4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3655]

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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 (§ 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 October 19, 2015 (80 FR 63228) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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 Annual Burden					179

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

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 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 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 followup test 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 of this document, we expect that three 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, we estimate a total burden of 179 hours. We base our estimate on our experience with the current CGMP regulations.

Dated: February 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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