**Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water**

**0910-0658**

**SUPPORTING STATEMENT**

**Terms of Clearance:** None.

## A. Justification

1. Circumstances Making the Collection of Information Necessary

The U.S. Environmental Protection Agency (EPA) promulgated the National Primary Drinking Water Regulation (NPDWR), the Ground Water Rule (GWR) (71 FR 65574; November 8, 2006), to provide for increased protection against fecal microbial pathogens in public water systems (PWSs) that use ground water sources (also referred to as ground water systems (GWSs)). In the GWR, EPA established treatment techniques intended to identify and target GWSs that are susceptible to fecal contamination and require such GWSs to monitor and, when necessary, take corrective action to prevent or remove such contamination.

Under section 410(b)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 349(b)(1)), when EPA issues a NPDWR for a contaminant under section 1412 of the Safe Drinking Water Act (SDWA) (42 U.S.C. 300g-1), the U.S. Food and Drug Administration (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. Section 410(b)(3) of the FD&C Act (21 U.S.C. 349(b)(3)) requires the standard of quality for a contaminant in bottled water to be no less stringent than EPA's maximum contaminant level (MCL) and no less protective of the public health than EPA's treatment technique requirements for the same contaminant. In addition, section 410(b)(2) of the FD&C Act (21 U.S.C. 349(b)(2)) 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 response to EPA's GWR and in accordance with section 410(b)(1) of the FD&C Act, FDA amended its bottled water regulations in parts 129 and 165 (21 CFR parts 129 and 165) by requiring that if any coliform organisms are detected in weekly total coliform testing of finished bottled water, follow-up testing must be conducted to determine whether any of the coliform organisms are E. coli. FDA also amended the adulteration provision of the bottled water standard (§ 165.110(d)) to indicate that finished product that tests positive for E. coli will be deemed adulterated under section 402(a)(3) of the FD&C Act. In addition, FDA amended the current good manufacturing practice (CGMP) regulations for bottled water in part 129 by requiring that source water from other than a PWS be tested at least weekly for total coliform. If any coliform organisms are detected in the source water, the bottled water manufacturers are required to determine whether any of the coliform organisms are E. coli. Source water found to contain E. coli is not considered water of a safe, sanitary quality and would be prohibited for use in production of bottled water. Before a bottler may use source water from a source that has tested positive for E.

coli, a bottler must take appropriate measures to rectify or otherwise eliminate the cause of the contamination. A source previously found to contain E. coli will be considered negative for E. coli after five samples collected over a 24-hour period from the same sampling site that originally tested positive for E. coli are tested and found to be E. coli negative.

FDA requests the extension of OMB approval of the information collection provisions in the following citations:

**21 CFR 129.35(a)(3)(i) – Recordkeeping**

Requires 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 to be maintained on file at the plant.

**21 CFR 129.80(g) – Recordkeeping**

Requires the plant to maintain records of date of sampling, type of product sampled, production code, and results of analysis.

**21 CFR 129.80 (h) – Recordkeeping**

Requires all records required by §§129.1, 129.20, 129.35, 129.37, 129.40, and 129.80 to be maintained at the plant for not less than 2 years; requires plants to retain, on file at the plant, current certificates or notifications of approval issued by the government agency or agencies approving the plant's source and supply of product water and operations water; requires all required documents to be available for official review at reasonable times.

2. Purpose and Use of the Information Collection

The potential exists for bottled water products from ground water sources to be contaminated from ground water sources or during processing and for bottled water products from other sources to be contaminated from source water or during processing. Therefore, FDA requires that source water subject to weekly microbiological testing be analyzed specifically for total coliform, as it is required for finished bottled water products. Further, FDA requires that if any coliform organisms are detected in weekly total coliform testing of source water or finished bottled water, follow-up testing must be conducted to determine whether any of the coliform organisms are E. coli. The requirements in these regulations help ensure that bottled water is subject to requirements no less protective of the public health than the treatment techniques adopted by EPA in the GWR for public drinking water.

Records of microbiological testing, including testing for total coliform and follow-up testing for E. coli when necessary, are needed to allow FDA to determine whether procedures to help prevent the occurrence of fecal microbial pathogens in bottled water products are being carried out in an effective manner over time. Furthermore, FDA personnel may not be present when producers perform sampling and analysis of bottled water. These records would allow FDA to verify that the required testing is conducted. These records would also allow FDA to confirm that test results meet FDA's standards and that producers are taking appropriate actions based on the results.

