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Contents

Federal Register

Vol. 90, No. 144

Wednesday, July 30, 2025

Census Bureau

NOTICES

2030 Census Redistricting Data Program, Commencement of Phase 1:
The Block Boundary Suggestion Project, 35843–35844
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Generic Clearance for Questionnaire Pretesting Research, 35842–35843

Centers for Medicare & Medicaid Services

NOTICES

Medicare Program:
Alternative Payment Model Incentive Payment Advisory for Clinicians—Request for Current Billing Information for Qualifying APM Participants, 35862–35863

Coast Guard

RULES

Safety Zone:
Francis Scott Key Bridge, Patapsco River, Baltimore, MD, 35836–35838

Special Local Regulation:
Seattle Seafair Unlimited Hydroplane Race, 35835

PROPOSED RULES

Security Zone:
Base San Juan, San Juan, PR, 35839–35841

Commerce Department

See Census Bureau
See Economic Analysis Bureau
See National Oceanic and Atmospheric Administration

Economic Analysis Bureau

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Direct Investment Surveys: BE–577, Quarterly Survey of U.S. Direct Investment Abroad—Transactions of U.S. Reporter with Foreign Affiliate, 35844–35845

Energy Department

See Energy Information Administration
See Federal Energy Regulatory Commission

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 35854
Hearings, Meetings, Proceedings, etc.:
Environmental Management Site-Specific Advisory Board, Nevada, 35854–35855

Energy Information Administration

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 35855–35856

Environmental Protection Agency

NOTICES

Toxic Substances Control Act:
Perchloroethylene, 35858–35859

Federal Aviation Administration

RULES

Airworthiness Directives:
Dassault Aviation Airplanes, 35827–35829
Deutsche Aircraft GmbH (Type Certificate Previously Held by 328 Support Services GmbH; AvCraft Aerospace GmbH; Fairchild Dornier GmbH; Dornier Luftfahrt GmbH) Airplanes, 35829–35831
Piaggio Aviation S.p.A. Airplanes, 35831–35835

Federal Deposit Insurance Corporation

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 35859–35861

Federal Energy Regulatory Commission

NOTICES

Application:
Pacific Gas and Electric Co., 35857–35858
Combined Filings, 35856–35857

Federal Railroad Administration

NOTICES

Petition for Waiver of Compliance, 35960

Federal Reserve System

NOTICES

Proposals to Engage in or to Acquire Companies Engaged in Permissible Nonbanking Activities, 35861–35862

Federal Retirement Thrift Investment Board

NOTICES

Performance Review Board Members, 35862

Food and Drug Administration

NOTICES

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2026, 35883–35889
Animal Generic Drug User Fee Program Rates and Payment Procedures for Fiscal Year 2026, 35889–35894
Biosimilar User Fee Rates for Fiscal Year 2026, 35872–35876
Charter Amendments, Establishments, Renewals and Terminations:
Arthritis Advisory Committee, 35876–35877
Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2026, 35910–35913
Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2026, 35906–35910
Food Safety Modernization Act Voluntary Qualified Importer Program User Fee Rate for Fiscal Year 2026, 35863–35866
Generic Drug User Fee Rates for Fiscal Year 2026, 35877–35883
Hearings, Meetings, Proceedings, etc.:
General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee, Dermal Fillers, 35910
Tobacco Products Scientific Advisory Committee, 35894–35895

Medical Device User Fee Rates for Fiscal Year 2026, 35895–35903

Outsourcing Facility Fee Rates for Fiscal Year 2026, 35903–35906

Prescription Drug User Fee Rates for Fiscal Year 2026, 35866–35872

Health and Human Services Department

See Centers for Medicare & Medicaid Services

See Food and Drug Administration

See Health Resources and Services Administration

Health Resources and Services Administration

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

The National Health Service Corps and Nurse Corps

Interest Capture Form, 35914–35915

The Stem Cell Therapeutic Outcomes Database, 35913–35914

Homeland Security Department

See Coast Guard

Interior Department

See Land Management Bureau

See National Park Service

See Surface Mining Reclamation and Enforcement Office

International Trade Commission

NOTICES

Investigations; Determinations, Modifications, and Rulings, etc.:

Fresh Tomatoes from Mexico, 35933

Justice Department

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Claims under the Radiation Exposure Compensation Act, 35933–35934

Hearings, Meetings, Proceedings, etc.:

Religious Liberty Commission, 35934

Labor Department

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Benefit Rights and Experience Report, 35934–35935

Land Management Bureau

NOTICES

Application:

Right-of-Way Application; Tennessee, 35915–35916

Implementing Executive Order 14153 for Special Areas

within the National Petroleum Reserve-Alaska, 35916–35917

National Highway Traffic Safety Administration

NOTICES

Petition:

Nix Coach Interiors, LLC; Temporary Exemption from Shoulder Belt Requirements for Side-Facing Seats on Motorcoaches, 35960–35963

National Oceanic and Atmospheric Administration

NOTICES

Hearings, Meetings, Proceedings, etc.:

Fisheries of the Gulf of America; Southeast Data, Assessment, and Review, 35853–35854

Taking or Importing of Marine Mammals:

Alaska Department of Transportation and Public

Facilities Prince William Sound Ferry Terminal

Improvement Projects in Cordova, Chenega, and

Tatitlek, AK, 35845–35846

Terminal 4 Expansion and Redevelopment Project at the Port of Grays Harbor, WA, 35846–35853

