

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	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

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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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

Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that SYMDEKO (tezacaftor/ivacaftor), manufactured by Vertex Pharmaceutical, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT:

Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Silver Spring, MD 20993-0002, 301-796-4061, Fax: 301-796-9856, althea.cuff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that SYMDEKO (tezacaftor/ivacaftor), manufactured by Vertex Pharmaceutical, Inc., meets the criteria for a priority review voucher. SYMDEKO (tezacaftor/ivacaftor) is indicated for the treatment of patients with cystic fibrosis aged 12 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about SYMDEKO (tezacaftor/ivacaftor), go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: March 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019-06138 Filed 3-28-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer’s Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer’s Research, Care, and Services (Advisory Council). The Advisory Council on Alzheimer’s Research, Care, and Services provides advice on how to prevent or reduce the burden of Alzheimer’s disease and related dementias on people with the disease and their caregivers. The April 29, 2019 meeting of the Advisory Council will focus on person-centered planning for older adults including information about implementation of care plans for people living with cognitive symptoms. There will also be discussion about the use of antipsychotic medication for people with dementia and other conditions living in community settings.

DATES: The meeting will be held on April 29, 2019 from 9 a.m. to 4:30 p.m. EST.

ADDRESSES: The meeting will be held in Room 800 in the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.

Comments: Time is allocated on the agenda to hear public comments. The time for oral comments will be limited to two (2) minutes per individual. In lieu of oral comments, formal written comments may be submitted for the record to Helen Lamont, Ph.D., OASPE, 200 Independence Avenue SW, Room 424E, Washington, DC 20201. Comments may also be sent to napa@hhs.gov. Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT:

Helen Lamont, 202-260-6075, helen.lamont@hhs.gov. Note: Seating may be limited. Those wishing to attend the meeting must send an email to napa@hhs.gov and put “April 29 Meeting Attendance” in the subject line by Friday, April 19 so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out.

Although the meeting is open to the public, procedures governing security and the entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). *Topics of the Meeting:* The April 29, 2019 meeting of the Advisory Council will focus on person-centered planning for older adults including information about implementation of care plans for people living with cognitive symptoms. There will also be discussion about the use of antipsychotic medication for people with dementia and other conditions living in community settings.

Procedure and Agenda: This meeting is open to the public. Please allow 30 minutes to go through security and walk to the meeting room. The meeting will also be webcast at www.hhs.gov/live.

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer’s Project Act. The panel is governed by provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: March 22, 2019.

Brenda Destro,

Deputy Assistant Secretary for Planning and Evaluation, Office of Human Services Policy.

[FR Doc. 2019-06135 Filed 3-28-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Deafness and Other Communication