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Dated: December 2, 2020.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Office of Child Support Enforcement; Statement of Organization, Functions, and Delegations of Authority

**AGENCY:** Administration for Children and Families, HHS.

**ACTION:** Notice.

**SUMMARY:** Statement of Organization, Functions, and Delegations of Authority.

The Administration for Children and Families (ACF) has reorganized the Office of Child Support Enforcement. This reorganization realigns the functions of the Office of Child Support Enforcement. It eliminates the Division of Performance and Statistical Analysis and moves the functions to the Division of Federal Systems.

**FOR FURTHER INFORMATION CONTACT:** Scott Lekan, Acting Commissioner, Office of Child Support Enforcement, 330 C Street SW, Washington, DC 20201; (202) 401–9369.

**SUPPLEMENTARY INFORMATION:** This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF), as follows: Chapter KF, Office of Child Support Enforcement (OCSE), as last amended in 78 FR 60880–60883, October 2, 2013.

I. Under Chapter KF, Office of Child Support Enforcement, delete KF in its entirety and replace with the following:

**KF.00 MISSION.** The Office of Child Support Enforcement (OCSE) advises the Secretary, through the Assistant

Secretary for Children and Families/ Director of the Office of Child Support Enforcement, on matters pertaining to the child support and access and visitation programs. OCSE provides direction, guidance, and oversight to state and tribal child support programs, the Central Authority for international child support cases, and state access and visitation programs for activities authorized and directed by title IV–D of the Social Security Act and other pertinent legislation. OCSE's core mission is dedicated to establishing paternity and obtaining child support in order to encourage responsible parenting, family self-sufficiency, and child well-being, and to recognize the essential role of both parents in supporting their children. The national child support program assures that assistance in obtaining support, including financial and medical, is available to children, through locating parents, establishing paternity, establishing and modifying support obligations, and monitoring and enforcing those obligations. The specific responsibilities of this Office are to develop, recommend, and issue policies, procedures, and interpretations for state and tribal programs for locating noncustodial parents, establishing paternity, and obtaining child support; approval procedures for review and approval or disapproval of state and tribal plan material; conduct audits of state child support programs; assist states and tribes in establishing adequate reporting procedures and maintaining records for the operation of their child support programs and of amounts collected and disbursed under the child support program and the costs incurred in collecting such amounts; operate the United States and Tribes Central Authority for International Child Support; monitor the access and visitation and fatherhood programs; and provide technical assistance and training to the states and tribes to help them develop effective procedures and systems for services provided by the child support program, including automation, outreach, referral, and case management in partnership with employers, courts, and responsible fatherhood, workforce, and other programs to increase the long-term reliability of support payments available to children. OCSE also operates competitive grant programs for child support in collaboration with several other components within ACF. It also operates the Federal Parent Locator Service (FPLS); certifies to the Secretary of the Treasury amounts of child support obligations that require

collection in appropriate instances; transmits to the Secretary of State certifications of arrearages for passport denial; submits reports to Congress, as requested, on activities undertaken relative to the child support program; approves advance data processing planning documents; and reviews, assesses, and inspects planning, design, and operation of state and tribal management information systems. FPLS also assists other federal, state, and local agencies not involved in child support to fulfill their respective missions, save taxpayer dollars, and improve service to the public.

**KF.10 ORGANIZATION.** The Office of Child Support Enforcement is headed by the Director. The office is organized as follows:

- Office of the Director/Deputy Director/ Commissioner (KFA)
- Office of Audit (KFAA)
- Office of the Deputy Commissioner (KFB)
- Division of Business and Resource Management (KFB2)
- Division of Customer Communications (KFB3)
- Division of Policy and Training (KFB5)
- Division of Program Innovation (KFB7)
- Division of Regional Operations (KFB8)
- Child Support Services Regional Program Units (KFB8DI–X)
- Division of Federal Systems (KFB9)
- Division of State and Tribal Systems (KFB10)

**KF.20 FUNCTIONS.** Office of the Director and Deputy Director/ Commissioner (KFA): The Director is also the Assistant Secretary for Children and Families and is directly responsible to the Secretary for carrying out OCSE's mission. The Deputy Director/ Commissioner has day-to-day operational responsibility for OCSE. The Deputy Director/Commissioner assists the Director in carrying out responsibilities of the Office and provides direction and leadership to the Office of the Deputy Commissioner and the Office of Audit.

