

“THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for a single hard copy of the draft guidance entitled “Review and Update of Device Establishment Inspection Processes and Standards” to the Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Building, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Tiffany Kelley, Office of Regulatory Affairs, Division of Operational Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-348-1970, [Tiffany.Kelley@fda.hhs.gov](mailto:Tiffany.Kelley@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled, “Review and Update of Device

Establishment Inspection Processes and Standards.” FDA is issuing this guidance document to comply with section 702(b) of FDARA (Pub. L. 115-52), which directs FDA to issue draft guidance that specifies how FDA will review processes and standards applicable to inspections of domestic and foreign device establishments in effect as of August 18, 2017, and update such processes and standards, as needed, through the adoption of uniform processes and standards that meet the criteria set forth in section 704(h)(1)(A) through (D) of the FD&C Act (21 U.S.C. 374(h)(1)(A) through (D)), as added by section 702(a) of FDARA. FDARA 702(b) also requires the draft guidance to provide for standardized methods of communication when communication is required under 704(h)(1), establish a standard timeframe for inspections, and identify practices for investigators and device establishments to facilitate the continuity of inspections of such establishments.

**II. Significance of Draft Guidance**

FDA is issuing this draft guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

**III. Paperwork Reduction Act of 1995**

This draft guidance refers to currently approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 803 have been approved under OMB control number 0910-0437. The collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073.

**IV. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet at either <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <https://www.regulations.gov>. Persons unable to

download an electronic copy of “Review and Update of Device Establishment Inspection Processes and Standards; Draft Guidance for Industry” may send an email request to [ORAPolicyStaffs@fda.hhs.gov](mailto:ORAPolicyStaffs@fda.hhs.gov) to receive an electronic copy of the document.

Dated: March 25, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

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**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 April 29, 2019.

**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 [oir submission@omb.eop.gov](mailto:oir 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, [PRStaff@fda.hhs.gov](mailto:PRStaff@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 <sup>1</sup>

21 CFR section; activity	Number of recordkeepers	Number 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

<sup>1</sup> 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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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-N-4609]

**Issuance of Priority Review Voucher; Rare Pediatric Disease Product**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation