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]

BILLING CODE 4164–01–P

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://*

www.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))).

Electronic copies of the guidance documents are available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act'' or ''Procedures for Handling Post-Approval Studies Imposed by PMA Order'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Megha Reddy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002, 240–402–2980.

SUPPLEMENTARY INFORMATION:

I. Background

The guidance ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act'' is intended to assist manufacturers of devices subject to section 522 orders, by providing:

- an overview of section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l),
- information on how to fulfill section 522 obligations, and
- recommendations on the format, content, and review of postmarket surveillance plan and report submissions.

The guidance ''Procedures for Handling Post-Approval Studies Imposed by PMA Order'' is intended to assist stakeholders with understanding PAS requirements imposed as a condition of PMA approval by providing:

- procedural information,
- recommendations concerning the format, content, and review of PAS-related submissions,
- recommendations to help facilitate FDA's review of a PAS protocol in a timely manner,
- recommendations for study timelines including enrollment milestones and study completion,
- revised definitions to PAS status categories that we believe better reflect progress of the PAS, and
- revised FDA review time goals for PAS-related submissions.

The primary changes for the guidance ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act'' from the 2016 version of this guidance document include: (1) clarification on when postmarket surveillance is considered commenced, (2) recommendations for achieving an approved postmarket surveillance plan in a timely manner, (3) recommendations for postmarket surveillance completion timelines, (4) updated surveillance status categories to better reflect progress, (5) revised FDA's review times for postmarket surveillance related submissions, and (6) updated FDA points of contact and organizational structure.

A notice of availability of the draft guidance ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act'' appeared in the **Federal Register** of May 27, 2021 (86 FR 28602). FDA considered comments received and revised this guidance as appropriate in response to the comments, including (1) by providing additional clarification on information to be included in postmarket surveillance plans, enrollment reports, interim reports, and final reports; (2) additional clarification on how changes to an approved postmarket surveillance plan should be made by the companies and reviewed by the FDA; and (3) additional clarification on information to be posted on FDA's 522 web page.

A notice of availability of the draft guidance ''Procedures for Handling Post-Approval Studies Imposed by PMA Order'' appeared in the **Federal Register** of May 27, 2021 (86 FR 28630). FDA considered comments received and revised this guidance as appropriate in response to the comments, including: (1) by providing additional clarification on information to be included in PAS protocols, enrollment reports, interim PAS reports, and final PAS reports; (2) additional clarification on how changes to an approved PAS protocol should be made by the sponsors and reviewed by the FDA; (3) additional clarification on using alternative study designs such as Real-World Data; and (4) one revised definition of PAS status.

These guidance documents are being issued consistent with FDA's good guidance practices regulation (§ 10.115). These guidance documents represent the current thinking of FDA on ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act,'' and ''Procedures for Handling Post-Approval Studies Imposed by PMA Order,'' respectively. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidances may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* These guidance documents are also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of either ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act (document number 19042)'' or ''Procedures for Handling Post-Approval Studies Imposed by PMA Order (document number 1043)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While these guidance documents contain no new collection of information, they do 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 these guidance documents. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
822	Postmarket Surveillance of Medical Devices	0910–0449
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Device; Humanitarian Device Exemption	0910–0332
860, subpart D	De Novo classification process	0910–0844
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program".	Q-submissions; Presubmissions	0910–0756

Dated: October 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21832 Filed 10–6–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0576]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational Device Exemptions

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 0910–0078. 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.

Investigational Device Exemptions—21 CFR Part 812

OMB Control Number 0910–0078—Extension

This information collection supports implementation of section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), which governs exemption for devices for investigational use. An investigational device exemption (IDE) allows a device to be used in investigations involving human subjects in which the safety and effectiveness of the device is being studied. For more information regarding IDE, please visit our website at *https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide.*

FDA has promulgated regulations in part 812 (21 CFR part 812) intended to encourage the discovery and development of useful devices intended for human use. The regulations set forth the scope and applicability of exemption requirements for devices for investigational use, as well as establish application procedures, corresponding instruction, and provisions for emergency research. The regulations also provide for requesting waivers from the requirements and explain sponsor responsibilities, including requirements for institutional review board (IRB) review and approval. Finally, the regulations in part 812, subpart G (21 CFR 812.140, 812.145, and 812.150) provide for required recordkeeping, the inspection of records, and the preparation and submission of reports to FDA and/or IRBs that oversee medical device investigations.

In the **Federal Register** of May 6, 2022 (87 FR 27168), 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]

Activity/21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
812.10; waivers	1	1	1	1	1
812.20, 812.25, and 812.27; applications, investigational plans, and supplements	229	1	229	80	18,320
812.27(b)(4)(i); prior investigations within the United States	400	1	400	1	400
812.27(b)(4)(ii); prior investigations outside the United States	100	1	100	0.25 (15 minutes)	25
812.28; acceptance of data from clinical investigations conducted outside the United States, and supporting information	1,500	1	1,500	10.25	15,375
812.28(c); waivers	10	1	10	1	10
812.35 and 812.150; application supplements	654	5	3,270	6	19,620
812.36(c); treatment IDE applications	1	1	1	120	120