Instrument respondent	Annual number of respondents	Number of responses per respondent	Average burden per response (hours)	Total annual burden hours
IMPACT				
Healthy Marriage Grantee Impact Evaluation				
(4) Introductory script Program staff	30	70.2	0.167	351
Program applicants	4,210	1	0.167	702
(5) Baseline survey Study participants	4,000	1	0.5	2,000
Healthy Marriage Grantee Implementation Evaluation—MIS				
(7) HM Study MIS Program staff	30	3,400	0.033	3,400
Responsible Fatherhood and Healthy Marriage Grantee Implementation Evaluation—Additional Implementation Data Collection Instruments				
(8) Semi-structured interview topic guide Program staff	250	2	1.03	517
(9) On-line survey Program staff	250	2	0.5	250
(10) Telephone interviews (with staff at referral organizations):				
Program staff at referral organizations	50	1	0.5	25
(11) On-line Working Alliance Inventory:				
(1) Program staff	50	20	0.167	167
(2) Program Participants	1,000	1	0.167	167
(12) Focus group guide Program participants	600	1	1.5	900
(13) Telephone interviews Program participants (program dropouts)	150	1	0.25	38
Responsible Fatherhood Grantee Qualitative Evaluation				
(14) Guide for in-person, in-depth interviews Study participants	32	3	2	192
(15) Check-in call guide Study participants	32	4	0.167	21
IMPLEMENTATION/QUALITATIVE ONLY				
Responsible Fatherhood Grantee Implementation Evaluation—Grantees With a Focus on Hispanic Populations				
(16) Semi-structured interview topic guide Program staff	42	1	1.5	63
(17) Focus group guide Program participants	20	1	1.5	30
(18) Questionnaires Program participants in focus groups	20	1	0.333	7
Total	.....	.....	.....	8,830

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Steven M. Hanmer,

Reports Clearance Officer.

[FR Doc. 2013–04307 Filed 2–27–13; 8:45 am]

BILLING CODE 4184–37–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0134]

Agency Information Collection Activities; Proposed Collection; Comment Request; Mammography Quality Standards Act Requirements

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 estimated reporting, recordkeeping, and third-party disclosure burden associated with the Mammography Quality Standards Act requirements.

DATES: Submit either electronic or written comments on the collection of information by April 29, 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 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: 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: 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.

Mammography Quality Standards Act Requirements—21 CFR Part 900 (OMB Control Number 0910–0309)—Extension

The Mammography Quality Standards Act 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 one 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity/21 CFR Section/FDA Form 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	.....	.....

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—Continued

Activity/21 CFR Section/FDA Form 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
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—FDA Form 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	No. of recordkeepers	No. of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [1]	Total capital costs	Total operating and 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		
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 and 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 [2]—900.4(c), 900.11(b)(1), and 900.11(b)(2)	2,885	1	2,885	1.44	4,154	
Clinical images; AB [3]—900.4(c)	5	1	5	416	2,080	230,773
Phantom images; facility [2]—900.4(d), 900.11(b)(1), and 900.11(b)(2)	2,885	1	2,885	0.72	2,077	
Phantom images; AB [3]—900.4(d)	5	1	5	208	1,040	
Annual equipment evaluation and survey; facility [2]—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 [3]—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	44,005,590	0.083	3,652,464	
Lay summary of examination; patient refusal [4]—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 [2]—900.12(j)(1)	20	1	20	200	4,000	300
Information regarding compromised quality; AB [3]—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
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.

Dated: February 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04677 Filed 2–27–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–E–0156]

Determination of Regulatory Review Period for Purposes of Patent Extension; ZYTIGA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ZYTIGA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6284, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the