Dated: June 25, 2013.

Michelle Snyder,

Deputy Chief Operating Officer, Centers for Medicare & Medicaid Services.

CMS Computer Match No. 2013–11; HHS Computer Match No. 1302

Name: ''Computer Matching Agreement between the Centers for Medicare & Medicaid Services and State-based Administering Entities for the Disclosure of Health Insurance Affordability Programs Information under the Patient Protection and Affordable Care Act.''

Security Classification: Unclassified.

Participating Agencies: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS), and State-based Administering Entities (AEs).

Authority For Conducting Matching Program: This Computer Matching Program (CMP) is executed to comply with the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, the Office of Management and Budget (OMB) Circular A–130 entitled, Management of Federal Information Resources, at 61 FR 6428–6435 (February 20, 1996), and OMB guidelines pertaining to computer matching at 54 FR 25818 (June 19, 1989) and 56 FR 18599 (April 23, 1991); and the computer matching portions of Appendix I to OMB Circular No. A–130 as amended at 61 FR 6428 (February 20, 1996).

Purpose(s) of the Matching Program: This Computer Matching Agreement (CMA) establishes the terms, conditions, safeguards, and procedures under which CMS will share certain information with the AEs in accordance with the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which are referred to collectively as the Affordable Care Act (ACA), as well as the implementing regulations. Under this CMA the State-based AEs will use the data, accessed through the CMS Data Services Hub, to make Eligibility Determinations for Insurance Affordability Programs and certificates of exemption. State-based AEs are state entities administering Insurance Affordability Programs and may include a State agency, a State Children's Health Insurance Program, a State basic health program or a Marketplace (Exchange).

Description of Records to be Used In the Matching Program:

System of Records Maintained by CMS

The matching program will be conducted with data maintained by CMS in the ''Health Insurance Exchanges (HIX) Program,'' System No. 09–70–0560 established at 78 FR 8538 on February 6, 2013, and amended at 78 FR 32256 on May 29, 2013.

Inclusive Dates of the Match: The CMP shall become effective no sooner than 40 days after the report of the Matching Program is sent to OMB and Congress, or 30 days after publication in the **Federal Register**, whichever is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. 2013–15819 Filed 7–1–13; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0134]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Mammography Quality Standards Act Requirements

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 August 1, 2013.

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: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0309. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@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.

Mammography Quality Standards Act Requirements—(OMB Control Number 0910–0309)—Extension

The Mammography Quality Standards Act (Pub. L. 102–539) requires the establishment of a Federal certification and inspection program for mammography facilities; regulations and standards for accreditation and certification bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. The intent of these regulations is to assure safe, reliable, and accurate mammography on a nationwide level. Under the regulations, as a first step in becoming certified, mammography facilities must become accredited by an FDA-approved accreditation body (AB). This requires undergoing a review of their clinical images and providing the AB with information showing that they meet the equipment, personnel, quality assurance, and quality control standards, and have a medical reporting and recordkeeping program, a medical outcomes audit program, and a consumer complaint mechanism. On the basis of this accreditation, facilities are then certified by FDA or an FDA-approved State certification agency and must prominently display their certificate. These actions are taken to ensure safe, accurate, and reliable mammography on a nationwide basis.

The following sections of Title 21 of the Code of Federal Regulations (CFR) are not included in the burden tables because they are considered usual and customary practice and were part of the standard of care prior to the implementation of the regulations. Therefore, they resulted in no additional burden: 21 CFR 900.12(c)(1) and (c)(3) and 21 CFR 900.3(f)(1). Section 900.24(c) was also not included in the burden tables because if a certifying State had its approval withdrawn, FDA would take over certifying authority for the affected facilities. Because FDA already has all the certifying State's electronic records, there wouldn't be an additional reporting burden.

We have rounded numbers in the ''Total Hours'' column in all three burden tables. (Where the number was a portion of 1 hour, it has been rounded to 1 hour. All other ''Total Hours'' have been rounded to the nearest whole number.)

We do not expect any respondents for § 900.3(c) because all four ABs are approved until April 2020.

In the **Federal Register** of February 28, 2013 (78 FR 13681), 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 REPORTING BURDEN

Activity/21 CFR section/form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [1]	Total capital costs	Total operating & maintenance costs
Notification of intent to become an AB—900.3(b)(1)	0.33	1	0.33	1	1	.....	.....
Application for approval as an AB; full [2]—900.3(b)(3)	0.33	1	0.33	320	106	$10,000	.....
Application for approval as an AB; limited [3]—900.3(b)(3)	5	1	5	30	150	.....	.....
AB renewal of approval—900.3(c)	0	1	0	15	1	.....	.....
AB application deficiencies—900.3(d)(2)	0.1	1	0.1	30	3	.....	.....
AB resubmission of denied applications—900.3(d)(5)	0.1	1	0.1	30	3	.....	.....
Letter of intent to relinquish accreditation authority—900.3(e)	0.1	1	0.1	1	1	.....	.....
Summary report describing all facility assessments—900.4(f)	330	1	330	7	2,310	.....	$77,600
AB reporting to FDA; facility [4]—900.4(h)	8,654	1	8,654	1	8,654	.....	4,327
AB reporting to FDA; AB [5]—900.4(h)	5	1	5	10	50	.....	.....
AB financial records—900.4(i)(2)	1	1	1	16	16	.....	.....
Former AB new application—900.6(c)(1)	0.1	1	0.1	60	6	.....	.....
Reconsideration of accreditation following appeal—900.15(d)(3)(ii)	1	1	1	2	2	.....	.....
Application for alternative standard—900.18(c)	2	1	2	2	4	.....	.....
Alternative standard amendment—900.18(e)	10	1	10	1	10	.....	.....
Certification agency application—900.21(b)	0.33	1	0.33	320	106	.....	208
Certification agency application deficiencies—900.21(c)(2)	0.1	1	0.1	30	3	.....	.....
Certification electronic data transmission—900.22(h)	5	200	1000	0.083	83	30,000	.....
Changes to standards—900.22(i)	2	1	2	30	60	.....	20
Certification agency minor deficiencies—900.24(b)	1	1	1	30	30	.....	.....
Appeal of adverse action taken by FDA—900.25(a)	0.2	1	0.2	16	3	.....	.....
Inspection fee exemption—Form FDA 3422	700	1	700	0.25	175	.....	.....
Total	.....	.....	.....	.....	11,777	40,000	82,155

[1] Total hours have been rounded.
[2] One time burden.
[3] Refers to accreditation bodies applying to accredit specific full-field digital mammography units.
[4] Refers to the facility component of the burden for this requirement.
[5] Refers to the AB component of the burden for this requirement.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [1]	Total capital costs	Total operating & maintenance costs
AB transfer of facility records—900.3(f)(1)	0.1	1	0.1	0	1	.....	.....
Consumer complaints system; AB—900.4(g)	5	1	5	1	5	.....	.....
Documentation of interpreting physician initial requirements—900.12(a)(1)(i)(B)(*2*)	87	1	87	8	696	.....	.....
Documentation of interpreting physician personnel requirements—900.12(a)(4)	8,654	4	34,616	1	34,616	.....	.....

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [1]	Total capital costs	Total operating & maintenance costs
Permanent medical record—900.12(c)(4)	8,654	1	8,654	1	8,654	$28,000	
Procedures for cleaning equipment—900.12(e)(13)	8,654	52	450,008	0.083	37,351		
Audit program—900.12(f)	8,654	1	8,654	16	138,464		
Consumer complaints system; facility—900.12(h)(2)	8,654	2	17,308	1	17,308		
Certification agency conflict of interest—900.22(a)	5	1	5	1	5		
Processes for suspension and revocation of certificates—900.22(d)	5	1	5	1	5		
Processes for appeals—900.22(e)	5	1	5	1	5		
Processes for additional mammography review—900.22(f)	5	1	5	1	5		
Processes for patient notifications—900.22(g)	3	1	3	1	3		$30
Evaluation of certification agency—900.23	5	1	5	20	100		
Appeals—900.25(b)	5	1	5	1	5		
Total					237,223	28,000	30