National Park Service

NOTICES

Inventory Completion:

Autry Museum of the American West, Los Angeles, CA, 35926–35927

Grand Rapids Public Museum, Grand Rapids, MI, 35923–35924

Heard Museum, Phoenix, AZ, 35922–35923

Kansas State Historical Society, Topeka, KS, 35918–35921, 35928

Sam Noble Oklahoma Museum of Natural History,

University of Oklahoma, Norman, OK, 35929–35930

San Bernardino County Museum, Redlands, CA, 35925–35926

The University of Tennessee, Department of

Anthropology, Knoxville, TN, 35917–35918

U.S. Army Corps of Engineers, Omaha District, Omaha, NE, and the University of North Dakota, Grand Forks, ND, 35927–35928

University of Wisconsin Oshkosh, Oshkosh, WI, 35921–35922, 35931–35932

Repatriation of Cultural Items:

Autry Museum of the American West, Los Angeles, CA, 35930–35931

University of California, Berkeley, Berkeley, CA, 35918, 35924–35925, 35928–35929

Virginia Museum of Fine Arts, Richmond, VA, 35919–35920

Nuclear Regulatory Commission

NOTICES

Licenses; Exemptions, Applications, Amendments, etc.:

Tennessee Valley Authority; Browns Ferry Nuclear Plant, Units 1, 2, and 3; Exemption, 35935–35937

Postal Regulatory Commission

NOTICES

New Postal Products, 35937–35938

Postal Service

NOTICES

Product Change:

Priority Mail Express, Priority Mail, and USPS Ground

Advantage Negotiated Service Agreements; Priority

Mail Negotiated Service Agreements, 35938

Securities and Exchange Commission

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 35949–35950

Application:

Deregistration under the Investment Company Act, 35939–35940

Self-Regulatory Organizations; Proposed Rule Changes:

Cboe EDGX Exchange, Inc., 35954

Investors Exchange LLC, 35940–35946
MIAX PEARL, LLC, 35946–35949
New York Stock Exchange LLC, 35946
New York Stock Exchange LLC; NYSE American LLC;
NYSE Arca, Inc., et al., 35950–35954

Small Business Administration**NOTICES**

Disaster Declaration:

California, 35955
Kentucky, 35954–35955, 35957–35958
Kentucky; Public Assistance Only, 35957
New Mexico, 35955–35956
North Carolina, 35956–35957
Texas, 35956
Texas; Public Assistance Only, 35957
West Virginia, 35955

Surface Mining Reclamation and Enforcement Office**NOTICES**Agency Information Collection Activities; Proposals,
Submissions, and Approvals:

Requirements for Permits and Permit Processing, 35932–
35933

Surface Transportation Board**NOTICES**

Exemption:

Control; OPSEU Pension Plan Trust Fund, Jaguar
Transport Holdings, LLC and Jaguar Rail Holdings,
LLC; Central Washington Railroad Co., LLC, 35958–
35959

Control; OPSEU Pension Plan Trust Fund, Jaguar
Transport Holdings, LLC, and Jaguar Rail Holdings,
LLC, Columbia Basin Railroad Company, LLC,
35959–35960

Transportation Department

See Federal Aviation Administration

See Federal Railroad Administration

See National Highway Traffic Safety Administration

Treasury Department**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals

Multiple Financial Crimes Enforcement Network, 35963–
35964

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:

Homeowner Assistance Fund Program Quarterly and
Annual Report Forms, 35964

Reader Aids

Consult the Reader Aids section at the end of this issue for
phone numbers, online resources, finding aids, and notice
of recently enacted public laws.

To subscribe to the Federal Register Table of Contents
electronic mailing list, go to [https://public.govdelivery.com/
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CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

14 CFR	
39 (3 documents)	35827, 35829, 35831
33 CFR	
100	35835
165	35836
Proposed Rules:	
165	35839

Rules and Regulations

Federal Register

Vol. 90, No. 144

Wednesday, July 30, 2025

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2025–0753; Project Identifier MCAI–2024–00681–T; Amendment 39–23093; AD 2025–15–06]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Dassault Aviation Model FALCON 2000EX airplanes. This AD was prompted by reports of the incorrect installation of the very high frequency omnidirectional range and localizer (VOR/LOC) antenna coupler. This AD requires implementing an operational limitation for Category (CAT) II and CAT III approaches, inspecting the VOR/LOC antenna coupler, and reinstalling the VOR/LOC antenna coupler if necessary. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 3, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of September 3, 2025.

ADDRESSES:

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2025–0753; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–

30, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu. You may find this material on the EASA website at ad.easa.europa.eu.

- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2025–0753.

FOR FURTHER INFORMATION CONTACT:

Jonathan Duong, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7362; email: 9-AVS-AIR-BACO-COS@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Dassault Aviation Model FALCON 2000EX airplanes. The NPRM was published in the **Federal Register** on May 15, 2025 (90 FR 20569). The NPRM was prompted by AD 2024–0219, dated November 18, 2024 (EASA AD 2024–0219) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI states that incorrect installations of the VOR/LOC antenna have been reported. This unsafe condition, if not addressed, could result in oscillations of the lateral deviation indication on both localizer (LOC) number 1 and LOC number 2 during an instrument landing system (ILS) approach, and in possible inaccurate or erroneous VOR indication and associated flight management system VOR/distance measuring equipment (DME) position updates.

