

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs)	Total burden (in hours)
Comparison Organization Staff (Telephone Interviews).	Advance Letter for Comparison Organizations. Comparison Organization Interview Protocol.	10	1	1	10
TOTAL	335

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0269]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request 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. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to Sherette.funncoleman@hhs.gov, or call the Reports Clearance Office on (202) 690-6162. Written comments and

recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above email address within 60 days.

Proposed Project: Complaint Forms for Discrimination; Health Information Privacy Complaints OMB No. 0990-0269—Extension—Office of Civil Rights.

Abstract: The Office for Civil Rights is seeking approval for a 3 year clearance on a previous collection. Individuals may file written complaints with the Office for Civil Rights when they believe they have been discriminated against by programs or entities that receive Federal financial assistance from the Health and Human Service or if they believe that their right to the privacy of protected health information has been violated.

Annual Number of Respondents: Frequency of submission is record keeping and reporting on occasion.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Civil Rights Complaint Form	Individuals or households, Not-for-profit institutions.	3037	1	45/60	2278
Health Information Privacy Complaint Form.	Individuals or households, Not-for-profit institutions.	8944	1	45/60	6708
Total	8986

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting of the President's Council on Bioethics

AGENCY: Department of Health and Human Services, Office of Public Health and Science, The President's Council on Bioethics.

ACTION: Notice.

SUMMARY: The President's Council on Bioethics (Edmund D. Pellegrino, MD, Chairman) will hold its thirty-seventh and final meeting. The full agenda will be posted on the Council's Web site at <http://www.bioethics.gov> prior to the meeting. Publications issued by the Council to date include: Human Cloning and Human Dignity: An Ethical Inquiry (July 2002); Beyond Therapy: Biotechnology and the Pursuit of Happiness (October 2003); Being Human: Readings from the President's Council on Bioethics (December 2003); Monitoring Stem Cell Research (January 2004); Reproduction and Responsibility: The Regulation of New Biotechnologies (March 2004); Alternative Sources of

Human Pluripotent Stem Cells: A White Paper (May 2005); Taking Care: Ethical Caregiving in Our Aging Society (September 2005); Human Dignity and Bioethics: Essays Commissioned by the President's Council on Bioethics (March 2008); The Changing Moral Focus of Newborn Screening: An Ethical Analysis by The President's Council on Bioethics (December 2008); and Controversies in the Determination of Death: A White Paper by The President's Council on Bioethics (December 2008). Reports are forthcoming on organ transplantation, health care reform, and the future of national bioethics commissions.

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.

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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: