public health. EPA published the GWR, in part, because data indicated that GWSs are susceptible to fecal contamination. Prior to the GWR, there were no Federal regulations requiring monitoring or disinfection of ground water sources or requiring corrective action when fecal

contamination or a risk of fecal contamination is found. The GWR puts in place a regulatory process, including treatment techniques, to identify and target GWSs that are susceptible to fecal contamination, and to require higher risk GWSs to monitor and, when necessary, take corrective action. As noted previously, if FDA fails to take action within the prescribed time period in response to the GWR, then under section 410(b)(4)(A) of the act, EPA's GWR will apply to bottled water. Further, section 410(b)(2) of the act requires that a standard of quality regulation issued by FDA shall include monitoring requirements that the agency determines to be appropriate for bottled water.

EPA determined that there is the potential for ground water to be contaminated with pathogenic bacteria or viruses, or both, and that the presence of fecal indicators can demonstrate a pathway for pathogenic enteric bacteria and viruses to enter GWSs. Ground water sources supply water for 70 to 75 percent of all U.S. bottled water products (Ref. 2). Based on EPA's findings in the GWR, FDA concludes that the potential for fecal contamination that exists for PWS ground water sources regulated by EPA's GWR also exists for bottled water using ground water sources. The potential also exists for bottled water products from ground water sources to be contaminated during processing and for bottled water products from other sources to be contaminated from source water or during processing.

Dun's Market Identifiers database lists 378 U.S. establishments under North American Industry Classification System (NAICS) code 312112 Bottled Water Manufacturing (69 FR 70082 at 70084, December 2, 2004). These 378 establishments correspond to 318 firms. Because a firm may own more than one establishment and each establishment may be a source, a bottling plant or both, this analysis will assume that each establishment corresponds to one source. Foreign bottled water establishments that produce and export their bottled water products for consumption in the United States will have to meet the same FDA requirements as domestic establishments. FDA is aware of at least 35 major brands of bottled water that are imported into the United States. When sales of a particular brand constitute a significant portion of the market share for this industry, then the brand is considered a major brand. If each imported brand corresponds to one foreign establishment, then an additional 35 foreign establishments will also be affected, giving a total of 413 establishments covered by this rule (Ref. 3). Because FDA assumes that each establishment is equivalent to a single water source, we estimate that 413 bottlers, both domestic and foreign, will be covered by this regulation. FDA received no comments on these estimates. However, in response to a comment on sampling after an *E. coli* positive, FDA noted that in some cases, bottlers may have more than one sampling site at a source or may combine water from more than one source for bottling. Because none of the comments provided information regarding the possible number of sources per bottler, for purposes of this analysis, FDA maintains in this final rule the one source to one establishment correspondence used in the cost estimates of the proposed rule.

2. Regulatory Options

FDA evaluated three regulatory options in the analysis of this rule:

Option 1. Take no action. If FDA fails to issue a standard of quality regulation or make a finding that such a regulation is not necessary to protect the public health, then EPA's GWR will apply to bottled water.

Option 2. Issue the regulations, as outlined in Option 3, but remove the existing exemption for weekly microbiological testing of source water from PWSs.

Option 3. Issue the regulations in this final rule. FDA is requiring that source water currently subject to weekly microbiological testing be analyzed specifically for total coliform and if any coliform organisms are detected in source water or in finished bottled water products, then bottled water manufacturers will be required to test for *E. coli*. 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. 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 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 that originally tested positive for *E. coli* are tested and found to be *E. coli* negative. Finished bottled water products containing *E. coli* will be deemed adulterated.

Several comments recommended that FDA consider an *E. coli* test result to be ''positive'' only if it has been confirmed so it is considered valid. In response, FDA pointed out that the test methods specified in the rule include confirmatory steps.

In evaluating the testing costs of the proposed rule, FDA based its estimates on EPA's GWR estimates for testing costs. At least some of the methods approved by EPA in the GWR include confirmatory testing for the fecal indicator organism. Therefore the costs of confirmatory testing are already included in the overall testing cost estimates used by EPA. Thus, the estimated testing costs in the economic impact analysis of the proposed rule remain the same for the economic impact analysis of this final rule.

Costs and Benefits of Options

Option 1. Take no action. If FDA does not issue a regulation by the statutory deadline, EPA's GWR for drinking water would become applicable to bottled water. EPA's GWR is designed for PWSs, which differ in significant ways from bottled water plants. Some of its provisions, such as those that address public water distribution systems, cannot be applied literally to bottled water plants, which do not have such distribution systems. Accordingly, FDA believes that Option 1 is not efficient and therefore less desirable than the chosen option.

Option 2. Change the testing requirements for source water and finished bottled water products to include total coliform testing of source water for all bottlers (i.e., remove the existing exemption for weekly microbiological testing of source water from PWSs) and require follow-up testing for *E. coli* when total coliform positives occur.

Bottlers that obtain their water from PWSs are not required to conduct microbiological testing of their source water under the CGMPs (§ 129.35(a)(3)(i)). FDA considered removing this exemption. This would have the advantage of requiring all bottlers to conduct the same tests (i.e., to test their source water for total coliform) and to conduct follow-up testing for *E. coli* when total coliform positives occur. However, removing the exemption for weekly microbiological testing of source water would be inefficient because PWSs are already covered by EPA drinking water regulations, including the GWR.

Option 3. FDA's Final Regulatory Action. Each requirement of FDA's regulatory action is evaluated separately in the following order:

1. Require that source water currently subject to weekly microbiological testing be analyzed specifically for total coliform;

2. Require follow-up testing for *E. coli* when total coliform positives occur in source water or finished bottled water products; and

3. Require bottlers, in the event the source water tests positive for *E. coli*, to rectify or otherwise eliminate the cause of contamination of the source, and then subsequently test samples from the same sampling site sufficiently until the source is considered negative for *E. coli*. Finished bottled water products that test positive for *E. coli* will be deemed adulterated.

Option 3 Explained

1. *Require that source water currently subject to weekly microbiological testing be analyzed specifically for total coliform.* The bottled water CGMPs at § 129.35(a)(3)(i) require that bottlers that obtain source water from other than a PWS conduct microbiological tests at least once a week. The CGMPs do not specify what organism to test for or the allowable level of bacterial contamination. FDA is now requiring that bottlers that obtain their water from other than a PWS must test their source water at least once a week for total coliform. FDA expects that most bottlers currently use total coliform testing to conduct these microbiological tests. For example, the Model Code of the International Bottled Water Association (IBWA), a trade association representing a large segment of the bottled water industry, requires total coliform testing of source water (Ref. 4). Furthermore, the 35 foreign producers mentioned in this analysis are members of IBWA. Because microbiological testing is already a requirement of the existing CGMPs and total coliform testing is a widely used test for microbiological quality of water, and because producers are already required to test for total coliform in finished products, FDA expects that the number of establishments affected by this requirement will be negligible and no additional costs are estimated for this provision.

2. *Require follow-up testing for E. coli when total coliform positives occur in source water or finished bottled water products.* As noted previously, FDA is requiring that bottlers that obtain their water from other than a PWS test their source water at least weekly for total coliform. Finished water products are already required to be tested for total coliform under the existing CGMPs. FDA is now requiring that if any coliform organisms are detected in source water or in finished water products, then the bottler must conduct follow-up testing for *E. coli*. The presence of any coliform indicates that the water may contain *E. coli*, an indicator of fecal contamination. Further, FDA agrees with EPA's conclusions that ground water sources may be vulnerable to fecal contamination and that such fecal contamination may pose a threat to health. Because ground water is the source water for approximately 75 percent of U.S. bottled water products, the potential for fecal contamination also exists for ground water sources used for bottled water. The potential also exists for finished bottled water products, whether from ground water sources or from other sources such as PWSs, to be contaminated during processing. FDA has determined that it is appropriate to require *E. coli* testing in response to a total coliform positive finding from weekly source and finished bottled water sampling. In this final rule, FDA estimates the costs of *E. coli* testing resulting from a total coliform positive. The estimated costs are based on the probability that the source water or a finished product will test positive for total coliform during any given year.

3. *Require bottlers, in the event the source water tests positive for E. coli, to rectify or otherwise eliminate the cause of contamination of the source, and then subsequently test samples from the same sampling site sufficiently until the source is considered negative for E. coli. Finished bottled water products that test positive for E. coli will be deemed adulterated.* If source water tests positive for *E. coli*, this cost model assumes that bottlers will respond by taking action to rectify or eliminate the cause of the contamination, by keeping records of those actions, and by subsequently testing samples from the same sampling site sufficiently until the source is considered negative for *E. coli*. The source will be considered negative for *E. coli* after five samples collected over a 24-hour period from the same sampling site that originally tested positive for *E. coli* are tested and found to be *E. coli* negative.

Finished bottled water products that test positive for *E. coli* will be deemed adulterated under section 402(a)(3) of the act and revised § 165.110(d) of the regulations. Costs to rectify or otherwise eliminate the cause of contamination in finished bottled water products are not estimated in this analysis.

Per Sample Testing Costs for E. coli

For purposes of this analysis, FDA assumes that 75 percent of domestic bottled water establishments obtain their water directly from sources other than a PWS and that the other 25 percent obtain their water from PWSs (66 FR 35439 at 35440 through 35441). FDA is assuming that all 35 foreign producers that export bottled water to the United States obtain their water from other than a PWS and are currently testing their sources for total coliform. As mentioned previously, FDA assumes that for all domestic and foreign producers, one establishment corresponds to one source. Thus, we estimate that 284 (75 percent) of 378 domestic establishments and all 35 foreign bottled water establishments (284 + 35 = 319) whose products are consumed in the United States obtain their water from other than a PWS. Based on this estimate, we further surmise that all 319 establishments are already conducting total coliform testing of their source water. And approximately 25 percent of the estimated total of 378 domestic bottled water establishments (approximately 95) obtains their water from a PWS.

Table 1 of this document covers *E. coli* testing costs per sample. The estimates of the laboratory fees and testing costs are derived from the GWR (Ref. 5). EPA estimated the national average testing costs per sample for *E. coli* based on 25 to 100 tests conducted annually. The estimated costs per sample can vary depending on whether the test is conducted in-house or at a commercial laboratory.

TABLE 1.—*E. coli* TESTING COSTS PER SAMPLE

Laboratory Type	Hourly Labor Cost	Labor Hours for Sample Collection	Cost of Sample Collection	Labor Hours for Sample Analysis	Analysis Materials	Per Sample Analysis Cost	Total Costs per Sample
In-house	$ 21.44	0.5	$ 10.72	0.5	$ 8.95	$ 19.67	$ 30.39
Commercial	$ 21.44	0.5	$ 10.72	0	$ 74.80	$ 74.80	$ 85.52

For in-house laboratories, the laboratory materials cost per sample is estimated to be $8.95 and the labor cost to be $21.44 for 1 labor hour per sample (one-half hour for collecting and handling the sample and another half hour for conducting the analysis). For an independent commercial laboratory analysis, the test cost per sample would include a shipping and commercial analysis fee of $74.80 and a labor cost of one-half hour to collect the sample and arrange for delivery to the laboratory.

FDA is not aware of how many potentially affected establishments will either use in-house testing facilities or outsource testing to commercial laboratories. For the purpose of this analysis, FDA assumes that all large bottlers will use in-house testing facilities and that either 50 percent (low-cost assumption) or 100 percent (high-cost assumption) of small bottled water establishments will outsource their testing. According to the Small Business Administration's definition of small business for this industry, about 82 percent of bottled water establishments are defined as small (69 FR 70082 at 70088). This may overestimate the number of bottlers that will outsource testing and thus may overestimate the cost of the rule. FDA did not receive any significant comments on this section.

Table 2 of this document shows the breakdown of bottlers by the low-cost and high-cost testing models, based on laboratory choice and an 82-percent small business rate. For the 319 bottlers using other than a PWS source, either 188 bottlers (59 percent) will use in-house testing facilities and 131 bottlers (41 percent) will use commercial laboratories or 57 bottlers (18 percent) will use in-house testing facilities and 262 bottlers (82 percent) will use commercial laboratories. For the 95 bottlers using PWS sources, either 56 bottlers (59 percent) will use in-house testing facilities and 39 bottlers (41 percent) will use commercial laboratories or 17 bottlers (18 percent) will use in-house testing facilities and 78 bottlers (82 percent) will use commercial laboratories.

TABLE 2.—HIGH-COST AND LOW-COST ASSUMPTIONS ABOUT THE NUMBER OF BOTTLED WATER ESTABLISHMENTS USING EITHER IN-HOUSE OR COMMERCIAL LABORATORIES

	Number of Bottlers Using Pther Than a PWS Source		Number of Bottlers Using a PWS Source	
	Low Cost	High Cost	Low Cost	High Cost
In-house laboratory	188 (59%)	57 (18%)	56 (59%)	17 (18%)
Commercial laboratory	131 (41%)	262 (82%)	39 (41%)	78 (82%)
	319	319	95	95

Total Coliform Frequency Estimates

To estimate the number of samples that are likely to test positive for total coliform each year, FDA assumes that the frequency of total coliform positive samples is proportional to EPA's total coliform positive frequency estimates (Ref. 6). FDA did not receive any comments on this section.

EPA's total coliform positive frequency estimates are dependent on the probability of a total coliform positive, which is dependent on the annual number of samples tested, which varies by system size. FDA requirements include at least weekly testing for total coliform in source water and finished products, or at least 52 source water samples and 52 finished product samples per year. For example, bottlers whose source is other than a PWS will have to test their source water at least once a week and also their finished product at least once a week. Bottlers whose source is a PWS are only required to test their finished product. (For this model, FDA assumes that each bottler is testing one type of finished product.) EPA found that the frequency rate for total coliform positives in ground water PWSs testing between 31 and 82 samples for total coliform each year, ranged between 0.22 and 3 samples per year per system (Ref. 6). FDA assumes that the same frequency rates are applicable to bottled water plants testing 52 samples a year, thus the expected annual frequency rate of total coliform positive samples per bottled water source is at most 3 per year. FDA further assumes that the annual frequency of a total coliform positive for finished product testing is also at most three per bottler. For example, bottlers that are conducting total coliform tests for both their source and finished product can expect to find three total coliform positives from their source and three total coliform positives in their finished product or a total of six total coliform positive samples per year. This means that they will need to conduct six tests for *E. coli* in 1 year. Bottlers whose sources are PWSs and are only required to conduct total coliform tests of their finished products can expect three positive samples per year. Combining this information, table 3 of this document shows *E. coli* testing costs for source water and finished bottled water products.