In the NPRM, the FAA proposed to require implementing an operational limitation for CAT II and CAT III approaches, inspecting the VOR/LOC antenna coupler, and reinstalling the VOR/LOC antenna coupler if necessary, as specified in EASA AD 2024–0219. The FAA is issuing this AD to address

lateral deviation LOC indications and inaccurate or erroneous VOR indication, which could lead to an airplane departing from its scheduled flight path and possible impact with terrain or obstacle.

You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2025–0753.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2024–0219 which specifies procedures for implementing an operational limitation prohibiting CAT II and CAT III approaches, inspecting/checking the installation of the VOR/LOC antenna coupler, and removing and reinstalling any incorrectly installed VOR/LOC antenna coupler. For airplanes with an operational approval to conduct CAT II or CAT III approaches, EASA AD 2024–0219 also specifies that the inspection and applicable corrective actions eliminate the need for the operational limitation. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates this AD affects 279 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
2 work-hours × \$85 per hour = \$170	\$0	\$170	\$47,430

The FAA estimates the following costs to do any necessary on-condition action that would be required based on

the results of any required actions. The FAA has no way of determining the

number of aircraft that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
1 work-hour × \$85 per hour = \$85	\$0	\$85

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency’s authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a “significant regulatory action” under Executive Order 12866,

- (2) Will not affect intrastate aviation in Alaska, and
- (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2025–15–06 **Dassault Aviation:**
Amendment 39–23093; Docket No. FAA–2025–0753; Project Identifier MCAI–2024–00681–T.

(a) Effective Date

This airworthiness directive (AD) is effective September 3, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Dassault Aviation Model FALCON 2000EX airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2024–0219, dated November 18, 2024 (EASA AD 2024–0219).

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Unsafe Condition

This AD was prompted by reports of the incorrect installation of the very high frequency omnidirectional range and localizer (VOR/LOC) antenna coupler. The FAA is issuing this AD to address the incorrect installation of the VOR/LOC antenna coupler. The unsafe condition, if not addressed, could result in oscillations of the lateral deviation indication on both LOC number 1 and LOC number 2 during an instrument landing system (ILS) approach, and possible inaccurate or erroneous VOR indication and associated flight management system VOR/distance measuring equipment (DME) position updates. The unsafe condition, if not addressed, could lead to an airplane departing from its scheduled flight path and possible impact with terrain or obstacle.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA 2024–0219.

(h) Exceptions to EASA AD 2024–0219

(1) Where EASA AD 2024–0219 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph (1) of EASA AD 2024–0219 specifies that “[a]mending the applicable AFM [airplane flight manual] by inserting a copy of this AD and, thereafter, operating the aeroplane accordingly, is an acceptable method to comply with this [operational limitation] requirement”, this AD does not require operating the airplane according to that AFM revision, as that action is already required by existing FAA operating regulations (see 14 CFR 91.9, 14 CFR 91.505, and 14 CFR 121.137).

(3) This AD does not adopt the “Remarks” section of EASA AD 2024–0219.

(i) Special Flight Permit

Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the airplane to a location where the airplane can be modified, provided category II and category III operations are prohibited.

(j) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD and email to: AMOC@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Dassault Aviation’s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Additional Information

For more information about this AD, contact Jonathan Duong, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7362; email: 9-AVS-AIR-BACO-COS@faa.gov.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2024–0219, dated November 18, 2024.

(ii) Reserved.

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu. You may find this material on the EASA website at ad.easa.europa.eu.

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on

the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

Issued on July 24, 2025.

Steven W. Thompson,

Acting Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2025–14440 Filed 7–29–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–2667; Project Identifier MCAI–2024–00473–T; Amendment 39–23092; AD 2025–15–05]

RIN 2120–AA64

Airworthiness Directives; Deutsche Aircraft GmbH (Type Certificate Previously Held by 328 Support Services GmbH; AvCraft Aerospace GmbH; Fairchild Dornier GmbH; Dornier Luftfahrt GmbH) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2024–03–07, which applied to all Deutsche Aircraft GmbH Model 328–100 and 328–300 airplanes. AD 2024–03–07 required a one-time detailed inspection of each affected part, and applicable corrective actions. Since the FAA issued AD 2024–03–07, the FAA determined that repetitive inspections are necessary. This AD continues to require the actions in AD 2024–03–07 and requires repetitive inspections of the affected part. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 3, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of September 3, 2025.

ADDRESSES:

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2024–2667; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–

30, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu. You may find this material on the EASA website at ad.easa.europa.eu.

- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at regulations.gov under Docket No. FAA–2024–2667.

FOR FURTHER INFORMATION CONTACT: Joe Salameh, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3536; email joe.salameh@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2024–03–07, Amendment 39–22677 (89 FR 17723, March 12, 2024) (AD 2024–03–07). AD 2024–03–07 applied to all Deutsche Aircraft GmbH Model 328–100 and 328–300 airplanes. AD 2024–03–07 required a one-time detailed inspection of each affected part, and applicable corrective actions. The FAA issued AD 2024–03–07 to address operator reports of worn and ruptured bonding straps inside the feeder wing tanks and in both outer and inner wing tanks.

