approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

INAPSINE (droperidol) injection, 2.5 mg/mL, is the subject of NDA 016796, held by Akorn, Inc., and initially approved on June 11, 1970. INAPSINE is indicated to reduce the incidence of nausea and vomiting associated with surgical and diagnosis procedure.

INAPSINE (droperidol) injection, 2.5 mg/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Mr. Robert van Osdel submitted a citizen petition dated January 15, 2025 (Docket No. FDA–2025–P–0253), under 21 CFR 10.30, requesting that the Agency determine whether INAPSINE (droperidol) injection, 2.5 mg/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that INAPSINE (droperidol) injection, 2.5 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that INAPSINE (droperidol) injection, 2.5 mg/mL was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of INAPSINE (droperidol) injection, 2.5 mg/mL from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list INAPSINE (droperidol) injection, 2.5 mg/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2026–06314 Filed 3–31–26; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2026–N–3004]**

### Issuance of Priority Review Voucher; Rare Pediatric Disease Product; YUVIWEL (navepegritide)

**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 the priority review voucher. FDA has determined that YUVIWEL (navepegritide), approved February 27, 2026, manufactured by Ascendis Pharma Growth Disorders (A/S), meets the criteria for a priority review voucher.

**FOR FURTHER INFORMATION CONTACT:** Quyen Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Room 5324, Silver Spring, MD 20993–0002, 301–796–2771, *Quyen.Tran1@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), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined YUVIWEL (navepegritide), manufactured by Ascendis Pharma Growth Disorders (A/S), meets the criteria for a priority review voucher. YUVIWEL (navepegritide) injection is indicated to increase linear growth in pediatric patients 2 years of age and older with achondroplasia with open epiphyses.

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 *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about YUVIWEL (navepegritide), go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2026–06316 Filed 3–31–26; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### Statement of Organization, Functions, and Delegations of Authority; Office of The National Coordinator for Health Information Technology

**AGENCY:** Office of the National Coordinator for Health Information Technology.

**ACTION:** Notice.

This reorganization by the Department of Health and Human Services (HHS) reverses the actions that created the management title of Assistant Secretary for Technology Policy, removes that title and role from HHS' leadership structure, and restores the Office of the National Coordinator for Health Information Technology (hereafter referred to as ONC) as a singularly titled office. The roles and responsibilities of the HHS Chief Technology Officer, Office of the HHS

Chief Artificial Intelligence Officer, and Office of the HHS Chief Data Officer will no longer be part of ONC.

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Chapter AR, Office of the National Coordinator for Health Information Technology (ONC), as last amended at 89 FR 60903 (July 29, 2024), 83 FR 19289 (May 2, 2018), 79 FR 31941 (June 3, 2014), 77 FR 29349–50 (May 17, 2012), 76 FR 65196 (Oct. 20, 2011), 76 FR 6795 (Feb. 8, 2011), 75 FR 49494 (Aug. 13, 2010), 74 FR 62785–86 (Dec. 1, 2009), 70 FR 48718–03 (Aug. 19, 2005) is amended.

The prior **Federal Register** Notice is amended as follows:

I. Under AR.10, Organization, delete all of components and replace with the following:

A. Immediate Office of the National Coordinator (ARA)
B. Office of Programs and Implementation (ARI)
C. Office of Standards, Certification, and Analysis (ARC)

II. Delete AR.20, Functions, in its entirety and replace with the following:

**Section AR.20, Functions**

*A. Immediate Office of the National Coordinator:* The Immediate Office (IO) is headed by the National Coordinator for Health Information Technology (henceforth referred to as the National Coordinator), who provides leadership and executive and strategic direction for the Office of the National Coordinator for Health Information Technology. The National Coordinator is responsible for carrying out ONC's mission and implementing the functions of the organization. The IO: (1) advances the interoperability of health information as central and foundational to the core mission of HHS to enhance and protect the health and well-being of all Americans; (2) ensures that health information technology (IT) initiatives for health and human services are coordinated across HHS programs, including aligning health information technology investments; (3) ensures that the health IT policy and programs of HHS are coordinated with those of relevant executive branch agencies (including Federal commissions and advisory committees) with a goal of avoiding duplication of effort and of helping to ensure that each agency undertakes activities primarily within the areas of its greatest expertise and technical capability; (4) leads the efforts to promulgate health IT regulations that advance interoperability across the entire health care sector, including across behavioral health, human services, and public health sectors; (5) leads Federal and industry efforts to advance the access, exchange, and use of health information across the healthcare sector. The Principal Deputy National Coordinator, a part of the IO, works with and reports directly to the National Coordinator and is responsible for supporting the National Coordinator in day-to-day programmatic operations and strategy for ONC, and programmatic staff management of the organization. The Principal Deputy National Coordinator is a career senior executive service position that, in conjunction with the National Coordinator, provides executive oversight for the activities of ONC offices.

The Deputy National Coordinator for Operations/Chief Operating Officer (henceforth referred to as the Chief Operating Officer) works with and reports directly to the National Coordinator. The Chief Operating Officer is a career senior executive service position. The Chief Operating Officer manages enterprise risk and formulates solutions to ensure ONC has the resources to achieve its mission and goals, ensures fiscal integrity and adherence to federal laws and regulations; and leads agency-wide strategy and services that are operational in nature.

*B. Office of Programs and Implementation:* The Office of Programs and Implementation is headed by a Deputy National Coordinator who serves as the Executive Director. The Deputy National Coordinator/Executive Director of the Office of Programs and Implementation is a career senior executive service position. This office is responsible for: (1) policy and rulemaking activities, including implementation of provisions included in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) and the 21st Century Cures Act; (2) ONC's domestic and global health IT initiatives; (3) coordination with executive branch agencies, Federal commissions, advisory committees, and external partners; (4) advanced analysis and the establishment of health IT policies for ONC and HHS to support health and human services initiatives, including in the areas of behavioral health, care transformation, health IT investment alignment, human services, information blocking, interoperability, privacy and security, and quality improvement; and (5) operational support for the Health Information Technology Advisory Committee established in the 21st Century Cures Act.

*C. Office of Standards, Certification, and Analysis:* The Office of Standards, Certification, and Analysis is headed by a Deputy National Coordinator who serves as the Executive Director. The Deputy National Coordinator/Executive Director of the Office of Standards, Certification, and Analysis is a career senior executive service position. This office is responsible for: (1) executing provisions included in the HITECH Act and the 21st Century Cures Act; (2) providing technical leadership and coordination within the health IT community to identify, evaluate, and influence the development of standards, implementation guidance, and best practices to advance nationwide interoperability for health and human services initiatives; (3) coordinating with Federal agencies and other public and private partners to implement and advance interoperability nationwide for health and human services initiatives; (4) leading the development of electronic testing tools, resources, and data to achieve interoperability, enhanced usability, and aid in the optimization of health IT; (5) administering the ONC Health IT Certification Program, including the Certified Health IT Product List; (6) and leading ONC's technical interoperability interests and investments to advance the development of innovative solutions for interoperability.

III. Delegation of Authority.

Pending further delegation, directives, or orders by the Secretary or by the National Coordinator 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.

**Robert F. Kennedy, Jr.,**

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

[FR Doc. 2026–06284 Filed 3–31–26; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Prospective Grant of an Exclusive Patent License: Pigment Epithelium-Derived Factor (PEDF) Peptides and Use for Treating Retinal Degeneration

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.