TABLE 3.—COSTS OF TESTING SOURCE WATER AND FINISHED BOTTLED WATER PRODUCTS FOR *E. coli*[1]

	A	B	C	(A X B X 6) + (A X C X 3)
	Cost per Sample	Number of Bottlers Testing Both Source Water and Finished Product (Six Tests/Year)	Number of Bottlers Testing Only Finished Product (Three Tests/Year)	Total Annual Costs of *E. coli* Testing
Low-cost assumption				
In-house laboratory	$30	188	56	$39,000
Commercial laboratory	$86	131	39	$77,000
Total low-cost assumption				$116,000

TABLE 3.—COSTS OF TESTING SOURCE WATER AND FINISHED BOTTLED WATER PRODUCTS FOR *E. coli*[1]—Continued

	A	B	C	(A X B X 6) + (A X C X 3)
	Cost per Sample	Number of Bottlers Testing Both Source Water and Finished Product (Six Tests/Year)	Number of Bottlers Testing Only Finished Product (Three Tests/Year)	Total Annual Costs of *E. coli* Testing
High-cost assumption				
In-house laboratory	$30	57	17	$12,000
Commercial laboratory	$86	262	78	$154,000
Total high-cost assumption				$166,000

[1] Estimates are not exact due to rounding.

Source water that tests positive for *E. coli* will not be considered to be of a safe and sanitary quality for bottling, as required in § 129.35(a)(1), and finished products that test positive for *E. coli* will be considered adulterated under section 402(a)(3) of the act and revised § 165.110(d) of the regulations.

A bottler could not use source water from a source found to contain *E. coli* for production of bottled water until the bottler has rectified or otherwise eliminated the cause of the contamination of the source, and has subsequently sufficiently tested samples from the same sampling site until the source can be considered negative for *E. coli*. 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 that originally tested positive for *E. coli* are tested and found to be *E. coli* negative.

This cost model assumes that bottlers will take action to rectify or eliminate the cause of contamination based on the first positive *E. coli* sample. Thus, the estimated number of bottlers that will find an *E. coli* positive sample per year will be equal to the estimated number of bottlers that will take action to rectify contamination each year. To estimate the number of establishments that are likely to take action to rectify contamination, FDA relied on EPA's estimate of the percentage of PWSs that use ground water sources with identified deficiencies (Ref. 7). EPA's estimate in turn was based on survey data from the Association of State Drinking Water Administrators (ASDWA 1997). FDA lacks better or more recent data. Establishments that have significant deficiencies or that detect fecal contamination are required to take corrective actions under the GWR. The survey responses indicated that 17 percent of systems had wells that were not constructed according to State regulations. FDA uses this percentage as an estimate of the number of systems that will have an *E. coli* positive result in source or product water over a 25-year period. EPA's cost model assumes deficiencies occur equally beginning in year 4 through 25 (22 years) of the analysis, which translates into 0.77 percent of all GWSs taking a corrective action each year over a 22-year period. Thus, of the 319 bottling establishments that use sources other than PWSs, about 53 (17 percent) are likely to take corrective action as a result of an *E. coli* finding in a 22-year period. This translates to 2.5 bottlers every year. For its analysis, FDA also assumes that each of these 2.5 bottlers will incur an *E. coli* positive finding only once in a given year. Table 4 of this document summarizes these estimates.

TABLE 4.—NUMBER OF BOTTLERS THAT INCUR AN *E. coli* POSITIVE IN SOURCE WATER AND MUST RECTIFY CONTAMINATION

Number of bottlers that use sources other than a PWS	319
Fraction of bottlers with potential source water contamination (17 percent/22 years)	0.0077
Number of bottlers that must rectify contamination each year over a 22-year period	2.5

As stated earlier, a source will be considered negative for *E. coli* after five samples collected over a 24-hour period from the same sampling site that originally tested positive for *E. coli* are tested and found to be negative. Therefore the number of bottlers that will test five more source samples after taking some type of action to rectify contamination is also 2.5. Assuming this secondary testing is conducted in-house or in a commercial laboratory, total annual costs of testing five additional samples for *E. coli* is estimated to be either $380 or $1,069 per year. Table 5 of this document summarizes these estimates.

TABLE 5.—TOTAL ANNUAL COSTS OF TESTING FIVE MORE SAMPLES FOR *E. coli* AFTER A POSITIVE FINDING[1]

	A	B	A X B X 5
	Cost per Sample	Number of Bottlers Testing Source Water	Total Annual Costs of Testing Five Samples for *E. coli*
In-house laboratory	$30	2.5	$380
Commercial laboratory	$86	2.5	$1,069

[1] Estimates are not exact due to rounding.

Costs to Rectify Contaminated Sources

As noted previously, FDA requires bottlers to rectify or otherwise eliminate the cause of contamination of a source before source water can be used from that source. FDA drew on EPA's Economic Impact Analysis of the GWR to provide estimates for costs of rectifying or eliminating contamination.