The NPRM was published in the **Federal Register** on December 23, 2024 (89 FR 104459). The NPRM was prompted by AD 2024–0154, dated August 2, 2024 (EASA AD 2024–0154) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI states that occurrences were reported of finding damaged affected parts (*i.e.*, worn and ruptured bonding straps). The extent of the detected damage of the affected parts did not ensure that appropriately low electrical impedance is obtained and maintained through the affected bonding path. This condition, if not detected and corrected, could lead to loss of bonding function and, in combination with a lightning strike, create a source of ignition in a fuel tank, possibly resulting in a fire or explosion and consequent loss of the airplane.

In the NPRM, the FAA proposed to continue to require the actions in AD

2024–03–07 and to require repetitive inspections of the affected parts, as specified in EASA AD 2024–0154. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–2667.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with this State of Design Authority, that authority

has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2024–0154, which specifies procedures for repetitive detailed inspections for damage of the bonding straps located inside the feeder wing tank (left-hand (LH) and right-hand (RH) sides), outer and inner wing tanks (LH and RH sides),

and replacement or repair of damaged affected parts. EASA AD 2024–0154 also specifies procedures for an optional modification to replace all the existing bonding straps with parts of the same cross-section and length but with nickel-plated surface protection. The optional modification still includes detailed inspections for damage of the bonding straps as required by EASA AD 2024–0154, but allows for the termination of repetitive inspections. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

Costs of Compliance

The FAA estimates that this AD affects 23 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
44 work-hours × \$85 per hour = \$3,740	\$0	\$3,740	\$86,020

ESTIMATED COSTS FOR OPTIONAL ACTIONS

Labor cost	Parts cost	Cost per product
56 work-hours × \$85 per hour = \$4,760	\$1,500	\$6,260

The FAA estimates the following costs to do any necessary on-condition action that would be required based on

the results of any required or optional actions. The FAA has no way of

determining the number of aircraft that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION REPLACEMENT

Labor cost	Parts cost	Cost per product
10 work-hours × \$85 per hour = \$850	\$117	\$967

The FAA has received no definitive data on which to base the cost estimates for the on-condition repairs specified in this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency’s authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil

aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a “significant regulatory action” under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator,

the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2024–03–07, Amendment 39–22677 (89 FR 17723, March 12, 2024); and

■ b. Adding the following new AD:

2025–15–05 Deutsche Aircraft GmbH (Type Certificate Previously Held by 328 Support Services GmbH; AvCraft Aerospace GmbH; Fairchild Dornier GmbH; Dornier Luftfahrt GmbH): Amendment 39–23092; Docket No. FAA–2024–2667; Project Identifier MCAI–2024–00473–T.

(a) Effective Date

This airworthiness directive (AD) is effective September 3, 2025.

(b) Affected ADs

This AD replaces AD 2024–03–07, Amendment 39–22677 (89 FR 17723, March 12, 2024) (AD 2024–03–07).

(c) Applicability

This AD applies to all Deutsche Aircraft GmbH (Type Certificate Previously Held by 328 Support Services GmbH; AvCraft Aerospace GmbH; Fairchild Dornier GmbH; Dornier Luftfahrt GmbH) Model 328–100 and 328–300 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Unsafe Condition

This AD was prompted by operator reports of worn and ruptured bonding straps inside the feeder wing tanks and in both outer and inner wing tanks. The FAA is issuing this AD to address damaged bonding straps. The unsafe condition, if not addressed, could result in the loss of bonding function and, in combination with a lightning strike, create a source of ignition in a fuel tank, possibly resulting in a fire or explosion and consequent loss of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2024–0154, dated August 2, 2024 (EASA AD 2024–0154).

(h) Exceptions to EASA AD 2024–0154

(1) Where EASA AD 2024–0154 refers to July 26, 2023 (the effective date of EASA AD 2023–0137), this AD requires using April 16, 2024 (the effective date of AD 2024–03–07).

(2) Where EASA AD 2024–0154 refers to its effective date, this AD requires using the effective date of this AD.

(3) This AD does not adopt the “Remarks” section of EASA AD 2024–0154.

(4) Where paragraph (3) of EASA AD 2024–0154 specifies if “any damage is detected as defined in the inspection ASB,” this AD requires replacing those words with “any worn or ruptured bonding strap is detected.”

(5) Where paragraph (4) of EASA AD 2024–0154 specifies “Modification of an aeroplane in accordance with the instructions of the modification SB,” this AD requires replacing those words with “Accomplishing a modification, including doing detailed inspections, of an airplane in accordance with the instructions of the modification SB, and doing corrective actions if any worn or ruptured bonding strap is detected as specified in paragraph (3)”.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD and email to: AMOC@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Deutsche Aircraft GmbH’s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Additional Information

For more information about this AD, contact Joe Salameh, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3536; email joe.salameh@faa.gov.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2024–0154, dated August 2, 2024.

(ii) [Reserved]

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADS@easa.europa.eu. You may find this material on the EASA website at ad.easa.europa.eu.

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

Issued on July 23, 2025.

