ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Report name	Respondents (state and local tuberculosis control programs)	Response format	No. response per respondent	Hours per response	Total burden (in hours)
					612

Dated: March 31, 2010.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–7935 Filed 4–7–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: The National Health Service Corps Loan Repayment Program (OMB No. 0915–0127)—Extension

The National Health Service Corps (NHSC) Loan Repayment Program (LRP) was established to assure an adequate supply of trained primary care health care professionals to provide services in the neediest Health Professional Shortage Areas (HPSAs) of the United States. Under this program, the Department of Health and Human Services agrees to repay the educational loans of the primary care health professionals. In return, the health professionals agree to serve for a specified period of time in a federally designated HPSA approved by the Secretary for LRP participants. The NHSC LRP forms provide information that is needed for select, award, and monitor participants. The LRP forms include the following: the NHSC LRP Application, the Employment Verification and Community Site Information form, the Loan Information and Verification form, the Authorization to Release Information form, the Applicant Checklist, and the Self-Certification form.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses/respondent	Total responses	Hours per response	Total burden hours
NHSC LRP Application	5,175	1	5,175	0.30	1,553
Employment Verification—Community Site Information Form	5,175	1	5,175	0.75	3,881
Loan Information and Verification Form	5,175	3	15,525	0.30	4,658
Authorization To Release Information	5,175	1	5,175	0.10	518
Applicant Checklist	5,175	1	5,175	0.25	1,294
Self-Certification Form	5,175	1	5,175	0.10	518
Lenders	65	1	65	0.30	20
Total	5,240	.....	41,465	.....	12,442

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: March 31, 2010.

Sahira Rafiullah,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010–7934 Filed 4–7–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0215]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; 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 collection of information entitled "Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50 Rockville, MD 20850, 301–796–3794. *Jonnalynn.capezzuto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 28, 2009 (74 FR 55557), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0658. The approval expires on March 31, 2013. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: April 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–7948 Filed 4–7–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0174]

Agency Information Collection Activities; Proposed Collection; Comment Request; Applications for Food and Drug Administration Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Valid or Will Not Be Infringed

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for submission and listing of patent information associated with a new drug application (NDA), an amendment, or a supplement.

DATES: Submit written or electronic comments on the collection of information by June 7, 2010.

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: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, e-mail: *Elizabeth.Berbakos@fda.hhs.gov*.

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, including each proposed extension of an existing 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.

Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed (OMB Control Number 0910–0513)—Extension.

Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(b)(1)) requires all NDA applicants to file, as part of the NDA, "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture[,] use, or sale of the drug." Section 505(c)(2) of the act (21 U.S.C. 355(c)(2)) imposes a similar patent submission obligation on holders of approved NDAs when the NDA holder could not have submitted the patent information with its application. Under section 505(b)(1) of the act, we publish patent information after approval of an NDA application in the list entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the Orange Book). If patent information is submitted after NDA approval, section 505(c)(2) of the act directs us to publish the information upon its submission.

FDA regulations at §§ 314.50(h) (21 CFR 314.50(h)) and 314.53 (21 CFR 314.53) clarify the types of patent information that must and must not be submitted to FDA as part of an NDA, an amendment, or a supplement, and require persons submitting an NDA, an amendment, or a supplement, or submitting information on a patent after NDA approval, to make a detailed patent declaration using Form FDA 3542a and Form FDA 3542.

The reporting burden for submitting an NDA, an amendment, or supplement in accordance with § 314.50 (a) through (f), and (k) has been estimated by FDA and the collection of information has been approved by OMB under OMB control number 0910–0001. We are not re-estimating these approved burdens in this document. Only the reporting burdens associated with patent submission and listing, as explained in the following paragraphs, are estimated in this document.

The information collection reporting requirements are as follows:

Section 314.50(h) requires that an NDA, an amendment, or a supplement