Recordkeeping not only helps the agency determine whether bottled water is manufactured, packaged, and held in a manner consistent with FDA's bottled water regulations, but also

provides a public health benefit to consumers. When bottled water manufacturers keep records, for example, of lot or batch numbers, the records facilitate a bottler's recall of suspect products in case a recall becomes necessary. This benefits consumers because the manufacturer can recall products that may be adulterated or misbranded more quickly.

Another requirement is that bottlers maintain records of measures taken to address a positive E. coli finding in source water. Records of corrective measures are needed for FDA to determine compliance with the rule's requirement that bottlers take appropriate measures to rectify or otherwise eliminate the cause of E. coli contamination in source water.

In summary, the records required for additional microbiological testing and for substantiation of corrective measures provide assurance to both the bottler and FDA that the risk of contamination of bottled water products with fecal microbial pathogens is being minimized.

*Description of Respondents*: The respondents to this information collection are domestic and foreign bottled water manufacturers that sell bottled water in the United States. Recordkeepers are from the private sector (for profit businesses).

3. Use of Improved Information Technology and Burden Reduction

Companies are free to use whatever forms of information technology may best assist them in retaining the appropriate records and making them available to regulatory officials. The FD&C Act does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. The agency estimates that about ninety percent (90%) of the records will be maintained electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only Federal agency that collects this information. There is no duplication of recordkeeping requirements.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that eighty percent (80%) of recordkeepers are small businesses. The SDWA contains no statutory exception for small businesses from its provisions. The same information is requested from large and small firms and is the minimal amount needed. There is no special burden placed on small businesses by these recordkeeping provisions. The recordkeeping provisions are applicable to all businesses including small businesses. FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs weekly. FDA believes that mandatory recordkeeping is consistent with the congressional intent of the SDWA and important for public health reasons. Less frequent recordkeeping would reduce or nullify the effectiveness of the regulation to provide assurance to both the bottler and FDA that source water and finished bottled water products are not contaminated with fecal microbial pathogens.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this information collection.

8. Comments in Response to the Federal Register Notice/Outside Consultation

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of January 18, 2013 (78 FR 4152). FDA received two letters in response to the notice, which contained multiple comments.

One comment suggested that laboratory quality assurance practices should be required for the testing of bottled water. FDA's CGMP regulations for bottled water in 21 CFR 129 do not specifically require laboratory quality assurance practices, and FDA does not have the specific statutory authority to require bottlers to use certified laboratories for water quality tests. However, the CGMP regulations for source water testing do require that "[t]est and sample methods shall be those recognized and approved by the government agency or agencies having jurisdiction over the approval of the water source, and shall be consistent with the minimum [standard of quality] requirements set forth in § 165.110(b) of this chapter" (§ 129.35(a)(3)(ii)). The CGMP regulations also state that "[a]nalysis of the sample may be performed for the plant by competent commercial laboratories (e.g., Environmental Protection Agency (EPA) and State-certified laboratories)" (§129.35(a)(3)(iii)). For product water, the regulations also state that bottled water manufacturers will "[a]nalyze such samples by methods approved by the government agency or agencies having jurisdiction" (§ 129.80(g)(3)).

One comment noted that the EPA issued a final rule on February 13, 2013, that established a maximum contaminant level for E. coli and stated that E. coli is a more specific indicator of fecal contamination and the potential presence of associated pathogen occurrence than fecal coliforms. FDA agrees that E. coli is an appropriate indicator of fecal contamination and that the presence of fecal indicators demonstrates the potential for the presence of fecal pathogens. FDA requires bottled water manufacturers to sample and analyze source water obtained from other than a public water system for total coliform at least once each week. If any coliform organisms are detected, manufacturers must conduct follow-up testing to determine whether any of the coliform organisms are E. coli. Source water found to contain E. coli is not considered water of a safe, sanitary quality as required for use in bottled water. Manufacturers must also analyze product water samples at least once a week for total coliform, and, if any coliform organisms are detected, they must conduct follow-up testing to determine whether any of the coliform organisms are E. coli. Product water containing E. coli is considered adulterated. Thus, the presence of the fecal indicator E. coli is the key factor for determining whether source water is of a safe, sanitary quality, and whether product water is adulterated. FDA is reviewing the EPA final rule referenced in the comment (National Primary Drinking Water Regulations: Revisions to the Total Coliform Rule, 78 FR 10269; February 13, 2013) to determine what actions, if any, FDA needs to take to respond to the rule.