Christopher R. Parker,

Acting Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2025–14439 Filed 7–29–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2025–0013; Project Identifier MCAI–2024–00375–A; Amendment 39–23097; AD 2025–15–10]

RIN 2120–AA64

Airworthiness Directives; Piaggio Aviation S.p.A. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2023–25–03, which applied to certain Piaggio Aviation S.p.A. (Piaggio) Model P–180 airplanes. AD 2023–25–03 required a one-time detailed inspection of the horizontal stabilizer (HS) central box for corrosion; an assessment of the corrosion level; and depending on the determination, repetitive detailed inspections of the HS central box for corrosion and the internal composite structure for surface cracks, distortion, and damage; and repair or replacement of the HS assembly. Repair or replacement of the HS assembly was terminating action for the repetitive inspections. Since the FAA issued AD 2023–25–03, it was determined that AD 2023–25–03 imposed an unintended restriction that is not in the mandatory continuing airworthiness information (MCAI). This AD retains certain actions of AD–2023–25–03 and removes the unintended restriction. The FAA is

issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 3, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of February 2, 2024 (88 FR 90085, December 29, 2023).

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2025–0013; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the MCAI, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Piaggio material identified in this AD, contact Piaggio Aviation S.p.A., P180 Customer Support, via Pionieri e Aviatori d'Italia, snc—16154 Genoa, Italy; phone: +39 331 679 74 93; email: *technicalsupport@piaggioaerospace.it*.

- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2025–0013.

FOR FURTHER INFORMATION CONTACT:

William McCully, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (404) 474–5548; email: *william.mccully@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2023–25–03, Amendment 39–22630 (88 FR 90085, December 29, 2023) (AD 2023–25–03). AD 2023–25–03 applied to certain Piaggio Model P–180 airplanes.

AD 2023–25–03 was prompted by AD 2023–0007, dated January 13, 2023 (EASA AD 2023–0007) (also referred to as the MCAI) issued by the European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union. The MCAI states that an occurrence of corrosion was found inside the HS central box of a Piaggio Model P–180 airplane during scheduled maintenance. A subsequent investigation and inspection of 16 other Piaggio Model P–

180 airplanes of various configurations and ages revealed that corrosion of differing levels of severity was found on various aluminum alloy reinforcements in the HS central box of all the inspected airplanes. The MCAI also states that this corrosion was caused by the formation of a humid environment inside the HS central box, from water ingress and/or condensation. Further investigation revealed that airplanes left in prolonged inactivity or parked outside are more prone to develop corrosion damage.

AD 2023–25–03 required a one-time detailed inspection of the HS central box for corrosion; an assessment of the corrosion level; and depending on the determination, repetitive detailed inspections of the HS central box for corrosion and the internal composite structure for surface cracks, distortion, and damage; and repair or replacement of the HS assembly. Repair or replacement of the HS assembly was terminating action for the repetitive inspections. The FAA issued AD 2023–25–03 to address corrosion on various aluminum alloy reinforcements in the HS central box caused by a humid environment inside the box from water ingress and/or condensation. Since the FAA issued AD 2023–25–03, it was determined that a portion of paragraph (g)(4)(ii) of that AD included an unintended requirement to replace or repair the HS assembly after 660 hours time-in-service (TIS) or 13 months, whichever occurs first, following a finding of level 2 corrosion.

The NPRM published in the **Federal Register** on January 30, 2025 (90 FR 8507). In the NPRM, the FAA proposed to retain certain actions of AD–2023–25–03 and remove the unintended restriction. The FAA is issuing this AD to address corrosion on the various aluminum alloy reinforcements in the HS central box caused by a humid environment inside the box from water ingress and/or condensation. The unsafe condition, if not addressed, could result in reduced structural integrity of the HS and loss of control of the airplane.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2025–0013.

Discussion of Final Airworthiness Directive

Comments

The FAA received one comment from an individual commenter. The following presents the comment received on the NPRM and the FAA's response to that comment.

Request To Allow Nondestructive Testing (NDT) Options

The commenter noted that in the NPRM the proposed cost estimate for repetitive inspections is based on traditional physical inspections, which require extensive airplane downtime. The commenter stated that allowing NDT methods, such as eddy current or ultrasonic inspections, provides a viable alternative to the traditional physical inspection methods specified in the proposed AD, that could significantly reduce the amount of labor hours while maintaining safety standards. The commenter mentioned that in the FAA's *Aviation Maintenance Technical Handbook—General* (FAA–H–8083–30B) 2023, NDT methods allow for the detection of subsurface corrosion without requiring component disassembly, so they are more efficient for routine inspections. The commenter stated that allowing NDT as an alternative compliance method would ensure continued airworthiness without imposing unnecessary financial burdens on operators. The FAA infers that the commenter requested that the proposed AD be revised to include NDT methods.

The FAA agrees with the commenter's statements about NDT methods allowing for the detection of subsurface corrosion without requiring component disassembly and that NDT would not impose unnecessary financial burdens upon operators. A borescope inspection is considered an NDT method. The costs of this AD account for borescope inspections. The FAA acknowledges that eddy current and ultrasound inspection methods are generally effective to detect subsurface damage in single or stacked layers of material because these methods can reveal damage in hidden or difficult to access areas. For this AD, a borescope inspection is considered the least invasive and has been determined to be the most effective in areas such as the HS central box. However, an operator may apply for an alternative method of compliance (AMOC) in accordance with paragraph (i) of this AD, along with substantiation data to show that eddy current and ultrasound methods would provide an acceptable level of safety.

The FAA has not changed this AD as a result of this comment.

Conclusion

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition

described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comment received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. This AD is adopted as proposed in the NPRM.

Material Incorporated by Reference Under 1 CFR Part 51

This AD requires Piaggio Aerospace Service Bulletin 80–0489, Revision 2, dated November 30, 2022, which the Director of the Federal Register approved for incorporation by reference as of February 2, 2024 (88 FR 90085, December 29, 2023).

This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Differences Between This AD and the Referenced Material

The Referenced Material requires contacting the manufacturer for a determination of the corrosion level if any corrosion is found during the initial inspection of the HS central box, and if it is determined that level 2 or 3 corrosion is present, having the manufacturer provide the threshold and intervals for doing repetitive inspections of the HS central box. This AD requires contacting either the FAA, EASA, or

Piaggio's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

Although Piaggio Aerospace Service Bulletin 80–0489, Revision 2, dated November 30, 2022, specifies to record the image of the location of corroded areas, this AD does not require that action.

Costs of Compliance

The FAA estimates that this AD affects 102 airplanes of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Initial inspection of HS central box for corrosion	6 work-hours × \$85 per hour = \$510	\$0	\$510	\$52,020

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repetitive inspections of HS central box for corrosion.	6 work-hours × \$85 per hour = \$510, per inspection cycle.	\$0	\$510, per inspection cycle.
Repetitive inspections for surface cracks, distortion, and damage.	6 work-hours × \$85 per hour = \$510, per inspection cycle.	0	\$510, per inspection cycle.
Replace HS assembly	10 work-hours × \$85 per hour = \$850	150,000	\$150,850.

The repair of the HS assembly that may be required as a result of any inspection could vary significantly from airplane to airplane. The FAA has no data to determine the costs to accomplish the repair or the number of airplanes that may require the repair.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or

develop on products identified in this rulemaking action.

Regulatory Findings

The FAA has determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Will not affect intrastate aviation in Alaska, and
- (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by:
- a. Removing Airworthiness Directive 2023–25–03, Amendment 39–22630 (88 FR 90085, December 29, 2023); and
 - b. Adding the following new airworthiness directive:

2025–15–10 Piaggio Aviation S.p.A.:
Amendment 39–23097; Docket No. FAA–2025–0013; Project Identifier MCAI–2024–00375–A.

(a) Effective Date

This airworthiness directive (AD) is effective September 3, 2025.

(b) Affected ADs

This AD replaces AD 2023–25–03, Amendment 39–22630 (88 FR 90085, December 29, 2023).

(c) Applicability

This AD applies to Piaggio Aviation S.p.A. Model P–180 airplanes, serial numbers (S/ Ns) 1002, 1004 through 1234 inclusive, 3001 through 3012 inclusive, and 3016, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 5510, Horizontal Stabilizer Structure.

(e) Unsafe Condition

This AD was prompted by a report of corrosion on the various aluminum alloy reinforcements in the horizontal stabilizer (HS) central box caused by a humid environment inside the box from water ingress and/or condensation. The FAA is issuing this AD to address this condition. The unsafe condition, if not addressed, could result in reduced structural integrity of the HS and loss of control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

(1) Within the applicable compliance time specified in table 1 to paragraph (g)(1) of this AD, do a detailed inspection of the HS central box for corrosion, in accordance with step (8), of Part A, of the Accomplishment Instructions in Piaggio Aerospace Service Bulletin 80–0489, Revision 2, dated November 30, 2022 (Piaggio SB 80–0489, Revision 2), except you are not required to record any images.

TABLE 1 TO PARAGRAPH (g)(1)—HS CENTRAL BOX ONE TIME INSPECTION

P–180 serial No.	Compliance time (hours Time-in-Service (TIS) or calendar time, whichever occurs first after February 2, 2024 (the effective date of AD 2023–25–03))
1002; and 1034 through 3016 inclusive.	Within 220 hours TIS or 13 months after February 2, 2024 (the effective date of AD 2023–25–03).
1004 through 1033 inclusive	Within 320 hours TIS or 13 months after February 2, 2024 (the effective date of AD 2023–25–03).

(2) If, during the inspection required by paragraph (g)(1) of this AD, any corrosion is detected, before next flight, contact either the Manager, International Validation Branch, FAA; European Union Aviation Safety Agency (EASA); or Piaggio’s EASA Design Organization Approval (DOA), for an assessment of the corrosion level (level 1, 2, or 3).

Note 1 to paragraph (g)(2): Appendix 1, Inspection Results Form, in Piaggio SB 80–0489, Revision 2, may be used when contacting the FAA, EASA, or Piaggio’s EASA DOA.

(3) If level 1 corrosion is found during the inspection required by paragraph (g)(1) of this AD, no further action is required by this AD.

(4) If level 2 corrosion is found during the inspection required by paragraph (g)(1) of this AD, do the action in either paragraph (g)(4)(i) or (ii) of this AD.

(i) Before further flight, replace the HS assembly or repair the HS assembly in accordance with instructions from either the Manager, International Validation Branch, FAA; EASA; or Piaggio’s EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(ii) Within 400 hours TIS or 12 months, whichever occurs first after the inspection required by paragraph (g)(1) of this AD, and thereafter at intervals not to exceed 400 hours TIS or 12 months, whichever occurs first after the most recent inspection, repeat the inspection required by paragraph (g)(1) of this AD. In addition, inspect the internal composite structure of the HS central box for surface cracks, distortion, and damage. After each repetitive inspection, before further flight, assess the inspection findings as required by paragraph (g)(2) of this AD. If it is determined that the level 2 corrosion has worsened since the last inspection; or if any surface cracks, distortion, or damage is found during any inspection; before further flight, replace the HS assembly or repair the HS assembly in accordance with instructions from either the Manager, International

Validation Branch, FAA; EASA; or Piaggio’s EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature. These inspections must be repeated at intervals not to exceed 400 hours TIS or 12 months, whichever occurs first after the most recent inspection.

