proposed revisions to the ACF–696T will provide reporting instructions to Tribal Lead Agencies who are approved under a temporary opportunity to retroactively request the use CCDF funds, including most COVID-relief funds, for construction and/or major renovation with the intent of offsetting increased costs of materials, labor, and other related project costs.

**DATES:** *Comments due within 14 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above and below.

**ADDRESSES:** Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* ACF programs require detailed financial information from their grantees that allows ACF to monitor various specialized cost categories within each program, to closely manage program activities, and to have sufficient financial information to enable periodic thorough and detailed audits. Generic Clearance for Financial Reports used for ACF Non-Discretionary Grant Programs allows ACF programs to efficiently develop and receive approval for financial reports that are tailored to specific funding recipients and the associated needs of the program. For more information about the umbrella generic, see: *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202108-0970-002*.

This specific GenIC collects financial data for tribal CCDF programs. The proposed revisions to the ACF–696T will provide reporting instructions to Tribal Lead Agencies who are approved under a temporary opportunity to retroactively request the use CCDF funds, including most COVID-relief funds, for construction and/or major renovation with the intent of offsetting increased costs of materials, labor, and other related project costs.

ANNUAL BURDEN ESTIMATES

| Title of information collection | Number of respondents | Annual frequency of responses | Hourly burden per response | Annual hourly burden |
|---|---|---|---|---|
| ACF–696T | 219 | 1 | 5 | 1,095 |

*Comments:* The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 14 days of this publication.

*Authority:* 42 U.S.C. 9857, 42 U.S.C. 618.

**Mary C. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2024–19916 Filed 9–4–24; 8:45 am]

**BILLING CODE 4184–25–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2024–N–3902]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution and Related Collections of Information

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, the 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 the information collections related to requirements for drug establishment registration and drug listing, including registrant reporting under the Federal Food, Drug, and Cosmetic Act (FD&C Act) with respect to listed drugs and certain guidances.

**DATES:** Either electronic or written comments on the collection of information must be submitted by November 4, 2024.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 4, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2024–N–3902 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution, and Related Collections of Information.'' 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.

**Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution and Related Collections of Information**

*OMB Control Number 0910–0045—Extension*

This information collection supports implementation of requirements related to drug establishment registration and listing governed by section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360), including registrant reporting under section 510(j)(3) of the FD&C Act with respect to listed drugs. Agency regulations implementing drug establishment and registration provisions are found in part 207 (21 CFR part 207) and include reporting and recordkeeping requirements. Agency guidance addressing reporting and recordkeeping provided for by section 510 of the FD&C Act is also addressed in this information collection. All Agency guidance documents are issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time. To search available FDA guidance documents, visit the FDA guidance web page at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Respondents to the collection of information are domestic establishments that manufacture, repack, relabel, or salvage a drug, or an animal feed bearing or containing a new animal drug, and foreign establishments that manufacture, repack, relabel, or salvage a drug, or an animal feed bearing or containing a new animal drug, that is imported or offered for import into the United States. As set forth in the regulations governing drug establishment registration and listing, when operations are conducted at more than one establishment and common ownership and control among all the establishments exists, the parent, subsidiary, or affiliate company may submit registration information for all establishments. Establishment registration information helps FDA identify who is manufacturing, repacking, relabeling, and salvaging drugs and where those operations are performed. Drug listing information gives FDA a current inventory of drugs manufactured, repacked, relabeled, or salvaged for commercial distribution. Data reported by registrants under section 510(j)(3) of the FD&C Act on the number of listed drugs they annually manufacture, prepare, propagate,

compound or process provide FDA with a more comprehensive picture of the drug supply chain, which can inform operational decisions and support the Agency's efforts to reduce drug shortage risk. All these types of information facilitate implementation and enforcement of the FDC Act and are used for many important public health purposes.