The Deputy Director/Commissioner provides leadership and direction to OCSE and is responsible for developing regulations, guidance, and standards for state/tribes to follow in locating absent parents; establishing paternity and support obligations; maintaining relationships with Department officials, other federal departments, state and tribal and local officials, and private organizations and individuals interested in the child support program; coordinating and planning child support program activities to maximize program effectiveness; program outreach, as well as access and

visitation programs and advocacy interests; and approving all instructions, policies, and publications. The Deputy Director/Commissioner is also responsible for the operations and maintenance of FPLS, management and financial analysis and strategy development, internal OCSE operations, and compliance with federal laws and policies. The Deputy Director/Commissioner is responsible for collaborating with the Office of Legislative Affairs and Budget and the Government Accountability Office on studies related to the child support program. In addition, the Deputy Director/Commissioner maintains OCSE's Continuity of Operations Plan.

*Office of Audit (KFAA):* The Office of Audit develops, plans, schedules, and conducts periodic audits of child support programs in accordance with audit standards promulgated by the Comptroller General. The office is headed by an Office Director and reports directly to the Commissioner. The Office conducts audits, at least once every 3 years (or more frequently if it is determined that a state has unreliable data or fails to meet the performance standards) to determine the reliability of state financial and statistical data reporting systems used in calculating the performance indicators used as the basis for the payment of performance-based financial incentives to the state. These audits include testing of the data produced by the system to ensure that it is valid, complete, and reliable. The audits also include a review of the state's physical security and access controls.

The Office will also conduct financial audits to determine whether federal and other funds made available to carry out the child support program are being appropriately expended, and properly and fully accounted for. These audits will also examine collections and disbursements of support payments for proper processing and accounting. In addition, the Office will also conduct other audits and examinations of program operations, as may be necessary or requested by program officials for the purpose of improving the efficiency, effectiveness, and economy of state, tribal, and local child support activities.

The Office develops consolidated reports for the Commissioner, based on findings, provides specifications for the development of audit regulations and requirements for audits of state programs, and coordinates and maintains effective liaison with the HHS Inspector General's Office and with the Government Accountability Office.

*Office of the Deputy Commissioner (KFB):* The Deputy Commissioner reports to the Deputy Director/Commissioner and assists the Commissioner in carrying out the responsibilities of OCSE. The Deputy Commissioner provides day-to-day supervision and oversight of the Division of Business and Resource Management, Division of Customer Communications, Division of Policy and Training, Division of Program Innovation, Division of Regional Operations, Division of Federal Systems, and Division of State and Tribal Systems. The Deputy Commissioner leads OCSE outreach efforts and builds collaborations with federal, state, tribal, local, and community agencies to efficiently improve child support services.

The Office of the Deputy Commissioner provides coordination for all OCSE contracts and internal IT systems.

*Division of Business and Resource Management (KFB2):* The Division of Business and Resource Management (DBRM) is responsible for the overall management and operation of OCSE administrative services. The Division is headed by a Division Director who reports directly to the Deputy Commissioner. DBRM leads all efforts related to personnel and the formulation and execution of the discretionary budgets for OCSE program funds and federal administration funds. DBRM develops, implements, and manages all personnel activities; provides guidance on all labor and employee relations; coordinates performance management, employee engagement, and recognition; provides training and technical assistance on business administrative services; manages OCSE-controlled space, facilities, assets, and messenger services; and provides for health and safety. DBRM also serves as the funding authority for all OCSE acquisitions and grant opportunities, procures all goods and services, and coordinates all travel and conference management activities.

*Division of Customer Communications (KFB3):* A Division Director leads the Division of Customer Communications (DCC) and reports to the Deputy Commissioner. The Division has two branches. The *Customer Service* branch responds to requests for information on specific child support cases from custodial and noncustodial parents, the White House, members of Congress, Office of Inspector General, state agencies, reciprocating countries, and various interest groups. The *Program Communications* branch plans, designs, and executes public outreach and communications campaigns to

convey information about the child support program and engage with child support stakeholders. The branch is responsible for providing guidance on strategies and approaches to improve public understanding of and access to OCSE programs and policies, develops and publishes informational materials on the OCSE website, and engages with our stakeholders through social media. With these information channels, DCC serves as a focal point for consistent, clear, and accurate program communication.

