For purposes of this analysis, we consider the number of respondents to correspond to the number of NDAs and efficacy supplements submitted or approved, respectively, in calendar year (CY) 2017, even though one company may submit or hold multiple NDAs or may submit multiple efficacy supplements to one or more NDAs. FDA approved 127 NDAs and 154 efficacy supplements to NDAs during CY 2017, which corresponds to 281 respondents. Based on information provided by the Orange Book staff, approximately 623 patent records were created in CY 2017, which corresponds to an estimated 513 Forms FDA 3542 submitted to FDA for listing of patent information in the Orange Book for NDAs approved in CY 2017 and an estimated 110 Forms FDA 3542 submitted to FDA for listing of patent information in the Orange Book for efficacy supplements approved in CY 2017. In addition, based on information provided by the Orange Book staff and FDA's experience, we estimate that approximately 185 Forms FDA 3542 were submitted in CY 2017 to modify patent information, which results in an estimated total of 808 Forms FDA 3542 submitted in CY 2017.

During calendar year 2017, FDA received 141 original NDAs and 169 efficacy supplements to NDAs for FDA review and approval. We estimate that applicants submitted approximately 405 Forms FDA 3542a for the original NDAs submitted during CY 2017. In addition, based on a review of the submitted efficacy supplements, FDA received 241 Forms FDA 3542a with the efficacy supplements received during CY 2017, resulting in a total of 646 Forms FDA 3542a submitted in CY 2017.

Our estimated burden for the information collection reflects an overall decrease. We attribute this adjustment to a decrease in the number of duplicative submissions of Forms FDA 3542a and 3542 in connection with supplements submitted or approved after the effective date of the MMA final rule, and improved data collection from upgraded data software tools.

Dated: August 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19130 Filed 9–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3657]

Agency Information Collection Activities; Proposed Collection; Comment Request; Accreditation Scheme for Conformity Assessment Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program.

DATES: Submit either electronic or written comments on the collection of information by November 4, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 4, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 4, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–3657 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not

in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@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, 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.

Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

OMB Control Number 0910–NEW

The FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52) amended section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d(d)) by adding a new subsection (d) entitled ''Pilot Accreditation Scheme for Conformity Assessment.'' [1] Section 514(d) of the FD&C Act requires FDA to establish a pilot program under which testing laboratories may be accredited by accreditation bodies meeting criteria specified by FDA to assess the conformance of a device within certain FDA-recognized standards. Determinations by testing laboratories so accredited that a device conforms with an eligible standard included as part of the ASCA Pilot Program shall be accepted by FDA for the purposes of demonstrating such conformity unless FDA finds that a particular such determination shall not be so accepted.[2]

The statute provides that FDA may review determinations by accredited testing laboratories, including by conducting periodic audits of such determinations or processes of accreditation bodies or testing laboratories.[3] Following such a review, or if FDA becomes aware of information materially bearing on safety or effectiveness of a device assessed by an accredited testing laboratory, FDA may take additional measures as determined appropriate, including suspension or withdrawal of accreditation of a testing laboratory or a request for additional information regarding a specific device.[4]

FDA intends to issue guidance regarding the goals and implementation of the voluntary Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program (hereafter referred to as the ASCA Pilot) in accordance with amendments made to section 514 of the FD&C Act [5] by FDARA, and as part of the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV).[6]

The establishment of the goals, scope, procedures, and a suitable framework for the voluntary ASCA Pilot supports the Agency's continued efforts to use its scientific resources effectively and efficiently to protect and promote public health. FDA believes the voluntary ASCA Pilot may further encourage international harmonization of medical device regulation because it incorporates elements, where appropriate, from a well-established set of international conformity assessment practices and standards (*e.g.,* ISO/IEC 17000 series). The voluntary ASCA Pilot does not supplant or alter any other existing statutory or regulatory requirements governing the decision making process for premarket submissions.

Under the ASCA Pilot's conformity assessment scheme, recognized accreditation bodies accredit testing laboratories using ASCA program specifications associated with each eligible standard and ISO/IEC 17025:2017: *General requirements for the competence of testing and calibration laboratories.* ASCA-accredited testing laboratories may conduct testing to determine conformance of a device with at least one of the standards eligible for inclusion in the ASCA Pilot. When an ASCA-accredited testing laboratory conducts such testing, it may provide a complete test report to the device manufacturer. A device manufacturer who utilizes an ASCA-accredited testing laboratory to perform testing in accordance with the provisions of the ASCA Pilot can then include a declaration of conformity with supplemental documentation (including a summary test report) as part of a premarket submission to FDA. Testing performed by an ASCA-accredited testing laboratory can be used to support a premarket submission for any device if the testing was conducted using a standard eligible for inclusion in the ASCA Pilot and in accordance with the ASCA Pilot program specifications for that standard.

The ASCA Pilot includes participation from accreditation bodies, testing laboratories, device manufacturers, and FDA staff. Each of these entities plays a critical role in the ASCA Pilot to ensure that patients and health care providers have timely and continued access to safe, effective, and high-quality medical devices.