EPA estimated costs using a high- and low-cost distribution. The low-cost scenario assumes a greater percentage (60 percent) of systems with significant deficiencies will have less expensive (low-cost) deficiencies to correct. The high-cost scenario assumes a greater percentage of systems will have more expensive (high-cost) deficiencies to correct. EPA provides examples of a low-cost deficiency (replacing a sanitary well seal) and a high-cost deficiency (rehabilitating an existing well) (Ref. 7). Unit costs for these repairs are based on the Technology and Cost Documents for the Final GWR (Ref. 8) and appear here in table 6 of this document. EPA expects that the costs of these significant deficiencies represent the range of costs that establishments would be expected to incur although there are many other corrective actions that could be taken. For example, drilling a new well or purchasing water from a different supplier could be done but in most cases would probably be more expensive than the options listed earlier.

Based on EPA's assumptions, FDA estimates one-time costs to bottlers of rectifying contamination range from approximately $17,000 to $22,000 each year.

TABLE 6.—ESTIMATED ANNUAL COSTS OF RECTIFYING CONTAMINATED SOURCES[1]

Action	Unit Cost	Distribution of Actions	Number of Bottlers That Will Rectify a Contaminated Source Each Year	Total Annual Costs of Rectifying Contaminated Sources
Replace a sanitary well seal	$3,627	.60	2.5	$5,441
Rehabilitate an existing well	$11,986	.40	2.5	$11,986
Total costs assuming a low-cost distribution (rounding up)				$17,427
Replace a sanitary well seal	$3,627	.40	2.5	$3,627
Rehabilitate an existing well	$11,986	.60	2.5	$17,979
Total costs assuming a high-cost distribution (rounding up)				$21,606

[1] Estimates are not exact due to rounding.

Based on discussions with experts, EPA suggests that still other corrective actions such as fencing off or limiting access to protective wells could actually cost less than the two options listed previously from their model (Ref. 7).

In addition to the costs of a sanitary well or the costs of rehabilitating an existing well, other potential costs could include product loss, temporarily shutting down the operation, or changing to an alternate source. FDA did not receive any comments on this section.

Recordkeeping Costs

Under this final rule, those bottlers that are required to test their source water and finished bottled water products at least weekly for total coliform (and for *E. coli* if any coliform organisms are detected) will be required to maintain records of the microbiological test results and corrective measures taken in response to a finding of *E. coli* for at least 2 years under revised § 129.35(a)(3)(i), as well as current § 129.80(g) and (h) of the CGMP regulations. The existing CGMP regulations 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. FDA concludes that any additional costs in recordkeeping based on the new testing requirements for source water and finished bottled water products would be negligible.

Summary of Costs

Total costs for this final rule, including the estimated annual costs for *E. coli* testing and for rectifying contaminated sources, are shown in tables 7 through 11 of this document. Annual testing costs are estimated as either low or high costs depending on the number of bottlers that use either in-house testing laboratories or outsource testing to commercial laboratories. Costs of rectifying contaminated sources are estimated using the low- and high-cost distribution from EPA's Economic Impact Analysis of the GWR.

FDA estimates that 95 establishments that use PWSs are likely to find a total coliform positive three times a year in their finished product and thus will incur testing costs for *E. coli* three times a year as shown in table 7 of this document. Of the 95 bottlers that use PWS sources in table 7, either 56 bottlers (59 percent) will use in-house testing facilities at $30 per sample and 39 bottlers (41 percent) will use commercial laboratories at $86 per sample totaling approximately $15,000 under the low-cost assumption, or about 17 bottlers (18 percent) will use in-house testing facilities at $30 per sample and 78 bottlers (82 percent) will use commercial laboratories at $86 per sample costing about $21,000 under the high-cost assumption.

TABLE 7.—ESTIMATED TOTAL ANNUAL AND DISCOUNTED *E. coli* TESTING COSTS TO BOTTLERS THAT USE PWSS[1]

Total *E. coli* Testing Costs	Annual Costs	Discounted Costs (20 years at 7 percent)
Number of bottlers with PWS source = 95		
Total cost of finished product testing (low-cost assumption)	$15,000	$160,000

TABLE 7.—ESTIMATED TOTAL ANNUAL AND DISCOUNTED *E. coli* TESTING COSTS TO BOTTLERS THAT USE PWSS[1]—Continued

Total *E. coli* Testing Costs	Annual Costs	Discounted Costs (20 years at 7 percent)
Total cost of finished product testing (high-cost assumption)	$21,000	$230,000

[1] Estimates are not exact due to rounding.

