Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
State Formula Grantees, SPR Generic	112	1	70.3	7,873.60
State Competitive Grants, PPR Generic	56	2	1.0	112
Tribal Formula Grantees, PPR Generic	282	1	60	16,920
Competitive Grantees, PPR Generic	1,189	2	10	23,780
Veteran Organization Competitive Grantees, PPR Generic	275	12	0.5	1,650
Total Annual Hours				50,335.60

Dated: November 30, 2023.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2023–26634 Filed 12–4–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA), Center for Biologics Evaluation and Research (CBER), Office of Blood Research and Review (OBRR) and the Office of Vaccines Research and Review (OVRR) have modified organizational structures.

DATES: These new organizational structures were approved by the Secretary of Health and Human Services on June 27, 2023.

FOR FURTHER INFORMATION CONTACT: Yashika Rahaman, Director, Office of Planning, Evaluation and Risk Management, Office of Finance, Budget, Acquisitions and Planning, FDA, 4041 Powder Mill Road, Beltsville, MD 20705–4304, 301–796–3843.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is revised to reflect FDA's reorganization of CBER, OBRR and OVRR.

CBER's mission is to protect and enhance public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies. With substantial growth in innovative, novel products, as well as a need to address an ever-changing landscape of potential public health threats, CBER is currently facing scientific, medical, and regulatory challenges that require changes to its structure.

In OBRR, the establishment of a Laboratory of Pathogen Reduction will address Center-level initiatives focusing on the optimization of new pathogen inactivation technologies. These technologies can dramatically help the American public and potentially reduce or eliminate donor deferral and/or testing requirements. Additionally, the proposed structural changes, keeping OBRR's functioning state of two divisions instead of three, will maintain operational consistency and enable the divisions to build on processes and efficiencies gained in the last 2 years.

In OVRR, the Division of Vaccines and Related Product Applications will split into the Division of Review Management and Regulatory Review and the Division of Clinical and Toxicology Review to allow for improved operational efficiency, appropriate supervisory ratios, and a better balance of workload within an area of increased demand.

Under Part D, FDA's CBER, Office of Blood Research and Review, has been restructured as follows:

DCB. ORGANIZATION. CBER is headed by the Center Director, Center for Biologics Evaluation and Research.

Center for Biologics Evaluation and Research (DCB)

Office of Blood Research and Review (DCBE)
- Administrative Staff (DCBE1)
- Regulatory Project Management Staff (DCBE2)

Laboratory of Pathogen Reduction (DCBE3)

Division of Emerging and Transfusion Transmitted Diseases (DCBEA)
- Laboratory of Molecular Virology (DCBEA1)
- Laboratory of Emerging Pathogens (DCBEA2)
- Product Review Branch (DCBEA4)
- Laboratory of Emerging Pathogens (DCBEA2)
- Product Review Branch (DCBEA4)

Division of Blood Components and Devices (DCBEB)
- Devices Review Branch (DCBEB2)
- Blood and Plasma Branch (DCBEB6)
- Laboratory of Cellular Hematology (DCBEB7)
- Laboratory of Biochemistry and Vascular Biology (DCBEB8)

Under Part D, FDA's CBER, Office of Vaccines Research and Review, has been restructured as follows:

DCB. ORGANIZATION. CBER is headed by the Center Director, Center for Biologics Evaluation and Research.

Center for Biologics Evaluation and Research (DCB)

Office of Vaccines Research and Review (DCBF)
- Program Operations Staff (DCBF1)

Division of Bacterial Parasitic and Allergenic Products (DCBFA)
- Laboratory of ImmunoBiochemistry (DCBFA1)
- Laboratory of Respiratory and Special Pathogens (DCBFA2)
- Laboratory of Bacterial Polysaccharides (DCBFA3)
- Laboratory of Mucosal Pathogens and Cellular Immunology (DCBFA4)

Division of Viral Products (DCBFB)
- Laboratory of Pediatric and Respiratory Viral Diseases (DCBFB1)
- Laboratory of Hepatitis Viruses (DCBFB2)
- Laboratory of Retroviruses (DCBFB3)
- Laboratory of DNA Viruses (DCBFB4)
- Laboratory of Vector Borne Diseases (DCBFB5)
- Laboratory of Method Development (DCBFB6)
- Laboratory of Immunoregulation (DCBFB7)

Division of Review Management and Regulatory Review (DCBFD)
- Regulatory Review Branch 1 (DCBFD1)
- Regulatory Review Branch 2

(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.