DATES: The meeting will take place Thursday, June 25, 2009, from 9 a.m. to 3 p.m., ET; and Friday, June 26, 2009, from 9 a.m. to 11:45 a.m., ET.

ADDRESSES: The Ritz-Carlton, Washington, DC, 1150 22nd Street, NW., Washington, DC 20037. Phone 202–835–0500.

FOR FURTHER INFORMATION CONTACT: Ms. Diane M. Gianelli, Director of Communications, The President's Council on Bioethics, 1425 New York Avenue, NW., Suite C100, Washington, DC 20005. Telephone: 202/296–4669. E-mail: *info@bioethics.gov.* Web site: *http://www.bioethics.gov.*

SUPPLEMENTARY INFORMATION: The meeting agenda will be posted at *http://www.bioethics.gov.* The Council encourages public input, either in person or in writing. At this meeting, interested members of the public may address the Council, beginning at 11:30 a.m., on Friday, June 26. Comments are limited to no more than five minutes per speaker or organization. As a courtesy, please inform Ms. Diane M. Gianelli, Director of Communications, in advance of your intention to make a public statement, and give your name and affiliation. To submit a written statement, mail or e-mail it to Ms. Gianelli at one of her contact addresses given above.

Dated: May 18, 2009.

F. Daniel Davis,

Executive Director, The President's Council on Bioethics.

[FR Doc. E9–12538 Filed 5–28–09; 8:45 am]

BILLING CODE 4154–06–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0215]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information provisions of the final rule, ''Beverages: Bottled Water,'' published elsewhere in this issue of the **Federal Register**, which requires both domestic and foreign bottled water manufacturers that sell bottled water in the United States to maintain records of *Escherichia coli* testing and corrective measures, in addition to existing recordkeeping requirements.

DATES: Submit written or electronic comments on the collection of information by July 28, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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)

FDA has 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 *E. coli*. FDA also amended the adulteration provision of the bottled water standard (§ 165.110(d)) to indicate that 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, FDA amended the Current Good Manufacturing Practices (CGMP) regulations for bottled water in part 129 by requiring 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 proposed information collection are domestic and foreign bottled water manufacturers that sell bottled water in the United States.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
§§ 129.35(a)(3)(i) and 129.80(h)	319 (bottlers subject to source water and finished product testing)	6	1,914	0.08	153
§§ 129.35(a)(3)(i) and 129.80(h)	2.5 (bottlers conducting secondary testing of source water)	5	12	0.08	1
§§ 129.35(a)(3)(i) and 129.80(h)	2.5 (bottlers rectifying contamination)	3	7.5	0.25	2
§ 129.80(g) and (h)	95 (bottlers testing finished product only)	3	285	0.08	23
Total Annual Burden					179

[1]There are no capital costs or operating 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. FDA therefore concludes that any additional burden and costs in recordkeeping based on the new testing requirements for source and finished bottled water are negligible. FDA estimates that the labor burden of keeping records of each test is about 5 minutes per test. FDA also requires follow-up testing of source water and finished bottled water products for *E. coli* when total coliform positives occur. FDA expects that 319 bottlers that use sources other than PWSs may find a total coliform positive sample about 3 times per year in source testing and about 3 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 3 times per year in finished product testing, for a total of 23 hours of recordkeeping. Upon finding a total coliform positive sample, bottlers will then have to conduct a follow-up test for *E. coli*.

FDA expects that recordkeeping for the follow-up test for *E. coli* will also take about 5 minutes per test. As shown in table 1 of this document, FDA expects that 2.5 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, FDA estimates a total burden of 179 hours. FDA bases its estimate on its experience with the current CGMP regulations.

Dated: May 18, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–12493 Filed 5–26–09; 4:15 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10078]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Matching Grants to States for the Operation of High Risk Pools; *Use:* CMS is requiring this information as a condition of eligibility for grants that were authorized in the Trade Act of 2002, the Deficit Reduction Act of 2005 and the State High Risk Pool Funding Extension Act of 2006. The information is necessary to determine if a state applicant meets the necessary eligibility criteria for a grant as required by law. The respondents will be States that have a high risk pool as defined in sections 2741, 2744, or 2745 of the Public Health Service Act. The grants will provide funds to States that incur losses in the operation of high risk pools. High risk pools are set up by States to provide health insurance to individuals that cannot obtain health insurance in the private market because of a history of illness; *Form Numbers:* CMS–10078 (OMB#: 0938–0887); *Frequency:* Recordkeeping, Reporting—Occasionally; Affected Public: State, Local and Tribal Governments; *Number of Respondents:* 31; *Total Annual Responses:* 31; *Total Annual Hours:* 1,240. (For policy questions regarding this collection contact Paul Scholz at 410–786–6178. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.