FDA estimates that 319 establishments that use sources other than PWSs are likely to find a total coliform positive about six times a year (three times in their source and three times in their finished product) and therefore, will incur testing costs for *E. coli* six times a year as shown in table 8 of this document. Of the 319 bottlers that obtain their water from other than a PWS, 188 bottlers (59 percent) will use in-house testing facilities at $30 per sample and 131 bottlers (41 percent) will use commercial laboratories at $86 per sample totaling approximately $101,000 under the low-cost assumption, and about 57 bottlers (18 percent) will use in-house testing facilities at $30 per sample and 262 bottlers (82 percent) will use commercial laboratories at $86 per sample costing about $145,000 under the high-cost assumption.

TABLE 8.—ESTIMATED TOTAL ANNUAL AND DISCOUNTED *E. coli* TESTING COSTS TO BOTTLERS THAT USE SOURCES OTHER THAN PWSS[1]

E. coli Testing Costs	Annual Costs	Discounted Costs (20 years at 7 percent)
Number of Bottlers = 319		
Total costs of source and finished product testing (low-cost assumption)	$101,000	$1 million
Total costs of source and finished product testing (high-cost assumption)	$145,000	$1.5 million

[1] Estimates are not exact due to rounding.

Of the 319 establishments that obtain their water from other than a PWS, it is likely that 2.5 establishments will test positive for *E. coli* annually over 22 years and may need to take corrective action and conduct secondary testing. Estimated costs to rectify the cause of contamination using low- and high-cost assumptions appear in table 9 of this document.

TABLE 9.—ESTIMATED TOTAL ANNUAL AND DISCOUNTED COSTS TO RECTIFY CONTAMINATION[1]

Costs to Rectify Contamination	Annual Costs	Discounted Costs (20 years at 7 percent)
Number of bottlers = 2.5		
Total costs to rectify contamination (low cost)	$17,000	$ 185,000
Total costs to rectify contamination (high cost)	$22,000	$ 230,000

[1] Estimates are not exact due to rounding.

Secondary testing costs are shown in table 10 of this document and illustrate costs for bottlers that will use either in-house or commercial laboratories.

TABLE 10.—ESTIMATED TOTAL ANNUAL AND DISCOUNTED SECONDARY TESTING COSTS FOR *E. coli*

Testing Costs	Annual Costs	Discounted Costs (20 years at 7 percent)
Number of bottlers	2.5	2.5
Total costs of five additional tests if using in-house laboratory	$380	$4,000
Total costs of five additional tests if using commercial laboratory	$1,069	$11,000

Table 11 of this document shows the estimated total annual costs of this final rule (Option 3) by adding tables 7, 8, 9, and 10 to be $134,000 (low cost) and $189,000 (high cost). The estimated total discounted or present value costs (using a 7-percent interest rate over a 20-year period) are $1.4 million (low) and $1.9 million (high).

TABLE 11.—ESTIMATED TOTAL ANNUAL AND DISCOUNTED COSTS OF FINAL RULE

	Total Annual Costs of Final Rule	Total Discounted Costs of Final Rule (20 years at 7 percent)
Low cost	$134,000	$1.4 million
High cost	$189,000	$1.9 million

Benefits

FDA is not aware of any outbreaks or enforcement actions associated with fecal pathogens in bottled water in the United States in the last 10 years. Therefore, we are not able to quantify any public health benefits of this option.

However, while FDA is not aware of any recent outbreaks associated with fecal pathogens in bottled water, this does not mean that such outbreaks could never occur. Under the current FDA regulations, the potential exists for fecal pathogens in ground water to be undetected and be distributed to consumers in bottled water and cause illness. Testing for the fecal indicator *E. coli*, if total coliform is present, and prohibiting *E. coli*-contaminated water from being used as source water or product water, would reduce this potential.

By issuing this regulation, FDA will ensure that FDA's standards for the minimum quality of bottled water, as affected by fecal contamination, will be no less protective of the public health than those set by EPA for public drinking water.

B. Small Entity Analysis

FDA examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities. The Small Business Administration's definition of a small business for NAICS code 312112 Bottled Water Manufacturing is an entity with 500 or fewer employees. Under this definition, 82 percent of the bottled water firms (260 of 318) in the Dun's Market Identifiers database are identified as small firms (69 FR 70082 at 70088). Assuming that 82 percent of total annual costs shown in table 11 of this document will be incurred by small firms, and that 92 percent of the small firms are domestic, then total annual domestic costs of $100,000 to $140,000 will be incurred by the 260 small firms. However, because it is possible that a firm may not find a total coliform positive in any year during a 20-year period, subsequent testing for *E. coli* or taking action to rectify contamination would not be needed and thus, average estimated annual costs per firm can be as low as $380. Average estimated annual costs per firm can be as high as $540 because it is also possible for a firm to incur costs to rectify contamination in any given year over a 20-year period as a result of finding total coliform and *E. coli* positives. This rule will affect a substantial number of small bottled water manufacturers. Although the number of small bottlers affected is large, the average annual costs per business are small. The annual average cost per small bottler (weighted by requirement costs) is summarized in table 12 of this document.

