(DCBFD2) Regulatory Review Branch 3 (DCBFD3)
Review Management Support Branch (DCBFD4)
Division of Clinical and Toxicology Review (DCBFE)
Clinical Review Branch 1 (DCBFE1)
Clinical Review Branch 2 (DCBFE2)
Clinical Review Branch 3 (DCBFE3)
Toxicology Staff (DCBFE4)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

After completion of the necessary requirements for implementation, this reorganization will be reflected in FDA's Staff Manual Guide (SMG) at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

Authority: 44 U.S.C. 3101.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–26512 Filed 12–4–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of priority review voucher. FDA has determined that XENPOZYME (olipudase alfa-rpcp), manufactured by Genzyme Corporation, meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that XENPOZYME (olipudase alfa-rpcp), manufactured by Genzyme Corporation, meets the criteria for a priority review voucher. XENPOZYME (olipudase alfa-rpcp) is indicated for treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about XENPOZYME (olipudase alfa-rpcp), go to the ''Drugs@FDA'' website at *http://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: November 30, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26652 Filed 12–4–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5569]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Device Tracking

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 January 4, 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 0910–0442. 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, 10 a.m.–12 p.m., 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.

Medical Devices; Device Tracking—21 CFR Part 821

OMB Control Number 0910–0442—Extension

Section 519(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)(1)) provides that FDA may require by order that a manufacturer adopt a method for tracking a class II or III medical device, if the device meets one of the three following criteria: (1) the failure of the device would be reasonably likely to have serious adverse health consequences, (2) the device is intended to be implanted in the human body for more than 1 year (referred to as a ''tracked implant''), or (3) the device is life-sustaining or life-supporting (referred to as a ''tracked l/s-l/s device'') and is used outside a device user facility. Tracked device information is collected to facilitate identifying the current location of medical devices and patients possessing those devices, to the extent that patients permit the collection of identifying information. Manufacturers and FDA (where necessary) use the data to: (1) expedite the recall of distributed medical devices that are dangerous or defective and (2) facilitate the timely notification of patients or licensed practitioners of the risks associated with the medical device.

In addition, applicable regulations in 21 CFR part 821 (21 CFR 821.1 through 821.60) include provisions for: (1) exemptions and variances; (2) system and content requirements for tracking; (3) obligations of persons other than device manufacturers, *e.g.,* distributors; (4) records and inspection requirements; (5) confidentiality; and (6) record retention requirements.

Respondents to the collection of information are medical device manufacturers, importers, and distributors of tracked implants or tracked l/s-l/s devices used outside a device user facility. Distributors include multiple and final distributors, including hospitals. We currently estimate 22,000 potential respondents.

In the **Federal Register** of August 8, 2023 (88 FR 53494), we published a 60-day notice soliciting 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
Discontinuation of business—821.1(d)	1	1	1	1	1
Exemption or variance—821.2 and 821.30(e)	1	1	1	1	1
Notification of failure to comply—821.25(d)	1	1	1	1	1
Multiple distributor data—821.30(c)(2)	1	1	1	1	1
Total					4

[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; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Tracking information—821.25(a)	12	1	12	76	912
Record of tracking data—821.25(b)	12	46,260	555,120	1	555,120
Standard operating procedures—821.25(c) [2]	12	1	12	63	756
Manufacturer data audit—821.25(c)(3)	12	1,124	13,488	1	13,488
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	22,000	1	22,000	1	22,000
Total					592,276

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One-time burden.

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

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Acquisition of tracked devices and final distributor data—821.30(a) and (b)	22,000	1	22,000	1	22,000
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	1,100	1	1,100	1	1,100
Total					23,100

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

Upon evaluation of the information collection, we have made no adjustment to our currently approved burden estimate of 615,380 hours annually, based on 12 tracking orders. We attribute the attendant burden to the following activities:

Under § 821.25(a), device manufacturers subject to FDA tracking orders must adopt a tracking method that can provide certain device, patient, and distributor information to FDA within 3 to 10 working days. Assuming one occurrence per year, we estimate it would take a firm 20 hours to provide FDA with location data for all tracked devices and 56 hours to identify all patients and/or multiple distributors possessing tracked devices.

Under § 821.25(d) manufacturers must notify FDA of distributor noncompliance with reporting requirements. Based on the number of audits manufacturers conduct annually, we estimate no more than one notice will be received in any year, and that it would take 1 hour per incident.

Under § 821.30(c)(2), multiple distributors must provide data on current users of tracked devices, current device locations, and other information, upon request from a manufacturer or FDA. Assuming one multiple distributor receives one request in a year from either a manufacturer or FDA, and that lists may be generated electronically, we estimate a burden of 1 hour to comply.

Under § 821.30(d) distributors must verify data or make required records available for auditing, if a manufacturer provides a written request. We assume 5 percent of tracked devices distributed for estimating burden. Each audited

database entry prompts one distributor audit response. Because lists may be generated electronically, we estimate a burden of 1 hour to comply.

Dated: November 30, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26653 Filed 12–4–23; 8:45 am]

BILLING CODE 4161–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Home Visiting Assessment of Implementation Quality Study: Exploring Family Voice and Leadership in Home Visiting

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than February 5, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Home Visiting Assessment of Implementation Quality Study: Exploring Family Voice and Leadership in Home Visiting, OMB No. 0915–xxxx—[NEW]

Abstract: The Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program, authorized by Social Security Act, title V, section 511 (42 U.S.C. 711) and administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and for parents with young children up to kindergarten entry. States, tribal entities, and certain nonprofit organizations are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities. Funding recipients may subaward grant funds to local implementing agencies (LIAs) to provide home visiting services to eligible families in at-risk communities.

Through the Home Visiting Assessment of Implementation Quality Study, HRSA aims to examine specific components of the Home Visiting Implementation Quality Conceptual Framework to inform strategies for implementing high quality home visiting programs. One of the three quality components the study will focus on is family voice and leadership (FVL), which involves including families in decisions related to program implementation. The requested information collection will provide a better understanding of how MIECHV-funded home visiting programs currently engage families and will provide preliminary information on how FVL may influence home visiting implementation and program quality. Data collection activities include an online survey, focus groups, and interviews.

Need and Proposed Use of the Information: HRSA is seeking additional information about how the MIECHV Program engages and supports families in leadership opportunities to inform and improve programs. HRSA intends to use this information to identify actionable strategies that MIECHV awardees and LIAs could take to engage families meaningfully and effectively in program decisions and to ensure that families' unique strengths, needs, cultures, and preferences drive service delivery.

Likely Respondents: MIECHV Program awardees that are states, nonprofit organizations, and Tribes, LIA staff (program directors, coordinators, supervisors, and home visitors); and families who have been engaged in FVL activities by MIECHV-funded home visiting programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
MIECHV Program FVL Online Survey	1,000	1	1,000	0.33	330
Family Focus Group Protocol	48	1	48	1.00	48
Tribal and State MIECHV Administrators Interview Guide	12	1	12	1.00	12
LIA Program Staff Focus Group Protocol	48	1	48	1.00	48
Total	1,108		1,108		438

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance