United States Food and Drug Administration

Microbiological Testing and Corrective Measures for Bottled Water

OMB Control No. 0910-0658 - Extension

SUPPORTING STATEMENT

**Part A: Justification**:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations. 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), 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 *Escherichia coli* (*E. coli*). The adulteration provision of the bottled water standard (§ 165.110(d)) provides that a finished product that tests positive for *E. coli* will be deemed adulterated under section 402(a)(3) of the FD&C Act. In addition, the current good manufacturing practice (CGMP) regulations for bottled water in part 129 require 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.

Before a bottler may use source water from a source that has tested positive for *E. coli*, a bottler much 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.

We therefore request extension of OMB 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 of automated technology. Based on our experience with similar information collections, we estimate (90%) of the records will be maintained electronically.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of any duplicative information collection. As discussed in Item 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 we estimate that eighty percent (80%) of recordkeepers are small businesses, we do not believe the information collection imposes undue burden on small entities. We assist small businesses in complying with our requirements through Regional Small Business Representatives and through scientific and administrative staffs within the agency. Assistance is also available for small businesses via the agency's website at https://www.fda.gov/industry/small-business-assistance.

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 and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice soliciting public comment in the *Federal Register* of July 23, 2024 (89 FR 59742). Five comments were received, of which one was PRA-related and supported necessity and practical utility of the FDA's recordkeeping requirements in this collection of information. Four comments were not related to the PRA and will not be addressed here.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII collected while maintaining microbial testing results could include name and email address. FDA determined that although PII is collected it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor or FDA do not use name or any other personal identifier to routinely retrieve records from the information collected. Through appropriate submission instruction, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden[1]

| 21 CFR section; Activity | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average 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 (5 minutes) | 153 |
| 129.80(g), 129.80(h); bottlers testing finished product only | 95 | 3 | 285 | 0.08 (5 minutes) | 23 |
| 129.35(a)(3)(i), 129.80(h); bottlers conducting secondary testing of source water | 3 | 5 | 15 | 0.08 (5 minutes) | 1 |
| 129.35(a)(3)(i), 129.80(h); bottlers rectifying contamination | 3 | 3 | 9 | 0.25 (15 minutes) | 2 |
| Total | | | | | 179 |

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

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. 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.

12b. Annualized Cost Burden Estimate

All wages rates are fully loaded to reflect the full cost of labor including fringe benefits.

Table 2.--Estimated Annual Cost Burden

| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|
| Bottlers | 179 | $95.06 | $17,015.74 |

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 in 2024 ($47.53/hour), and doubling this wage to account for overhead costs, we calculate a total annual cost to respondents of cumulative cost of $17,015.74 (179 burden hours x $95.06/hr).

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or 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 for an employee at a base rate of $47.53 per hour, which is the GS-12/Step 1 level in the Washington-Baltimore-Northern Virginia area in 2024 and multiplying that figure by 5 hours equals $237.65. We increase this figure by 100% to account for overhead, making the total annualized cost to the Federal Government $475.30 per review. Assuming we perform approximately 143 inspections per year, the total cost to the Federal government is $67,967.90.

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

The information collected will not be published or tabulated.

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.