TABLE 12.—WEIGHTED AVERAGE ANNUAL COSTS PER SMALL ENTITY

Annual Costs per Requirement	Weighted Average Annual Costs per Entity	
	Low Cost	High Cost
Number of small firms = 260		
E. coli testing of source water and finished products	$285	$407
E. coli testing finished products only	$50	$70
E. coli secondary testing	$1	$3
Costs to rectify contamination	$50	$60
Average costs per bottler	$380	$540

To investigate the potential significance of these impacts, FDA entered these costs into a model created under contract by the Eastern Research Group (ERG) (Ref. 9). The model is designed to estimate the percentage of small firms that would go out of business because of compliance costs if those costs accrued to all small firms in a given industry. According to this model, an annual cost of $380 to $540 would generate a near zero percent probability that a small firm with less than 20 employees that faced those costs would go out of business. Because the costs per entity of this rule are small, the agency concludes that this final rule will not have a significant economic impact on a substantial number of small entities. FDA did not receive any comments on this section.

VI. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Comments on the information collection provisions of this final rule are being solicited in a separate notice published elsewhere in this issue of the **Federal Register**. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VII. Federalism[3]

FDA has analyzed this rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.''

Section 403A of the act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a) of the act provides that: ''* * * no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—(1) any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(g) * * *.'' FDA has interpreted this provision to apply to standards of quality (21 CFR 100.1(c)(4)).

FDA has determined that the revisions to the standard of quality for bottled water relating to microbiological quality (§ 165.110(b)(2)) will have a preemptive effect on State law. Although this rule has a preemptive effect in that it will preclude States from issuing requirements for microbiological testing in bottled water that are not identical to the requirements for microbiological testing in bottled water as set forth in this rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act. Section 403A(a)(1) of the act displaces both State legislative requirements and State common law duties (*Riegel* v. *Medtronic*, 128 S. Ct. 999 (2008)).

VIII. References

The following references have been placed on display in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified all Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Bacteriological Analytical Manual (BAM) Online. September 2002. Chapter 4: Enumeration of *Escherichia coli* and the Coliform Bacteria. Accessed online at *http://www.cfsan.fda.gov/~ebam/bam-4.html*.

2. International Bottled Water Association, 2007. Personal communication. August 30, 2007.

3. Skipton, Hay, Albrecht, ''Drinking Water: Bottled or Tap?'' University of Nebraska of Nebraska-Lincoln, Institute of Agriculture and Natural Resources, G1448, January 2002. Accessed online at *http://www.ianrpubs.unl.edu/epublic/live/g1448/build/g1448.pdf*.

4. International Bottled Water Association, 2005, IBWA Model Code, Version March 2005. Accessed online at *http://www.bottledwater.org/public/pdf/IBWA05ModelCode_Mar2.pdf*.

5. Economic Analysis for the Final Groundwater Rule. Office of Water (4606–M) EPA 815–R–06–014 October 2006. Section 6.2.2 Laboratory Fees. Accessed online at: *http://www.epa.gov/safewater/disinfection/gwr/pdfs/support_gwr_economicanalysis.pdf*.

6. Economic Analysis for the Final Groundwater Rule. Office of Water (4606–M) EPA 815–R–06–014 October 2006. Section 4.2.7 Triggered Monitoring Baseline. p. 4–21 and 4–22. Accessed online at *http://www.epa.gov/safewater/disinfection/gwr/pdfs/support_gwr_economicanalysis.pdf*.

7. Economic Analysis for the Final Groundwater Rule. Office of Water (4606–M) EPA 815–R–06–014 October 2006. Section 6.4.4 Sanitary Survey Corrective Actions. p. 6–33. Accessed online at *http://www.epa.gov/safewater/disinfection/gwr/pdfs/support_gwr_economicanalysis.pdf*.

8. Technology and Cost Document for the Final Ground Water Rule. Office of Water (4606–M) EPA 815–R–06–015 October 2006. Section 5.3.1 Significant Deficiency Corrective Actions. p. 5–11. Accessed online at *http://www.epa.gov/safewater/disinfection/gwr/pdfs/support_gwr_cost-technologies.pdf*.

9. Eastern Research Group, Inc., ''Model for Estimating the Impacts of Regulatory Costs on the Survival of Small Businesses and its Application to Four FDA-Regulated Industries,'' Contract No. 223–01–2461, June 7, 2002.

List of Subjects

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.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 129 and 165 are amended as follows:

PART 129—PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

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

Authority: 21 U.S.C. 342, 348, 371, 374; 42 U.S.C. 264.

■ 2. Section 129.35 is amended by revising paragraphs (a)(3)(i) and (a)(4)(iv) to read as follows:

§ 129.35 Sanitary facilities.