[1] Total hours have been rounded.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURES [1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]	Total operating & maintenance costs
Notification of facilities that AB relinquishes its accreditation—900.3(f)(2)	0.1	1	0.1	200	20	$50
Clinical images; facility [3]—900.4(c), 900.11(b)(1), and 900.11(b)(2)	2,885	1	2,885	1.44	4,154	
Clinical images; AB [4]—900.4(c)	5	1	5	416	2,080	230,773
Phantom images; facility [3]—900.4(d), 900.11(b)(1), and 900.11(b)(2)	2,885	1	2,885	0.72	2,077	
Phantom images; AB [4]—900.4(d)	5	1	5	208	1,040	
Annual equipment evaluation and survey; facility [3]—900.4(e), 900.11(b)(1), and 900.11(b)(2)	8,654	1	8,654	1	8,654	8,654
Annual equipment evaluation and survey; AB [4]—900.4(e)	5	1	5	1,730	8,650	
Provisional mammography facility certificate extension application—900.11(b)(3)	0	1	0	0.5	1	
Mammography facility certificate reinstatement application—900.11(c)	312	1	312	5	1,560	24,000,000
Lay summary of examination—900.12(c)(2)	8,654	5,085	44,055,590	0.083	3,652,464	
Lay summary of examination; patient refusal [5]—900.12(c)(2)	87	1	87	0.5	44	
Report of unresolved serious complaints—900.12(h)(4)	20	1	20	1	20	
Information regarding compromised quality; facility [3]—900.12(j)(1)	20	1	20	200	4,000	300
Information regarding compromised quality; AB [4]—900.12(j)(1)	20	1	20	320	6,400	600
Patient notification of serious risk—900.12(j)(2)	5	1	5	100	500	19,375
Reconsideration of accreditation—900.15(c)	5	1	5	2	10	
Notification of requirement to correct major deficiencies—900.24(a)	0.4	1	0.4	200	80	68
Notification of loss of approval; major deficiencies—900.24(a)(2)	0.15	1	0.15	100	15	25.50
Notification of probationary status—900.24(b)(1)	0.3	1	0.3	200	60	51
Notification of loss of approval; minor deficiencies—900.24(b)(3)	0.15	1	0.15	100	15	25.50

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURES [1]—Continued

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]	Total operating & maintenance costs
Total	.....	.....	.....	.....	3,691,842	24,259,921

[1] There are no capital costs associated with this collection of information.
[2] Total hours have been rounded.
[3] Refers to the facility component of the burden for this requirement.
[4] Refers to the AB component of the burden for this requirement.
[5] Refers to the situation where a patient specifically does not want to receive the lay summary of her exam.

Dated: June 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–15790 Filed 7–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1108]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Interstate Shellfish Dealer's Certificate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Interstate Shellfish Dealer's Certificate'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5733, *domini.bean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On March 25, 2013, the Agency submitted a proposed collection of information entitled, ''Interstate Shellfish Dealer's Certificate'' 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 0910–0021. The approval expires on May 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: June 26, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–15795 Filed 7–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0033]

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: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5733, *domini.bean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On March 26, 2013, the Agency submitted a proposed collection of information entitled ''Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water'' 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 May 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: June 26, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–15793 Filed 7–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0716]

Agency Information Collection Activities; Proposed Collection; Comment Request; Designated New Animal Drugs for Minor Use and Minor Species

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 paperwork associated with designation under the Minor Use and Minor Species (MUMS) Act.

DATES: Submit either electronic or written comments on the collection of information by September 3, 2013.

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