it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this draft guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information for the submission of ANDAs have been approved under OMB control number 0910–0001. Applicant submission of controlled correspondence related to generic drug development and FDA approval is approved under OMB control number 0910–0797. The collections of information that support Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies have been approved under OMB control number 0910–0119. The collections of information in 21 CFR part 320 for ''Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans'' have been approved under OMB control number 0910–0014. The recordkeeping requirement for Current Good Manufacturing Practice (CGMP) sample retention in 21 CFR 211.170 has been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: October 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23016 Filed 10–21–22; 8:45 am]

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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 or we) 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: Submit written comments (including recommendations) on the collection of information by November 23, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0309. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@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—21 CFR Part 900

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; standards for accreditation and certification bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. Implementing regulations are found in part 900 (21 CFR part 900). The regulations are intended 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.

FDA meets with its National Mammography Quality Assurance Advisory Committee (NMQAAC) for the purposes of advising FDA's mammography program on advances in mammography technology and procedures and on appropriate quality standards for mammography facilities. NMQAAC is made up of representatives of the mammography community, consumer and industry groups, and government. The meetings are open to the public and time is allotted for public statements on issues of concern in the mammography field. The chairperson may also call upon attendees to contribute to the committee discussions.

FDA also regularly meets or holds teleconferences with its approved accreditation bodies and State certification agencies to discuss issues of mutual concern. We also engage with the Conference of State Radiation Program Directors (CRCPD), a professional organization of State agencies concerned with radiation protection. The CRCPD has established a standing Mammography Committee, which meets with FDA mammography staff at least once a year.

Finally, in recent years, FDA mammography staff have met several times with representatives of manufacturers working on the new applications of digital technology in mammography to resolve problems preventing the making of that technology generally available. FDA mammography staff have also worked with representatives of the manufacturers to develop quality assurance manuals for full field digital mammography units.

In the **Federal Register** of August 8, 2022 (87 FR 48678), we published a notice soliciting public comment of the proposed information collection. No comments were received.

We estimate 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]
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
Application for approval as an AB; limited [3]—900.3(b)(3).	5	1	5	30	150
AB renewal of approval—900.3(c)	1	1	1	15	15
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
AB reporting to FDA; facility [4]—900.4(h)	8,718	1	8,718	1	8,718
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
Certification agency application deficiencies—900.21(c)(2).	0.1	1	0.1	30	3
Certification electronic data transmission—900.22(h)	5	200	1,000	0.083 (5 minutes)	83
Changes to standards—900.22(i)	2	1	2	30	60
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	419	1	419	0.25 (15 minutes)	105
Total					11,785

[1] Numbers 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]
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).	8,718	4	34,872	1	34,872
Permanent medical record—900.12(c)(4)	8,718	1	8,718	1	8,718
Procedures for cleaning equipment—900.12(e)(13)	8,718	52	453,336	0.083 (5 minutes)	37,627
Audit program—900.12(f)	8,718	1	8,718	16	139,488
Consumer complaints system; facility—900.12(h)(2)	8,718	2	17,436	1	17,436
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
Evaluation of certification agency—900.23	5	1	5	20	100
Appeals—900.25(b)	5	1	5	1	5
Total					238,971

[1] Total hours have been rounded.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [1]
Notification of facilities that AB relinquishes its accreditation—900.3(f)(2).	0.1	1	0.1	200	20
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
Phantom images; facility [2]—900.4(d), 900.11(b)(1), and 900.11(b)(2).	2,885	1	2,885	0.72 (43 minutes)	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).	8,718	1	8,718	1	8,718
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 (30 minutes)	1
Mammography facility certificate reinstatement application—900.11(c).	281	1	281	5	1,405
Lay summary of examination—900.12(c)(2)	8,718	5,085	44,331,030	0.083 (5 minutes)	3,679,475
Lay summary of examination; patient refusal [4]—900.12(c)(2).	87	1	87	0.5 (30 minutes)	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
Information regarding compromised quality; AB [3]—900.12(j)(1).	20	1	20	320	6,400
Patient notification of serious risk—900.12(j)(2)	5	1	5	100	500
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
Notification of loss of approval; major deficiencies—900.24(a)(2).	0.15	1	0.15	100	15
Notification of probationary status—900.24(b)(1)	0.3	1	0.3	200	60
Notification of loss of approval; minor deficiencies—900.24(b)(3).	0.15	1	0.15	100	15
Total					3,718,764

[1] Total hours have been rounded.
[2] Refers to the facility component of the burden for this requirement.
[3] Refers to the AB component of the burden for this requirement.
[4] Refers to the situation where a patient specifically does not want to receive the lay summary of her exam.

Respondents use the Mammography Program Reporting and Information System to submit information. Our estimated burden for the information collection reflects an overall increase of 28,664 hours and a corresponding increase of 9,137,449 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last few years. We do not include burden for §§ 900.12(c)(1) and (3), 900.3(f)(1), and 900.24(c) 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, we assume no additional reporting burden.

Dated: October 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23028 Filed 10–21–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–2101]

Human Gene Therapy for Neurodegenerative Diseases; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Human Gene Therapy for Neurodegenerative Diseases; Guidance for Industry.'' Neurodegenerative diseases are a heterogeneous group of disorders characterized by progressive degeneration of the structure and function of the central nervous system or peripheral nervous system. The guidance document provides recommendations to sponsors developing human gene therapy (GT) products for neurodegenerative diseases affecting adult and pediatric patients. The guidance focuses on considerations for product development, preclinical testing, and clinical trial design. The guidance announced in this notice finalizes the draft guidance of the same title dated January 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on October 24, 2022.