applications to FDA. FDA confirms whether certain information in the application is consistent with FDA's existing records. This helps the third-party appraiser to determine the manufacturers' eligibility for participation in the VIP. We expect each application will take approximately 5 minutes to submit.

Aggregate Data Reporting

The third-party appraiser provides FDA with aggregated data across all participating manufacturer sites quarterly. The aggregate data is used to identify broad industry trends and patterns that FDA may consider in the benefit-risk considerations FDA routinely uses to inform planning, improve FDA resource allocations, improve review efficiency, and inform risk-based inspection planning. We expect that it will take approximately 8 hours to prepare and submit the aggregate data.

Summary of Site Appraisal

The third-party appraiser provides FDA with a summary of the appraisal result for each participating site. FDA intends to consider this information in the benefit-risk considerations FDA routinely uses to inform planning, improve FDA resource allocations, improve review efficiency, and inform risk-based inspection planning for firms that demonstrate capability and transparency around their manufacturing and product performance. We expect it will take approximately 20 hours to complete each summary.

The VIP and Certain Regulatory Submissions

FDA expects to gain insights into a participant's manufacturing processes and control capabilities intended to satisfy recommendations for certain PMA or HDE submissions (*e.g.,* PMA/HDE 30-Day Change Notices, PMA/HDE Manufacturing Site Change Supplements, PMA/HDE Manufacturing Modules). Thus, participants in the VIP may be able to avail themselves of efficiencies that would prevent duplicate information and/or allow for least burdensome submissions to FDA. FDA plans to improve stakeholder opportunities to use modified templates for such submissions.

The draft guidance also refers to previously approved collections of information. These collections of information are subject to review by the OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
7	Recalls	0910–0432
803	Medical Device Reporting	0910–0437
807, subparts A through D	Establishment Registration and Listing	0910–0625

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09734 Filed 5–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0576]

Agency Information Collection Activities; Proposed Collection; 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 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, 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 information collection associated with investigational device exemptions.

DATES: Submit either electronic or written comments on the collection of information by July 5, 2022.

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 July 5, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 5, 2022. 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–2022–N–0576 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational Device Exemptions.'' 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, 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.

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: Under the PRA (44 U.S.C. 3501–3521), 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.

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 (§§ 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.

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 U.S	400	1	400	1	400
812.27(b)(4)(ii); prior investigations outside the U.S	100	1	100	0.25	25
812.28; acceptance of data from clinical investigations conducted outside the U.S., and supporting information	1,500	1	1,500	10.25	15,375

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
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
812.36(f); treatment IDE reports	1	1	1	20	20
812.150; non-significant risk study reports	1	1	1	6	6
Total			5,513		53,897

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

Our estimate of the average reporting burden is based on our continued experience with the information collection. We have adjusted the currently approved burden to reflect an increase we attribute to Agency rulemaking that has become effective (OMB control number 0910–AG48) since our last evaluation. Regulations in part 812 were amended to provide for reporting associated with the acceptance of data from clinical investigations conducted outside the United States.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
812.2(c)(3); records regarding leftover specimens not individually identifiable used in certain studies	700	1	700	4	2,800
812.28(d); records for clinical investigations conducted outside U.S	1,500	1	1,500	1	1,500
812.140; retention of records	1,249	3.09	3,865	1.9937	7,706
Total					12,006

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

In the guidance document ''Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable'' (April 2006), available for download at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-informed-consent-vitro-diagnostic-device-studies-using-leftover-human-specimens-are-not,* FDA communicates its enforcement policy with regard to the informed consent regulations (as required by section 520(g) of the FD&C Act and 21 CFR part 50) for in vitro diagnostic device studies that are conducted using leftover specimens and that meet the criteria for exemption from IDE regulation at 21 CFR 812.2(c)(3). We include burden that may be attributable to FDA recommendations that sponsors of studies document certain information, in table 2, row 1. We have otherwise adjusted our estimate upward of the average recordkeeping burden attributable to provisions in part 812 to reflect those requirements associated with clinical investigations conducted outside the United States, and in recognition of the required retention period for records.

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09751 Filed 5–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0131]

Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients With Type 2 Diabetes Mellitus; 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 or Agency) is announcing the availability of a final guidance entitled ''Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus.'' This guidance provides recommendations for feasibility and early feasibility clinical studies for certain medical devices intended to therapeutically improve glycemic control in patients with Type 2 Diabetes Mellitus. These medical devices are intended to therapeutically reduce glycated hemoglobin in Type 2 Diabetes Mellitus patients independent of medication (*e.g.,* insulin) delivery.

DATES: The announcement of the guidance is published in the **Federal Register** on May 6, 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