(5) If level 3 corrosion is found during the inspection required by paragraph (g)(1) of this AD, do the actions required by paragraph (g)(5)(i) or (ii) of this AD.

(i) Before further flight after the inspection required by paragraph (g)(1) of this AD, replace the HS assembly or repair the HS assembly in accordance with instructions from either the Manager, International Validation Branch, FAA; EASA; or Piaggio’s EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(ii) Within 200 hours TIS or 6 months, whichever occurs first after the inspection required by paragraph (g)(1) of this AD, and thereafter at intervals not to exceed 200 hours TIS or 6 months, whichever occurs first after the most recent inspection, repeat the inspection required by paragraph (g)(1) of this AD. In addition, inspect the internal composite structure of the HS central box for surface cracks, distortion, and damage. After each repetitive inspection, before further flight, assess the inspection findings as required by paragraph (g)(2) of this AD. If it is determined that the level 3 corrosion has worsened since the last inspection; or if any surface cracks, distortion, or damage is found; before further flight, replace the HS assembly or repair the HS assembly in accordance with instructions from either the Manager, International Validation Branch, FAA; EASA; or Piaggio’s EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature. These inspections must be repeated at intervals not to exceed 200 hours TIS or 6 months, whichever occurs first after the most recent inspection, until a maximum of 660 hours TIS or 13 months, whichever occurs first after the inspection required by paragraph

(g)(1) of this AD, at which time the HS assembly must be repaired or replaced.
(6) Repair or replacement of the HS assembly is terminating action for the repetitive inspections required by paragraphs (g)(4)(ii) and (g)(5)(ii) of this AD.

(h) Credit for Previous Actions

You may take credit for the actions required by paragraphs (g)(1) through (5) of this AD if you performed those actions before February 2, 2024 (the effective date of AD 2023–25–03) using Piaggio Aerospace Service Bulletin 80–0489, Revision 1, dated May 13, 2022.

(i) Alternative Methods of Compliance (AMOCs)

The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (j) of this AD or email to: AMOC@faa.gov. If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Additional Information

For more information about this AD, contact William McCully, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (404) 474–5548; email: william.mccully@faa.gov.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following material was approved for IBR on February 2, 2024 (88 FR 90085, December 29, 2023).

(i) Piaggio Aerospace Service Bulletin 80–0489, Revision 2, dated November 30, 2022.

(ii) [Reserved]

(4) For Piaggio material identified in this AD, contact Piaggio Aviation S.p.A., P180 Customer Support, via Pionieri e Aviatori d'Italia, snc—16154 Genoa, Italy; phone: +39 331 679 74 93; email: technicalsupport@piaggioaerospace.it.

(5) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

(6) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

Issued on July 25, 2025.

Steven W. Thompson,

Acting Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2025–14390 Filed 7–29–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2025–0659]

Special Local Regulation, Seattle Seafair Unlimited Hydroplane Race

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulations for the Seattle Seafair Unlimited Hydroplane Race from 8 a.m. until 5 p.m., each day from July 31, 2025, through August 3, 2025, to provide for the safety of life on navigable waterways during this event. The regulation for this event identifies the regulated area on Lake Washington, Seattle, Washington. During the enforcement periods, vessels and persons in the regulated area must comply with the lawful directions from the Coast Guard designated Patrol Commander, the established Coast Guard patrol, and any federal, state, and

local law enforcement agencies assisting the Patrol Commander.

DATES: The regulations in 33 CFR 100.1301 will be enforced from 8 a.m. until 5 p.m., each day, from July 31, 2025, through August 3, 2025.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant Anthony Pinto, U.S. Coast Guard, Sector Puget Sound, Waterways Management Division; by telephone 206–217–6051, or email SectorPugetSoundWWM@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation in 33 CFR 100.1301 for the Seattle Seafair Unlimited Hydroplane Race from 8 a.m. until 5 p.m., each day, on July 31, 2025 through August 3, 2025. This action is being taken to provide for the safety of life on navigable waterways during this event. The regulation for this event, 33 CFR 100.1301(b), specifies the location of the regulated area for the Seattle Seafair Unlimited Hydroplane Race which encompasses portions of Lake Washington, Seattle, Washington. The regulated area is divided into two zones. The zones are separated by a line perpendicular from the I–90 Bridge to the northwest corner of the East log boom and a line extending from the southeast corner of the East log boom to the southeast corner of the hydroplane race-course and then to the northerly tip of Ohlers Island in Andrews Bay. The western zone is designated Zone I, the eastern zone, Zone II. The Coast Guard will maintain a patrol consisting of Coast Guard vessels, assisted by Auxiliary Coast Guard vessels in Zone II. The Coast Guard patrol of this area is under the direction of the Coast Guard Patrol Commander (Patrol Commander). The Patrol Commander is empowered to control the movement of vessels on the race-course and in the adjoining waters during the periods this regulation is in effect. The Patrol Commander may be assisted by other federal, state, and local law enforcement agencies.

