Dated: October 3, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–21904 Filed 10–5–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0514]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Procedures for Clinical Laboratory Improvement Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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 7, 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 0910–0607. 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.

Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988

OMB Control Number 0910–0607—Revision

This information collection helps support implementation of statutory provisions applicable to laboratories that conduct testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). These requirements are codified in 42 U.S.C. 263a and implementing regulations are found in 42 CFR 493. Regulations in 42 CFR 493.17 set forth certain notice requirements and establish test categorization criteria with regard to laboratory tests and are implemented by FDA's Center for Devices and Radiological Health. The guidance document entitled ''Administrative Procedures for CLIA Categorization'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/administrative-procedures-clia-categorization*) describes procedures FDA uses to assign the complexity category to a device. Typically, FDA assigns complexity categorizations to devices at the time of clearance or approval of the device. In some cases, however, a manufacturer may request CLIA categorization even if FDA is not simultaneously reviewing a 510(k) or premarket approval application. One example is when a manufacturer requests that FDA assign CLIA categorization to a previously cleared device that has changed names since the original CLIA categorization. Another example is when a device is exempt from premarket review. In such cases, the guidance recommends that manufacturers provide FDA with a copy of the package insert for the device and a cover letter indicating why the manufacturer is requesting a categorization (*e.g.,* name change, exempt from 510(k) review). The guidance recommends that in the correspondence to FDA the manufacturer should identify the product code and classification as well as reference to the original 510(k) when this is available.

We are revising the information collection to include provisions associated with certificates of waiver. On February 26, 2020, FDA revised the guidance document entitled ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices—Guidance for Industry and FDA Staff'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-clinical-laboratory-improvement-amendments-1988-clia-waiver-applications*). This guidance describes recommendations for device manufacturers submitting to FDA an application for determination that a cleared or approved device meets this CLIA standard (CLIA waiver application). The guidance recommends that CLIA waiver applications include a description of the features of the device that make it ''simple''; a report describing a hazard analysis that identifies potential sources of error, including a summary of the design and results of flex studies and conclusions drawn from the flex studies; a description of fail-safe and failure alert mechanisms and a description of the studies validating these mechanisms; a description of clinical tests that demonstrate the accuracy of the test in the hands of intended operators; and statistical analyses of clinical study results.

In the **Federal Register** of June 16, 2022 (87 FR 36330), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Request for CLIA categorization (see 42 CFR 493.17)	80	5	400	1	400	$2,000
CLIA Waiver Application Submissions	13	1	13	1,200	15,600	$350,000
Total						$352,000

[1] There are no capital costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Information collection activity	Number of Record-keepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
CLIA Waiver Recordkeeping as discussed in FDA Guidance	13	1	13	2,800	36,400

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

We have revised the information collection to include coverage previously accounted for under OMB control number 0910–0598 and discussed in revised Agency guidance. We otherwise retain our estimates of the burden we attribute to the individual elements included in the information collection.

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21843 Filed 10–6–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0514 and FDA–2005–D–0027]

Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry and Food and Drug Administration Staff; and Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of the final guidance documents entitled ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act'' and ''Procedures for Handling Post-Approval Studies Imposed by PMA [Premarket Approval Application] Order.'' These guidance documents are intended to facilitate and set expectations for timely initiation and completion of certain studies fulfilling postmarket surveillance requirements and of Post-Approval Studies (PAS), respectively. Additionally, these guidance documents are intended to increase transparency to stakeholders on FDA's approach to the issuance and tracking of postmarket surveillance orders and of PAS requirements. The final guidance ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act'' is intended to update and replace the guidance issued in May 2016; the final guidance ''Procedures for Handling Post-Approval Studies Imposed by PMA Order'' is intended to update and replace the guidance issued in June 2009.

DATES: The announcement of the guidance is published in the **Federal Register** on October 7, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2011–D–0514 for ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act'' or Docket No. FDA–2005–D–0027 for ''Procedures for Handling Post-Approval Studies Imposed by PMA Order.'' Received comments 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, 240–402–7500.

- 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://*