*Division of Policy and Training (KFB5):* The Division of Policy and Training (DPT) proposes and implements national policy for the child support program and provides policy guidance and interpretations to states and tribes in developing and operating their programs according to federal law. DPT is headed by a Division Director who directly reports to the Deputy Commissioner and is supported by the *Policy* Branch and the *Training* Branch. The *Policy* Branch develops legislative proposals and regulations to implement new legislation, court decisions, or directives from higher authority, and provides comments on pending legislative proposals. It develops new state plan preprint requirements and procedures for review and approval by the Division of Regional Operations. Additionally, the *Policy* Branch reviews the state plan submittals and prepares justifications for plan disapproval action. DPT coordinates with the Office of General Counsel on pending departmental appeals and collaborates with ACF on audit resolution. DPT also implements Central Authority activities for international support enforcement and functions as the U.S. Central Authority for international support enforcement. The *Training* Branch provides national direction and leadership for OCSE training activities to increase child support program effectiveness at federal, state, and tribal levels; coordinates child support program training activities; and provides logistical support for child support training events, meetings, and conferences.

*Division of Program Innovation (KFB7):* The Division of Program Innovation (DPI) develops, evaluates, and refines new strategies to improve child support program effectiveness, and disseminates information about promising and evidence-based practice. The Division is headed by a Division Director who reports directly to the Deputy Commissioner. DPI manages research and demonstration projects, including Section 1115 grants and waivers and Special Improvement

Project grants, and promotes program evaluation at the state and local levels. DPI also implements special projects of regional or national significance, pilots new child support approaches, and administers the Access and Visitation Grant Program.

*The Division of Regional Operations (KFB8):* The Division of Regional Operations (DRO) provides direct oversight of all child support Regional Program Unit operations, including ensuring customer-focused partnerships to child support programs and services, and implementation of child support regional operations, policies, budgets, and program compliance of all 10 regions. This includes oversight of Regional Program Units providing technical assistance and support to state and tribal child support agencies. The Division is headed by a Director, who reports directly to the Deputy Commissioner. DRO provides management and oversight of the Regions through coordinating activities between Central Office Divisions and the Regional Program Units. The Division provides information to improve public understanding of and across to OCSE programs and policies. The Division is responsible for providing oversight of all Regional representation at conferences and meetings both within the child support community and other collaborative programs and partners. The Division is also responsible for the management, receipt, review, and analysis of public inquiries and the preparation of formal (both written and electronic) responses to external inquiries for child support program information and assistance in obtaining child support services.

*Child Support Enforcement Regional Program Units (KFB8DI-X):* Each OCSE Regional Program Unit is headed by the OCSE Regional Program Manager who reports to the Director of the Division of Regional Operations. The OCSE Regional Program Manager, through regional staff and in collaboration with program stakeholders, is responsible for (1) providing program and technical administration of the ACF entitlement and discretionary programs related to OCSE; (2) collaborating with the ACF central office, states, tribes, and other external programs and grantees on all significant program and policy matters; (3) providing technical assistance and training to entities responsible for administering OCSE programs to resolve identified problems; (4) ensuring that appropriate procedures and practices are adopted; (5) working with appropriate state, tribal, and local offices to develop innovative practices to support family self-sufficiency; and

(6) monitoring the programs to ensure their efficiency and effectiveness, and ensuring that these entities conform to federal laws, regulations, policies, and procedures governing the programs.

*Division of Federal Systems (KFB9):* The Division of Federal Systems (DFS) is responsible for the design, development, deployment, maintenance, and implementation of FPLS. The Division is headed by a Division Director who directly reports to the Deputy Commissioner. FPLS is made up of a group of data sharing, collection, and program systems, such as the federal tax refund offset program, that helps OCSE support the core mission of the child support program and helps prevent improper payments in state and federal benefit programs through NDNH data matching. DFS provides states with data to help them locate parents, establish fair and equitable child support obligations, process income withholding and payments, collect and enforce past-due child support, and communicate effectively and efficiently. DFS provides outreach, technical support, and training to child support agencies, employers, insurers, financial institutions, and other private and government partners to ensure that the FPLS systems are used to their maximum benefit.

DFS is responsible for automation of data and timeliness of transactions. Other responsibilities include, but are not limited to, oversight of collaborations with the Social Security Administration (SSA) on technical aspects of their use of OCSE's data and OCSE's use of SSA data center resources; conduct analyses and feasibility assessments; develop requirements; and design, develop, and implement system enhancements to increase efficiencies and support users of FPLS information. DFS also ensures that all IT projects are managed according to OMB/HHS/ACF standards for architecture, capital planning, security, and privacy, and fall within tolerances for acceptance.

Additionally, DFS provides guidance, analysis, technical assistance, and oversight to state and tribal child support programs regarding performance measurement; statistical, policy, and program analysis; synthesis and dissemination of data sets to inform the program; and application of emerging technologies, such as business intelligence and data analytics to improve and enhance the effectiveness of programs and service. DFS is also responsible for collection, compilation, analysis, and dissemination of state and tribal data to Congress and the general

public. The Division also provides statistical and budgeting support in coordination with other divisions. DFS is responsible for promoting public access and understanding of data; managing academic/research projects; and providing support for researchers. DFS provides technical assistance to states in developing their self-assessment capabilities and implementing the annual reporting requirements contained in the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

*Division of State and Tribal Systems (KFB10):* The Division of State and Tribal Systems (DSTS) reviews, analyzes, and approves/disapproves state and tribal requests for Federal Financial Participation for automated systems development and operations activities that support the child support program. DSTS is headed by a Division Director who directly reports to the Deputy Commissioner. DSTS provides assistance to states and tribes in developing or modifying automation plans to conform to federal requirements. DSTS monitors approved state and tribal systems development activities; certifies state-wide automated systems; and conducts periodic reviews to assure state and tribal compliance with regulatory requirements applicable to automated systems supported by Federal Financial Participation. DSTS provides guidance to states and tribes on functional requirements for these automated information systems, and works with federal, state, local, and tribal health and human services agencies to foster and promote interoperability and collaboration across the automated systems that support their programs. The Division promotes interstate and tribal transfer of existing automated systems and provides assistance and guidance to improve ACF's programs through the use of automated systems and technology. It provides development support and guidance to tribes on the installation, implementation, and maintenance of the Model Tribal System.

II. Continuation of Policy. Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within ACF, heretofore issued and in effect on this date of this reorganization are continued in full force and effect.

III. Delegation of Authority. 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.

IV. Funds, Personnel, and Equipment. Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

This reorganization will be effective upon date of signature.

**Authority:** 42 U.S.C. 652

Dated: December 1, 2020.

**Megan E. Steel,**

*Office of the Executive Secretariat,  
Administration for Children and Families.*

[FR Doc. 2020-26778 Filed 12-4-20; 8:45 am]

**BILLING CODE 4184-01-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), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), 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 the priority review voucher. FDA has determined that DANYELZA (naxitamab-gqgk) manufactured by Y-mAbs Therapeutics, Inc., (Cato Research LLC., US Agent) meets the criteria for a priority review voucher.

**FOR FURTHER INFORMATION CONTACT:** Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4061, FAX: 301-796-9856, email: [althea.cuff@fda.hhs.gov](mailto:althea.cuff@fda.hhs.gov).

**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), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product

applications that meet certain criteria. FDA has determined that DANYELZA (naxitamab-gqgk) manufactured by Y-mAbs Therapeutics, Inc., (Cato Research LLC., US Agent), meets the criteria for a priority review voucher.

DANYELZA (naxitamab-gqgk) indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy.

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 DANYELZA (naxitamab) go to the "Drugs@FDA" website at <http://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: December 1, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-N-5900]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Endorser Status and Explicitness of Payment in Direct-to-Consumer Promotion

**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 January 6, 2021.

**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 Comment" or by using the search function. The title of this information collection is "Endorser Status and Explicitness of Payment in Direct-to-Consumer Promotion." Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

*For copies of the questionnaires contact:* Office of Prescription Drug Promotion (OPDP) Research Team, [DTCresearch@fda.hhs.gov](mailto:DTCresearch@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.

#### Endorser Status and Explicitness of Payment in Direct-to-Consumer Promotion

OMB Control Number 0910—NEW

#### I. Background

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

The Office of Prescription Drug Promotion's (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission. Our research focuses in particular on three main topic areas: Advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features, we assess how elements such as graphics, format, and disease and