

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* March 29, 2024. The applicant claims December 15, 2023, as the date the biologics license application (BLA) for ZIIHERA (BLA 761416) was initially submitted. However, FDA records indicate that BLA 761416 was submitted on March 29, 2024.

3. *The date the application was approved:* November 20, 2024. The applicant claims November 21, 2024, as the date the biologics license application was approved. However, FDA records indicate that BLA 761416 was approved on November 20, 2024.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,346 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) is issuing this notice to revise its Statement of Organization, Functions, and Delegations of Authority for the Office of the Secretary (OS). This reorganization removes the Office of the Chief Information Officer (OCIO) from the organizational description for the Office of the Assistant Secretary for Administration (ASA), and establishes the OCIO as a stand-alone organization that reports directly to the Secretary and Deputy Secretary. These changes supersede the OCIO-related organizational language contained in the notice published at 74 FR 57747 (November 9, 2009) (document number E9–26963) and any subsequent amendments, as well as corresponding OCIO references in the Assistant Secretary for Administration **Federal Register** notice published at 90 FR 3655 (January 10, 2025) (document number 2025–00382).

DATES: This reorganization is effective upon date of publication of this notice in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Bobby D. Flanders, Jr., Office of the Chief Information Officer, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, telephone: 202–969–3622, email: bobby.flanders@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Office of the Assistant Secretary for Administration (ASA)

Under the heading “Office of the Assistant Secretary for Administration” in the **Federal Register** notice published at 90 FR 3655 (January 10, 2025) (document number 2025–00382), all references to the “Office of the Chief Information Officer” (OCIO), including its subcomponents, functions, and delegations, are removed.

Any functions, responsibilities, or delegations previously assigned to OCIO under the ASA are reassigned to the Office of the Chief Information Officer established in Section II of this notice.

II. Office of the Chief Information Officer (OCIO)

A. Mission

The Office of the Chief Information Officer (OCIO) is established within the Office of the Secretary as an independent organization that reports directly to the Secretary and Deputy Secretary. OCIO supports the HHS mission by leading the development, modernization, and secure operation of enterprise information technology across the Department; setting strategy and governance for IT, data, cybersecurity, and artificial intelligence; and delivering shared technology capabilities that enable HHS programs to focus on their unique missions while providing better, more efficient, and more affordable services to the American people.

B. Organization

The Office of the Chief Information Officer (OCIO) is led by the Chief Information Officer (CIO). The Deputy Chief Information Officer (DCIO), the Chief Technology Officer (CTO), who leads the Office of the Chief Technology Officer (OCTO), and the Chief Artificial Intelligence Officer (CAIO), who leads the Office of the Chief Artificial Intelligence Officer (OCAIO), report directly to the CIO.

The OCIO consists of the following components:

1. Immediate Office (AO1)
2. Office of Information Security (AO2)
3. Office of Operations (AO3)
4. Office of HR IT Modernization (AO4)
5. Office of the Chief Data Officer (AO5)
6. Office of the Chief Technology Officer (AO6)
7. Office of the Chief Artificial Intelligence Officer (AO7)

The Executive Officer (XO), who leads the Immediate Office (IO); the Chief Data Officer (CDO), who leads the Office of the Chief Data Officer (OCDO); the Chief Information Security Officer (CISO) and Executive Director, Office of Information Security (OIS), who leads OIS; the Executive Director, Operations (Ops), who leads Ops; and the Executive Director, HR IT Modernization, who leads HRITMod, all report to the DCIO.

C. Functions

1. Immediate Office (AO1)

The Immediate Office (IO), led by the Executive Officer (XO), provides executive leadership, strategic planning, and overall management of OCIO. The IO leads enterprise-wide IT governance; coordinates with HHS Operating Divisions and Staff Divisions; and manages budget formulation and

execution, acquisitions strategy and oversight for department-wide IT investments (including category management, major investment governance, and vendor management), and other business operations for OCIO. The IO also provides policy development and review, communications and stakeholder engagement, audit liaison and enterprise risk management coordination, and support for Department-wide IT data calls, reporting, and related cross-cutting initiatives on behalf of the Chief Information Officer.

2. Office of Information Security (AO2)

The Office of Information Security (OIS), led by the Chief Information Security Officer (CISO) and Executive Director, OIS, serves as the central organization for HHS cybersecurity and information security risk management. OIS develops and implements department-wide information security policies and standards; oversees implementation of Federal information security and cybersecurity requirements; conducts security operations, continuous monitoring, and incident response; and provides security engineering, guidance, and oversight for HHS systems and networks. OIS also provides leadership for privacy and information management, including collaboration with privacy officials on safeguarding sensitive information; coordinates department-wide activities related to information collection under the Paperwork Reduction Act; and oversees records management policy and guidance for information and IT resources, in alignment with applicable law and HHS policy. In addition, OIS supports Health Sector cybersecurity coordination and information sharing activities to help protect critical health and public health sector infrastructure.

3. Office of Operations (AO3)

The Office of Operations (Ops), led by the Executive Director, Ops, is responsible for planning, delivering, and sustaining enterprise IT infrastructure and shared services that support HHS missions. Ops designs, builds, and operates enterprise networks, data centers, cloud and platform environments, identity and access management services, collaboration and mobility solutions, and end-user computing services; manages IT service management processes, performance, and resilience; and leads continuity of operations and disaster recovery planning for enterprise IT services. Ops also provides engineering, deployment, and lifecycle management of shared technology

platforms; supports modernization and optimization of infrastructure and hosting; and delivers integrated operational support to HHS Operating and Staff Divisions to promote reliable, secure, and cost-effective IT service delivery.

4. Office of HR IT Modernization (AO4)

The Office of HR IT Modernization (HRITMod), led by the Executive Director, HR IT Modernization, provides leadership for modernizing enterprise human resources information technology. HRITMod collaborates with HHS human resources and IT stakeholders to plan and manage HR IT transformation efforts; supports implementation, integration, and optimization of HR IT systems and services; and promotes continuous improvement of HR technology solutions that align with Departmental IT, data, and security frameworks and support workforce management and employee services.

5. Office of the Chief Data Officer (AO5)

The Office of the Chief Data Officer (OCDO), led by the Chief Data Officer, provides Department-wide leadership for data strategy and governance. OCDO develops and oversees HHS-wide data policies, standards, and governance frameworks; promotes effective, lawful, and ethical use of data to support HHS programs, public health, research, and decision-making; and advances data interoperability and data-sharing consistent with applicable privacy and security requirements. OCDO also supports enterprise data architecture, data cataloging, and metadata practices, and coordinates cross-cutting activities related to analytical, statistical, and geospatial data in collaboration with HHS Operating and Staff Divisions and other senior officials.

6. Office of the Chief Technology Officer (AO6)

The Office of the Chief Technology Officer (OCTO), led by the Chief Technology Officer, provides strategic leadership on emerging technologies and digital innovation for HHS. OCTO advises on enterprise technology direction and standards; collaborates with HHS components to identify, explore, and support innovative technology approaches and pilot initiatives; and promotes the use of modern digital, cloud, and platform capabilities to enhance HHS programs and services, in coordination with the Chief Information Officer and other senior officials.

7. Office of the Chief Artificial Intelligence Officer (AO7)

The Office of the Chief Artificial Intelligence Officer (OCAIO), led by the Chief Artificial Intelligence Officer, provides Department-wide leadership for artificial intelligence strategy and governance. OCAIO develops and coordinates policies and guidance for responsible and trustworthy use of AI; supports planning and implementation of AI capabilities that advance HHS missions; and works with HHS components and other senior officials to integrate AI considerations into enterprise information, data, and technology management frameworks, in alignment with applicable Federal requirements and Departmental priorities.

III. Delegations of Authority

All delegations of authority to the HHS Chief Information Officer and to OCIO that were previously issued under the Office of the Assistant Secretary for Administration are unaffected by this reorganization and are deemed to be delegations to the Office of the Chief Information Officer established by this notice, unless otherwise modified or revoked.

The Secretary delegates to the Chief Information Officer the authority to carry out the functions described in this notice and as otherwise assigned under applicable law and HHS policy.

Robert F. Kennedy Jr.,

Secretary, U.S. Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIDA.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Drug Abuse, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would