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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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under 21 CFR 10.30, requesting that the Agency determine whether INAPSINE (droperidol) injection, 2.5 mg/mL, was withdrawn from sale for reasons of safety or effectiveness.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we have at this time, FDA has determined under § 314.161 that INAPSINE (droperidol) injection, 2.5 mg/mL, was not withdrawn for reasons of safety or effectiveness.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petitioner has identified no data or other information suggesting that INAPSINE (droperidol) injection, 2.5 mg/mL was withdrawn for reasons of safety or effectiveness.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 We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.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