UNITED STATES FOOD & DRUG ADMINISTRATION

Recordkeeping Requirements for Microbiological
Testing and Corrective Measures for Bottled Water

OMB Control No. 0910-0658

SUPPORTING STATEMENT **Part 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.

Accordingly, we are requesting continued approval for the recordkeeping provisions found in 21 CFR 129: *Processing and Bottling of Bottled Drinking Water* and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Reviewing records of microbiological testing, including testing for total coliform and follow-up testing for E. coli when necessary, allows us 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 allow us to verify that the required testing is conducted. These records also allow us to confirm that test results meet applicable standards and that producers are taking appropriate actions based on the results. 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 us to determine compliance with requirements that bottlers take appropriate measures to rectify or otherwise eliminate the cause of E. coli contamination in source water.

3. Use of Improved Information Technology and Burden Reduction

Respondents may use whatever means best assists them in retaining the appropriate records and making them available to regulatory officials, however we encourage the use the automated technology. Based on our experience with similar information collection we estimate (90%) of the records will be maintained electronically.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. As discussed under *Question 1*, statutory provisions require FDA regulation regarding certain testing associated with bottled water. The information collection is limited in scope to those regulations found in 21 CFR part 129.

5. Impact on Small Businesses or Other Small Entities

Although estimate eighty percent (80%) of recordkeepers are small businesses, we do not believe the information collection imposes undue burden on small entities. At the same time, we assist small businesses in complying with our requirements through Regional Small Business Representatives and through scientific and administrative staffs within the agency. We also provide a Small Business Guide on our website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with regulatory requirements. Data collection occurs weekly. We believe the mandatory recordkeeping is consistent with the congressional intent of the SDWA and important for public health reasons. Less frequent recordkeeping might reduce or nullify the effectiveness of the regulation to provide assurance 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 soliciting public comment in the Federal Register of November 7, 2018 (83 FR 55726). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The information collection does not contain an assurance of confidentiality. Records containing confidential commercial information are 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, we assure will 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: Respondents to the 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

We estimate the burden for the information collection as follows:

Table 1 – Estimated Annual Recordkeeping Burden[1]					
21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	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					179

1, There are no capital, or operating and maintenance costs associated with the information collection.

Current CGMP regulation 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. We therefore conclude 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.

We assume the labor burden of keeping records of each test is about 5 minutes per test (0.08 hours). Follow-up testing of source water and finished bottled water products for E. coli is also required when total coliform positives occur. We assume 319 bottlers using 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 using 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 then have to conduct a follow-up test for E. coli. We assume recordkeeping for follow-up testing for E. coli takes 5 minutes per test. As shown above, we assume 3 bottlers per year will carry out the additional E. coli testing, requiring 1 hour. These bottlers will also 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, we estimate a total burden of 179 hours.

12b. Annualized Cost Burden Estimate

Type of Recordkeeper	Total Burden Hours	Hourly Wage Rate	Total Recordkeeper Costs
Bottlers	179	$71.76	$12,845.04

Assuming an average hourly wage for employees retaining records to be equivalent to a GS-12/Step-1 level in the Washington-Baltimore-Northern Virginia region ($35.88/hour), and doubling this wage to account for overhead costs, we calculate a total annual cost to respondents of cumulative cost of $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

Our review of the retained records occurs as part of an inspection. We allocate 5 hours per inspection to the review of records. Assuming an hourly cost for review and evaluation at a base rate of $35.88 per hour for a Washington-Baltimore-Northern Virginia employee, and multiplying that figure by 5 hours equals $179.40. We increase this figure by 100% to account for overhead, making the total annualized cost to the Federal Government $358.80 per review. Assuming we perform approximately 143 inspections per year, the total cost to the Federal government is $51,308.40.

15. Explanation for Program Changes or Adjustments

Our review shows the information collection remains constant and we have therefore retained the currently approved burden estimate. At the same time, we have consolidated the 4 ICs previously appearing at www.reginfo.gov into one IC to reflect the cumulative burden for the recordkeeping provisions under 21 CFR part 129.

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

Display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.