* * * * *

(a) * * *

(3) * * *

(i) Samples of source water from each source in use by the plant are to be taken and analyzed by the plant as often as necessary, but at a minimum frequency of once each year for chemical contaminants and once every 4 years for radiological contaminants. Additionally, source water obtained from other than a public water system is to be sampled and analyzed for total coliform at least once each week. If any coliform organisms are detected, follow-up testing must be conducted to determine whether any of the coliform organisms are *Escherichia coli*. This sampling is in addition to any performed by government agencies having jurisdiction. Source water found to contain *E. coli* is not considered water of a safe, sanitary quality as required for use in bottled water by paragraph (a)(1) of this section. 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 otherwise eliminate the cause of *E. coli* contamination of that source in a manner sufficient to prevent its reoccurrence. 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 that originally tested positive for *E. coli* are tested and found to be *E. coli* negative. Records of approval of the source water by government agencies having jurisdiction, records of sampling and analyses for which the plant is responsible, and records describing corrective measures taken in response to a finding of *E. coli* are to be maintained on file at the plant.

* * * * *

(4) * * *

(iv) The finished bottled water must comply with bottled water quality standards (§ 165.110(b) of this chapter) and section 402(a)(1) and (a)(3) of the

[3] As stated in the Background section of this document, if FDA fails to take action within the prescribed time period in response to the NPDWR issued by EPA, EPA's NPDWR will apply to bottled water. On May 20, 2009, President Obama issued a Memorandum for the Heads of Executive Departments and Agencies on preemption. FDA will analyze this rule in light of the President's Memorandum and will amend the rule if needed to reflect the express preemption provision in section 403A(a) of the act.

Federal Food, Drug, and Cosmetic Act dealing with adulterated foods.

* * * * *

■ 3. Section 129.80 is amended by revising paragraph (g)(1) to read as follows:

§ 129.80 Processes and controls.

* * * * *

(g) * * *

(1) For bacteriological purposes, take and analyze at least once a week for total coliform a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The representative sample shall consist of primary containers of product or unit packages of product. If any coliform organisms are detected, follow-up testing must be conducted to determine whether any of the coliform organisms are *E. coli*.

* * * * *

PART 165—BEVERAGES

■ 4. The authority citation for 21 CFR part 165 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 343–1, 348, 349, 371, 379e.

■ 5. Section 165.110 is amended by revising paragraphs (b)(2), (b)(3) introductory text, (c)(1), and (d) to read as follows:

§ 165.110 Bottled water.

* * * * *

(b) * * *

(2) *Microbiological quality.* (i) Bottled water shall, when a sample consisting of analytical units of equal volume is examined by the methods described in paragraph (b)(2)(ii) of this section, meet the following standards of microbiological quality:

(A) *Total coliform—*(*1*) *Multiple-tube fermentation (MTF) 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

(*2*) *Membrane filter (MF) 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.

(B) *E. coli.* If *E. coli* is present, then the bottled water will be deemed adulterated under paragraph (d) of this section.

(ii) Analyses conducted to determine compliance with paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section and § 129.35(a)(3)(i) of this chapter shall be made in accordance with the multiple-tube fermentation (MTF) or the membrane filter (MF) methods described in the applicable sections of ''Standard Methods for the Examination of Water and Wastewater,'' 21st Ed. (2005), American Public Health Association. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the American Public Health Association, 800 I St. NW., Washington, DC 20001, 202–777–2742 (APHA). You may inspect a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(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), 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, 800 I St. NW., Washington, DC 20001, 202–777–2742 (APHA), or a copy may be examined at the National Archives and Records Administration (NARA), or at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2163, for information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*), meet the following standards of physical quality:

* * * * *

(c) *Label statements.* * * *

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

* * * * *

(d) *Adulteration.* Bottled water containing a substance at a level considered injurious to health under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the act), or that consists in whole or in part of any filthy, putrid, or decomposed substance, or that is otherwise unfit for food under section 402(a)(3) 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. If *E. coli* is present in bottled water, then the bottled water will be deemed adulterated under section 402(a)(3) of the act.

Dated: May 21, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–12494 Filed 5–26–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2009–0391]

RIN 1625–AA00

Safety Zone; Chicago Harbor, Navy Pier Southeast, Chicago, IL

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Navy Pier Southeast Safety Zone in Chicago Harbor from May 2009 through June 2009. This action is necessary protect vessels and people from the hazards associated with fireworks displays. During the enforcement period, no person or vessel may enter the security zone without the permission of the Captain of the Port Lake Michigan Zone.

DATES: The regulations in § 165.931 will be enforced from May 23, until June 27, 2009.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or e-mail BM2 Kraft, Prevention Department, Coast Guard Sector Lake Michigan, Milwaukee, WI at (414) 747–7154, e-mail *adam.d.kraft@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Safety Zone; Chicago Harbor, Navy Pier Southeast, Chicago, IL in 33 CFR 165.931 for the following events during the dates and times indicated below:

(1) *Navy Pier Sunday Fireworks;* on May 24, 2009 from 9:15 p.m. through 9:45 p.m.

(2) *Navy Pier Wednesday Fireworks;* on May 27, 2009 from 9:15 p.m. through 9:45 p.m.; on June 3, 2009 from 9:15