The estimated annual reporting burden on industry is 37.35 hours as shown in table 1 of this document. Industry estimates it takes about 1/4 hour to submit the application. We estimate 135 original and supplemental applications, and voluntary revocations for a total of 33.75 hours (135 submissions x 1/4 hour). An additional 3.6 hours is added for the rare notice of opportunity for a hearing to not approve or revoke an application. Finally, we estimate 30 hours for maintaining and retrieving labels as required by 21 CFR 510.305 and shown in table 2 of this document. We estimated 0.03 hours for each of the approximately 1,000 licensees. Thus, the total annual burden for reporting and recordkeeping requirements is estimated to be 67.35 hours.

Dated: October 20, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25915 Filed 10–27–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0215]

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 November 27, 2009.

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: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title ''Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water.'' Also include the FDA 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, e-mail: *JonnaLynn.Capezzuto@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) and 129.80(g) and (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, followup 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.

In the **Federal Register** of May 29, 2009 (74 FR 25752), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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 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. 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 followup 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 followup test for *E. coli*.

FDA expects 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, 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: October 20, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; A Generic Submission for Formative Research, Pretesting, and Customer Satisfaction of NCI's Communication and Education Resources (NCI)

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: A Generic Submission For Formative Research, Pretesting, and Customer Satisfaction of NCI's Communication and Education Resources. *Type of Information Collection Request:* REVISION. *Need and Use of Information Collection:* In order to carry out NCI's legislative mandate to educate and disseminate information about cancer prevention, detection, diagnosis, and treatment to a wide variety of audiences and organizations (*e.g.,* cancer patients, their families, the general public, health providers, the media, voluntary groups, scientific and medical organizations), it is beneficial for NCI, through its Office of Communications and Education (OCE), to pretest NCI communications strategies, concepts, and messages while they are under development. This pretesting, or formative evaluation, helps ensure that the messages, communication materials, and information services created by NCI have the greatest capacity of being received, understood, and accepted by their target audiences. Since NCI's OCE also is responsible for the design, implementation, and evaluation of education programs over the entire cancer continuum, and management of NCI initiatives that address specific challenges in cancer research and treatment, it is also necessary to ensure that customers are satisfied with programs. This customer satisfaction research helps ensure the relevance, utility, and appropriateness of the many educational programs and products that OCE and NCI produce. OCE will use a variety of qualitative (focus groups, interviews) and quantitative (paper, phone, in-person, and Web surveys) methodologies to conduct this formative and customer satisfaction research, allowing NCI to: (1) Understand characteristics (attitudes, beliefs, and behaviors) of the intended target audience and use this information in the development of effective communication tools and strategies; (2) use a feedback loop to help refine, revise, and enhance messages, materials, products, and programs—ensuring that they have the greatest relevance, utility, appropriateness, and impact for/to target audiences; and (3) expend limited program resource dollars wisely and effectively. This package represents the combination of a currently approved generic submission, ''Pretesting of NCI's Office of Communications Messages,'' (OMB No. 0925–0046) and a formerly approved generic submission, ''Customer Satisfaction with Educational Programs and Products of the NCI'' (OMB No. 0925–0526).

Frequency of Response: On occasion. *Affected Public:* Individuals or households; Businesses or other for profit; Not-for-profit institutions; Federal Government; State, Local, or Tribal Government. *Type of Respondents:* Adult cancer patients; members of the public; health care professionals; researchers; organizational representatives. The table below outlines the estimated burden hours required for a three-year approval of this generic submission. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

TABLE 1—ESTIMATES FOR BURDEN HOURS FOR THREE YEARS

[Generic study]

Survey method	Total number of respondents	Frequency of response	Minutes/hour per response	Total burden hours
Focus Groups	900	1	90/60 (1.5)	1,350.00
Individual In-Depth Interviews (Typically longer than 15 minutes, includes Web site usability testing)	600	1	45/60 (.75)	450.00
Brief Interviews (Typically less than 5 minutes)	19,000	1	10/60 (.17)	3,166.67
Surveys (Web, phone, in-person, paper-and-pencil)	12,500	1	10/60 (.17)	2,083.33
Totals	33,000			7,050.00