To the extent that the comments recommended changes to FDA's bottled water regulations, which can only be accomplished by rulemaking, the comments were outside the scope of the four collection of information topics on which the notice requested comments and will not be discussed in this document.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The regulation does not contain an assurance of confidentiality. The agency expects that it may inspect firm records containing confidential commercial information. Confidential commercial information is protected from disclosure under the Freedom of Information Act under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). To the extent 21 CFR 20.64 applies, FDA will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

11. Justification for Sensitive Questions

This information collection does not contain questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

*Description of Respondents*: The respondents to this proposed information collection are domestic and foreign bottled water manufacturers that sell bottled water in the United States. Recordkeepers are from the private sector (for profit businesses).

12a. Annualized Hour Burden Estimate

FDA estimates the burden for this information collection as follows:

Table 1 – Estimated Annual Recordkeeping Burden

| 21 CFR Section and Type of Recordkeeper | No. of Record-keepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Record-keeping | Total Hours |
|---|---|---|---|---|---|
| § 129.35(a)(3)(i), § 129.80(h) (bottlers subject to source water and finished product testing) | 319 | 6 | 1,914 | 0.08 | 153 |

| | | | | | |
|---|---|---|---|---|---|
| § 129.80(g), § 129.80(h) (bottlers testing finished product only) | 95 | 3 | 285 | 0.08 | 23 |
| § 129.35(a)(3)(i), § 129.80(h) (bottlers conducting secondary testing of source water) | 3 | 5 | 15 | 0.08 | 1 |
| § 129.35(a)(3)(i), § 129.80(h) (bottlers rectifying contamination) | 3 | 3 | 9 | 0.25 | 2 |
| Total Annual Burden | | | | | 179 |

The current 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 therefore concludes that any additional burden and costs in recordkeeping based on follow-up testing that is required if any coliform organisms detected in the source water test positive for E. coli are negligible. FDA estimates that the labor burden of keeping records of each test is about 5 minutes per test (0.08 hours). FDA also requires follow-up testing of source water and finished bottled water products for E. coli when total coliform positives occur. FDA expects that 319 bottlers that use sources other than PWSs may find a total coliform positive sample about three times per year in source testing and about three times in finished product testing, for a total of 153 hours of recordkeeping. In addition to the 319 bottlers, about 95 bottlers that use PWSs may find a total coliform positive sample about three times per year in finished product testing, for a total of 23 hours of recordkeeping. Upon finding a total coliform sample, bottlers will then have to conduct a follow-up test for E. coli.

FDA expects that recordkeeping for the follow-up test for E. coli will also take about 5 minutes per test. As shown in table 1 of this document, FDA expects that 3 bottlers per year will have to carry out the additional E. coli testing, with a burden of 1 hour. These bottlers will also have to keep records about rectifying the source contamination, for a burden of 2 hours. For all expected total coliform testing, E. coli testing, and source rectification, FDA estimates a total burden of 179 hours. FDA bases its estimate on its experience with the current CGMP regulations.

12b. Annualized Cost Burden Estimate

| Type of Recordkeeper | Total Burden Hours | Hourly Wage Rate | Total Recordkeeper |
|---|---|---|---|

| | | | |
|---|---|---|---|
| | | | Costs |
| Bottlers | 179 | $71.76 | $12,845.04 |

The annual hour cost burden to recordkeepers is approximately $12,845.04 per year. FDA estimates that the average hourly wage for the employee retaining records would be equivalent to a GS-12/Step-1 level in the locality pay area of Washington-Baltimore-Northern Virginia for 2013, approximately $35.88/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to recordkeepers to be $71.76/hour. Thus, the overall estimated cost incurred by the recordkeepers is $12,845.04 (179 burden hours x $71.76/hr).

13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

FDA's review of the retained records would generally occur as part of an inspection. FDA would devote approximately 5 hours per inspection to the inspection of records. FDA estimates the annualized cost to the Federal Government for the review of records retained by a firm to be $358.80 per review. In this calculation of cost, FDA estimates the hourly cost for review and evaluation at a base GS-12/Step 1 salary of $35.88 per hour for the locality pay area of Washington-Baltimore-Northern Virginia for 2013. Five hours multiplied by $35.88 per hour equals $179.40. To account for overhead, this cost is increased by 100 percent, making the total annualized cost to the Federal Government $358.80 per review. FDA estimates that it will perform approximately 143 inspections per year, for a total cost of $51,308.40.

15. Explanation for Program Changes or Adjustments

The hour burden is unchanged.

16. Plans for Tabulation and Publication and Project Time Schedule

We have no plans to publish data from this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are not seeking approval to not display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.