To participate in the ASCA Pilot, accreditation bodies and testing laboratories apply to FDA to demonstrate that they have the qualifications for their respective roles within the pilot. An application includes agreement to terms of participation. For example, a participating accreditation body or

[1] *See* Public Law 115–52, section 205.

[2] *See* section 514(d)(1)(B) of the FD&C Act.

[3] *See* section 514(d)(2)(A) of the FD&C Act.

[4] *See* section 514(d)(2)(A)–(B) of the FD&C Act.

[5] *See* section 514(d)(3)(B) of the FD&C Act.

[6] *See also* MDUFA IV Commitment Letter: *https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM526395.pdf.*

testing laboratory agrees to attend training, regularly communicate with FDA, and support periodic FDA audits. FDA recognizes qualified applicants as participants. In its recognition, FDA will identify the scope of recognition of specific standards and test methods to which each participant may accredit or test as part of the ASCA Pilot.

After recognizing a testing laboratory as a participant in the ASCA Pilot, FDA will generally grant the testing laboratory ASCA Accreditation. During the ASCA Pilot, FDA generally will accept determinations from ASCA-accredited testing laboratories that a medical device is in conformity with the specified testing to a particular standard, and does not intend to review complete test reports from ASCA-accredited testing laboratories in support of a declaration of conformity submitted with a premarket submission except in certain circumstances.

Note that ASCA Accreditation is separate from any accreditation that an accreditation body may provide to a testing laboratory for purposes other than the ASCA Pilot. FDA's decision to recognize the accreditation for purposes of the ASCA Pilot is separate and distinct from any independent decision by the accreditation body with respect to a testing laboratory for purposes outside of the ASCA Pilot.

The ASCA Pilot does not address specific content for a particular premarket submission. Information collections associated with premarket submissions have been previously approved.

This collection also refers to previously approved collections of information found in FDA regulations and guidance. The collections of information in 21 CFR part 807, subpart E (premarket notification) have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 (investigational device exemption) have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814, subparts A through E (premarket approval) have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H (humanitarian device exemption) have been approved under OMB control number 0910–0332; the collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 312 (investigational new drug application) have been approved under OMB control number 0910–0014; and the collections of information in 21 CFR part 601 (biologics license application) have been approved under OMB control number 0910–0338.

Respondents are accreditation bodies (ABs) and testing laboratories (TLs). In tables 1 through 3, these abbreviations are used.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours [2]
Application by AB for ASCA recognition	8	1	8	6	48
Request by AB to continue participation in ASCA	1	1	1	6	6
Request by AB to participate (subsequent to withdrawal).	1	1	1	6	6
Request by AB to expand scope of participation	1	1	1	6	6
AB annual status report	8	1	8	3	24
AB notification of change	8	1	8	1	8
Application by TL for ASCA recognition	150	1	150	4	600
Request by TL to continue participation in ASCA	15	1	15	4	60
Request by TL to participate (subsequent to withdrawal or suspension).	5	1	5	4	20
Request by TL to expand scope of participation	75	1	75	4	300
TL annual status report	150	1	150	1.5	225
TL notification of change	5	1	5	1	5
Request for withdrawal (ABs or TLs) or suspension (TLs) from ASCA program.	6	1	6	0.08 (5 minutes)	1
Pilot feedback questionnaire (ABs and TLs)	158	1	158	0.5 (30 minutes)	79
Total					1,388

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals have been rounded to the nearest hour.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of respondents	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)
AB setup documentation standard operating procedures (SOPs) and training (one-time burden)	8	1	8	25	200
TL setup documentation (SOPs) and training (one-time burden)	150	1	150	25	3,750
AB record maintenance	8	1	8	1	8
TL record maintenance	150	1	150	1	150

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity	Number of respondents	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)
Total					4,108

[1] There are no capital costs or operating and maintenance costs associated with the collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (hours)	Total hours
Request for Accreditation (TLs requesting accreditation from ABs).	150	1	150	0.5 (30 minutes)	75
Review/Acknowledgement of accreditation request (ABs).	8	22	176	40	7,040
Test Report (TLs)	880	1	880	1	880
Total					7,995

[1] There are no capital costs or operating and maintenance costs associated with the collection of information.

Our estimate of eight ABs is based on the number of International Laboratory Accreditation Cooperation (ILAC) signatories in the United States economy. We estimate that approximately 150 testing laboratories will seek accreditation. Our estimate of Test Reports is based on the number of premarket submissions we expect per year with testing from an ASCA-accredited testing laboratory as part of the ASCA Pilot Program.

Our estimates for the average burden per response, recordkeeping, and disclosure are based on the burden for similar programs.

Dated: August 27, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19102 Filed 9–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–E–2597]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for GIAPREZA 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 the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by November 4, 2019. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 3, 2020. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 4, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 4, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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Instructions: All submissions received must include the Docket No. FDA–