other stakeholders, on the following topics:

1. How are rockfish (*Sebastes* spp.) currently labeled and marketed in intrastate commerce? Please provide supporting evidence.

2. How do consumers perceive the quality, taste, texture, and value of products labeled as rockfish (*Sebastes* spp.) as compared to other species? Please provide supporting evidence.

3. What new or alternative market names for rockfish (*Sebastes* spp.), if any, would be scientifically accurate, consumer-friendly, and minimize confusion with existing product categories? Please explain.

4. There are biological and taxonomical differences between rockfish (*Sebastes* spp.) and other species, such as snapper (*Lutjanus* spp.). Is there data or any information available to support allowing rockfish to be labeled with the market name of another species? Please explain.

5. Given the food hazard differences that may exist between rockfish (*Sebastes* spp.) and other species, what food safety incidents, if any, have been associated with labeling rockfish (*Sebastes* spp.) with other market names within intrastate commerce? How could these be minimized in any changes to the acceptable market name for rockfish (*Sebastes* spp.)? Please explain.

6. Are there economic or other impacts anticipated if rockfish (*Sebastes* spp.) were labeled with the market name of another species (versus a new market name)?

7. How would changes to the acceptable market name for rockfish (*Sebastes* spp.) affect Hazard Analysis and Critical Control Point (HACCP) plans and other food safety programs? Please explain and include information on any estimated compliance costs for industry to update labeling, recordkeeping, and HACCP plans.

IV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

* 1. U.S. Food and Drug Administration. January 2026. ''The Seafood List.'' . Accessed February 27, 2026. Available at *https://hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=SeafoodList.*
* 2. U.S. Food and Drug Administration. July 2020. ''CPG Sec 540.750—Use of The Seafood List to Determine Acceptable Seafood Names.'' Accessed February 27, 2026. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-540750-use-seafood-list-determine-acceptable-seafood-names.*
* 3. Integrated Taxonomic Information System (ITIS) online database. ''Sebastes.'' Accessed February 27, 2026. Available at *https://www.itis.gov,* CC0 *https://doi.org/10.5066/F7KH0KBK.*
* 4. Integrated Taxonomic Information System (ITIS) online database. ''Lutjanidae.'' Accessed February 27, 2026. Available at *http://www.itis.gov,* CC0 *https://doi.org/10.5066/F7KH0KBK.*
* 5. U.S. Food and Drug Administration. October 1980. ''CPG Sec 540.475 Snapper—Labeling.'' Accessed February 27, 2026. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-540475-snapper-labeling.*
* 6. U.S. Food and Drug Administration. March 2024. ''FDA DNA Testing at Wholesale Level to Evaluate Proper Labeling of Seafood Species.'' Available at *https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fda-dna-testing-wholesale-level-evaluate-proper-labeling-seafood-species.*
* 7. U.S. Food and Drug Administration. March 2024. ''Seafood Species Substitution and Economic Fraud.'' Accessed March 13, 2026. Available at: *https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/seafood-species-substitution-and-economic-fraud.*
* 8. U.S. Food and Drug Administration. June 2022. ''Fish and Fishery Products Hazards and Controls.'' Available at: *https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls.*
* 9. U.S. Food and Drug Administration. August 2023. ''Guidance for Industry: The Seafood List FDA's Guide to Determine Acceptable Seafood Names.'' Accessed February 27, 2026. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-seafood-list-fdas-guide-determine-acceptable-seafood-names#principles.*
* 10. Frontiers in Immunology. April 2014. ''Fish Allergens at a Glance: Variable Allergenicity of Parvalbumins, the Major Fish Allergens.'' Accessed February 27, 2026. Available at *https://pmc.ncbi.nlm.nih.gov/articles/PMC4001008/.*
* 11. The Journal of Allergy and Clinical Immunology: In Practice. November 2018. ''Patients Allergic to Fish Tolerate Ray Based on the Low Allergenicity of Its Parvalbumin.'' Accessed February 27, 2026. Available at *https://pmc.ncbi.nlm.nih.gov/articles/PMC7060078/.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–06294 Filed 3–31–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–P–0253]

Determination That INAPSINE (Droperidol) Injection, 2.5 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that INAPSINE (droperidol) injection, 2.5 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Alexander Poonai, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–3600, *alexander.poonai@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain

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]

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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