While there are 10,480 establishments currently registered with FDA, registration and listing data is subject to frequent fluctuation as a result of the volume of activity. Consistent with provisions in § 207.61, except as provided in § 207.65, all information submitted under part 207 must be transmitted to FDA in an electronic format by using our electronic drug registration and listing system, in a form that we can process, review, and archive. For more information regarding FDA's Electronic Drug Registration and Listing System (eDRLS), including ''Latest News'' updates, we encourage respondents to visit our website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/electronic-drug-registration-and-listing-system-edrls.* To assist respondents in complying with electronic submission requirements related to drug establishment registration and drug listing under section 510 of the FD&C Act, we issued the guidance document entitled ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing'' (June 2009) (available at *https://www.fda.gov/media/71146/download*). Updated daily, we also maintain a registration database that includes a publication of currently registered establishments on our website at *https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site.*

Since our last evaluation of the collection of information, there have been modifications to certain reporting and recordkeeping requirements under section 510 of the FD&C Act resulting from amendments made by the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. 116–136). Relevant to the information collection described herein, section 510(j) of the FD&C Act was amended to include the following information collection activities:

- Section 510(j)(3) of the FD&C Act, as added by the CARES Act, requires that registrants under section 510 of the FD&C Act must annually report the amount of each listed drug that they manufactured, prepared, propagated, compounded, or processed (hereinafter manufactured) for commercial distribution. Section 510(j)(3) of the FD&C Act also authorizes FDA to require that registrants report this information electronically, and to require that registrants report this information at the time a public health emergency is declared. To provide guidance on the submission of the reporting required under section 510(j)(3) of the FD&C Act, we issued the guidance document entitled ''Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act'' (February 2024) (available at *https://www.fda.gov/media/175933/download*). In addition to supporting FDA's response to drug shortages, this guidance on reporting under section 510(j)(3) also facilitates FDA's access to information useful in making decisions regarding the appropriate level of drug facility surveillance.
- The guidance document entitled ''Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products'' (March 2011) (available at *https://www.fda.gov/media/120092/download*) is intended to encourage manufacturers of drug and therapeutic biological products, and any raw materials and components used in those products, to develop a written Emergency Plan (Plan) for maintaining an adequate supply of medically necessary drug products during an emergency that results in high employee absenteeism; that guidance discusses the elements that should be covered by such a Plan. The guidance also recommends respondents notify FDA's Center for Drug Evaluation and Research (CDER) when activating or deactivating a Plan.
- As we continue to receive similar information regarding animal drug shortages, we developed and issued the guidance document ''Reporting and Mitigating Animal Drug Shortages'' (Center for Veterinary Medicine GFI #271) (May 2023) (available at *https://www.fda.gov/media/137722/download*) intended to assist respondents in notifying FDA about changes in the production of animal drugs that will, in turn, help the Agency in its efforts to prevent or mitigate shortages of animal drugs.
- The Secretary may issue an order under section 510(j)(3)(B) of the FD&C Act to exempt certain biological products or categories of biological products regulated under section 351 of the Public Health Service Act (42 U.S.C. 242) from some or all of the reporting requirements established in section 510(j)(3)(A) of the FD&C Act, if the Secretary determines that applying such reporting requirements to those products (or product categories) is not necessary to protect the public health, We most recently revised the information collection to reflect reporting exemptions via such an order pertaining to: (1) blood and blood components for transfusion and (2) cell and gene therapy products, where one lot treats a single patient, as announced in the **Federal Register** of April 13, 2023 (88 FR 22454) (April 2023 final order).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity; 21 CFR section; statutory citation; guidance section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Initial establishment registration; §§ 207.17, 207.21, and 207.25 | 593 | 2 | 1,186 | 1 | 1,186 |
| Annual review and update of registration information (including expedited updates); § 207.29 | 10,480 | 3 | 31,440 | 0.5 (30 minutes) | 15,720 |
| Initial listing (including National Drug Code (NDC)); §§ 207.33, 207.41, 207.45, 207.49, 207.53, 207.54, and 207.55 | 3,040 | ~7.28 | 22,130 | 1.5 | 33,197 |
| June and December review and update (or certification) of listing; §§ 207.35 and 207.57 | 5,153 | 20 | 103,060 | 0.75 (45 minutes) | 77,295 |
| Waiver requests; § 207.65 | 1 | 1 | 1 | 0.5 (30 minutes) | 1 |

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

| Activity; 21 CFR section; statutory citation; guidance section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Public disclosure exemption request; § 207.81(c) | 30 | 1 | 30 | 1 | 30 |
| Manufacturing amount information; section 510(j)(3) of the FD&C Act | 8,700 | 22.5 | 195,750 | 1 | 195,750 |
| Notify FDA of changes in the production of animal drugs; ''Reporting and Mitigating Animal Drug Shortages,'' section III | 30 | 2 | 60 | 1 | 60 |
| Notify CDER when activating/deactivating Plan; ''Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products,'' section III.F | 2 | 1 | 2 | 16 | 32 |
| Total | | | 353,659 | | 323,271 |

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| Activity; guidance section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| Preparing Standard Operating Procedures for Creating and Uploading the Structured Product Labeling File | 1,000 | 1 | 1,000 | 40 | 40,000 |
| Develop initial Plan; ''Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products,'' section III | 70 | 1 | 70 | 250 | 17,500 |
| Total | | | 1,070 | | 57,500 |

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

According to internal data, we estimate 593 respondents will submit 1,186 new establishment registrations annually. We estimate that 10,480 registrants will provide 31,440 annual reviews and updates of registration information (including expedited updates) or reviews and certifications that no changes have occurred. The estimates include the registration of establishments for both domestic and foreign manufacturers, repackers, relabelers, and drug product salvagers, and registration information submitted by anyone acting as an authorized agent for an establishment that manufactures, repacks, relabels, or salvages drugs. The estimates include an additional 80 positron emission tomography drug producers who are not exempt from registration and approximately 30 manufacturers of plasma derivatives.

We assume 1 hour is necessary for registrants to submit initial registration information electronically for each new establishment. We assume 30 minutes is necessary for each annual review and update of registration information (including any expedited updates) or each review and certification that no changes have occurred. Our estimate reflects the average amount of time and effort necessary to register a domestic or foreign establishment, and the average amount of time and effort necessary to review and update registration information or review registration information and certify no changes have occurred.

Based on the number of drugs listed annually over the last few years, we estimate 3,040 registrants will report approximately 22,131 new listings annually (including the information submitted to obtain a labeler code and to reserve an NDC for future use). Based on the number of drugs in our listing database and the current number of changes to listing information submitted, we estimate 5,153 registrants will each report 20 reviews and updates (including the information submitted to revise an NDC) for a total of 103,060 annually. The estimates for the number of drug listings include both domestic and foreign listings, listings submitted by registrants for products sold under their own names as well as products intended for private label distribution, and information submitted related to an NDC and to obtain a labeler code. The estimate for the number of drugs subject to the listing requirements includes positron emission tomography drugs and approximately 30 plasma derivatives. The estimates for the number of June and December reviews and updates of listing information include the number of changes to drug characteristics pertaining to the drug product code to obtain a new NDC and the reports of the withdrawal of an approved drug from sale under § 314.81(b)(3)(iii) (21 CFR 314.81(b)(3)(iii)).

Based on our experience with electronically listing submissions over the last few years, we assume it takes 1 hour and 30 minutes to submit information electronically for each drug listed for the first time (for both foreign and domestic registrant listings). These estimates are an average of the time it will take manufacturers, repackers, relabelers, and drug product salvagers, with drug product salvagers taking considerably less time than manufacturers. The estimates include the time for submitting the content of labeling and other labeling in an electronic format (for drugs subject to an approved marketing application, the electronic submission of the content of labeling under 21 CFR 314.50(*l*)(1)(i) is approved under OMB control number 0910–0001). We assume it takes 45 minutes for each June and December review and update. These estimates represent the average amount of time to review and update listing information or to review and certify that no changes have occurred. The estimates include the time for submitting any labeling for each drug, changes to the drug's characteristics submitted for a new NDC

and reports of the withdrawal of an approved drug from sale under § 314.81(b)(3)(iii).

