4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-4130]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0658. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water--21 CFR 129.35(a)(3)(i), 129.80(g), and 129.80(h)

OMB Control Number 0910-0658--Extension

The bottled water regulations in parts 129 and 165 (21 CFR parts 129 and 165) require that if any coliform organisms are detected in weekly total coliform testing of finished bottled water, followup testing must be conducted to determine whether any of the coliform organisms are *Escherichia coli*. The adulteration provision of the bottled water standard (21 CFR 165.110(d)) provides that a finished product that tests positive for *E. coli* will be deemed adulterated under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(3)). In addition, the current good manufacturing practice (CGMP) regulations for bottled water in part 129 require that source water from other than a public water system (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 unsuitable for bottled water production. Before a bottler may use source water from a source that has tested positive for *E. coli*, a bottler must take appropriate measures to rectify or otherwise eliminate the cause of the contamination. A source previously found to contain *E. coli* will be considered negative for *E. coli* after five samples collected over a 24-hour period from the same sampling site are tested and found to be *E. coli* negative.

Description of Respondents: The respondents to this information collection are domestic and foreign bottled water manufacturers that sell bottled water in the United States.

In the *Federal Register* of November 7, 2018 (83 FR 55726), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates 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) and 129.80(h) (bottlers subject to both source water and finished product testing)	319	6	1,914	0.08 (5 minutes)	153
§ 129.80(g) and (h) (bottlers only subject to finished product testing)	95	3	285	0.08 (5 minutes)	23
§§ 129.35(a)(3)(i) and 129.80(h) (bottlers conducting secondary testing of source water)	3	5	15	0.08 (5 minutes)	1
§§ 129.35(a)(3)(i) and 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.

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

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. We therefore conclude that any additional burden and costs in recordkeeping based on followup testing that is required if any coliform organisms detected in the source water test positive for *E. coli* are negligible.

We estimate that the labor burden of keeping records of each *E. coli* followup test is about 5 minutes per test. We also require followup testing of source water and finished bottled water products for *E. coli* when total coliform positives occur. We expect that 319 bottlers that use sources other than PWSs may find a total coliform positive sample about 3 times per year in

source water testing and about 3 times in finished product testing and thus would need to conduct 6 tests for *E. coli*, for a total of 153 hours of recordkeeping. In addition, about 95 bottlers that use PWSs may find a total coliform positive sample about 3 times per year in finished product testing and thus would need to conduct 3 tests for *E. coli*, for a total of 23 hours of recordkeeping.

We expect that three bottlers per year will test positive for *E. coli* in source water and will need to take actions to rectify or eliminate the cause of the contamination and verify that *E. coli* is negative by taking five samples over a 24-hour period from the same sampling site that originally tested positive for *E. coli*. We expect that recordkeeping for the followup test for *E. coli* will also take about 5 minutes per test. As shown in table 1, we expect that three bottlers per year will test positive for *E. coli* in source water and 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, we estimate a total burden of 179 hours. We base our estimate on our experience with the current CGMP regulations.

Dated: March 22, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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