We estimate 1,000 firms will expend 40 hours to prepare, review, and approve a standard operating procedure (SOP), for a total of 40,000 hours annually. Although we expect most respondents will have already prepared and implemented an SOP for the electronic submission of drug establishment registration and drug listing information, we retain an estimate for new firms that will do so, as recommended in the guidance document.

Additionally, we assume 10,480 registrants, (accounting for both biological product and drug product registrants) are subject to the reporting provisions under section 510(j)(3) of the FD&C Act but exclude 1,780 respondents to reflect the reporting exemptions implemented under section 510(j)(3)(B) pertaining to: (1) blood and blood components for transfusion and (2) cell and gene therapy products, where one lot treats a single patient. Also, based on informal communications, we have increased the estimated burden we attribute to prepare and submit the requisite information for reporting provisions under section 510(j)(3) of the FD&C Act from 15 minutes to 1 hour.

Regarding notifications to FDA of changes in the production of animal drugs associated with the guidance document entitled ''Reporting and Mitigating Animal Drug Shortages,'' we estimate that 30 respondents will provide two notifications each year and that it will take 1 hour to prepare and submit each notification.

Finally, regarding the information collection associated with the guidance document entitled ''Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products,'' we assume two notifications (for purposes of this analysis, we consider an activation and a deactivation notification to equal one notification) will be submitted to CDER annually, and estimate each notification requires 16 hours to prepare and submit. As FDA issued the guidance in 2011, we now assume that most respondents have developed the recommended Plan, and therefore, we limit our current burden estimate to updates and maintenance. Accordingly, we estimate 70 manufacturers will update or maintain the recommended Plan and those changes would take approximately 250 hours per manufacturer.

Our estimated burden for the information collection reflects an overall decrease of 65,934 responses/records but an overall increase of 144,913 hours annually. We attribute adjustments to our reevaluation of the number of submissions we received over the last few years for the provisions in part 207 and the increase in the estimated burden per response to 1 hour to prepare and submit the requisite information for the reporting provisions under section 510(j)(3) of the FD&C Act.

Dated: August 29, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–19862 Filed 9–4–24; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–N–1894]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation B12 Pediatric Device Survey

**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 October 7, 2024.

**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 0910–0912. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

### Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation (CERSI) B12 Pediatric Device Survey

*OMB Control Number 0910–0912—Reinstatement*

Despite numerous legislative, regulatory, and scientific efforts, there has been little change in the number of devices approved for use in pediatric patients. This has often led to devices being adapted for use in children without an appropriate level of evidence, exposing them to inconsistent benefit risk profiles. This health inequity highlights the need for devices that are designed, evaluated, and labeled for pediatric patients. To address these challenges, this collection is being done to survey industry and other key stakeholders in the medical device ecosystem to identify the barriers that prevent product developers from entering the pediatric device market as well as the proper incentives that would motivate them to innovate and sustain within this market.

This survey is a followup to the public meeting that FDA held in August 2018, entitled, ''Pediatric Medical Device Development.'' As mandated by section 502(d) of the FDA Reauthorization Act of 2017 (Pub. L. 115–52) the meeting was convened to address several topics, including consideration of ways to: (1) increase FDA assistance to medical device manufacturers in developing devices for pediatric populations that are approved or cleared, and labeled, for their use and (2) identify current barriers to pediatric device development and incentives to address such barriers.

Feedback from this meeting clarified the need to better understand factors influencing suboptimal engagement and participation by diverse innovators in the pediatric medical device space. Information garnered from this survey may help inform strategic plans to optimize existing programs for the needs of pediatric medical device innovators and develop new programs that will support sustained development in this space.

In the **Federal Register** of May 22, 2024 (89 FR 44993), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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