Only authorized vessels may be allowed to enter Zone I during the hours this regulation is in effect. Vessels in the vicinity of Zone I shall maneuver and anchor as directed by Coast Guard Officers or Petty Officers.

During the times in which the regulation is in effect, swimming, wading, or otherwise entering the water in Zone I by any person is prohibited while hydroplane boats are on the race-

course. At other times in Zone I, any person entering the water from the shoreline shall remain west of the swim line, denoted by buoys, and any person entering the water from the log boom shall remain within ten (10) feet of the log boom.

During the times in which the regulation is in effect, any person swimming or otherwise entering the water in Zone II shall remain within ten (10) feet of a vessel.

During the times this regulation is in effect, rafting to a log boom will be limited to groups of three (3) vessels.

During the times this regulation is in effect, up to six (6) vessels may raft together in Zone II if none of the vessels are secured to a log boom.

During the times this regulation is in effect, only vessels authorized by the Patrol Commander, other law enforcement agencies, or event sponsors shall be permitted to tow other watercraft of inflatable devices.

Vessels proceeding in either Zone I or Zone II during the hours this regulation is in effect shall do so only at speeds which will create minimum wake, seven (7) miles per hour or less. This maximum speed may be reduced at the discretion of the Patrol Commander.

Upon completion of the daily racing activities, all vessels leaving either Zone I or Zone II shall proceed at speeds of seven (7) miles per hour or less. The maximum speed may be reduced at the discretion of the Patrol Commander.

A succession of sharp, short signals by whistle or horn from vessels controlling the areas under the direction of the Patrol Commander shall serve as signal to stop. Vessels signaled shall stop and shall comply with lawful orders of the patrol vessel; failure to do so may result in expulsion from the area, citation for failure to comply, or both.

The Coast Guard may be assisted by other federal, state, and local law enforcement agencies, as well as official Seafair event craft.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via marine information broadcasts, and Local Notice to Mariners.

Dated: July 23, 2025.

Mark A. McDonnell,

Captain, U.S. Coast Guard, Captain of the Port, Sector Puget Sound.

[FR Doc. 2025–14396 Filed 7–29–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165****[Docket Number USCG–2025–0680]****RIN 1625–AA00****Safety Zone; Francis Scott Key Bridge, Patapsco River, Baltimore, MD****AGENCY:** Coast Guard, DHS.**ACTION:** Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone for certain waters of the Patapsco River, in Baltimore, MD. This action is necessary to provide for the safety of life on these navigable waters at the Francis Scott Key Bridge during demolition and construction operations. This rulemaking prohibits persons and vessels from being in the safety zone unless authorized by the Captain of the Port, Maryland-National Capital Region or a designated representative.

DATES: This rule is effective from August 15, 2025, through October 15, 2025.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2025–0680 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LCDR Kate M. Newkirk, Sector Maryland-NCR, Waterways Management Division, U.S. Coast Guard; telephone 410–576–2674, email D05-DG-SectorMD-NCR-Prevention-WWM@uscg.mil.

SUPPLEMENTARY INFORMATION:**I. Table of Abbreviations**

CFR Code of Federal Regulations
COTP Captain of the Port, Sector Maryland-National Capital Region
DHS Department of Homeland Security
FR Federal Register
MDTA Maryland Transportation Authority
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Maryland Transportation Authority (MDTA) has notified the Coast Guard that it will be conducting demolition and construction activities on the Patapsco River at the site of the Francis Scott Key Bridge, which was hit

by a container ship on March 26, 2024, see 89 FR 24385 (April 8, 2024). Debris removal and hydrographic surveying will be conducted on the Sollers Point side of the remaining bridge segments. Marine equipment, including barges, positioned in the Patapsco River will be used to support bridge demolition and debris removal operations. This operation requires the use of a temporary commercial mooring buoy on the Patapsco River, in the vicinity of the old bridge. This operation will not prevent vessels from using the federal navigation channel.

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable to publish an NPRM without delaying promulgation of the final rule establishing this safety zone past August 15, 2025, when demolition operations will begin.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because the rule must be in effect by August 15, 2025 to respond to the potential safety hazards associated with demolition operations at the old Francis Scott Key (US–695) Bridge.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port, Sector Maryland-National Capital Region (COTP) has determined that potential hazards associated with bridge demolition, which are scheduled to start August 15, 2025, will be a safety concern for anyone near the old Francis Scott Key Bridge (US–695) demolition site. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the bridge is being demolished.

IV. Discussion of the Rule

The COTP is establishing a safety zone from 12:01 a.m. on August 15, 2025, to 11:59 p.m. on October 15, 2025.

The safety zone will cover the following area: all navigable waters of the Patapsco River, encompassed by a line connecting the following points beginning at 39°13.40 N, 076°31.28' W, thence east to 39°13.317' N, 076°31.167' W, thence southwest to 39°13.067' N, 076°31.55' W, thence northwest to 39°13.133' N, 076°31.65' W, and thence northeast to the beginning point, located in the vicinity of Sollers Point.

The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled demolition and debris removal. Except for marine equipment and vessels operated by MDTA or its subcontractors, no vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The term designated representative includes an MDTA supervisor or contractor on site for the sole purposes of designating and establishing safe transit corridors, to permit passage into or through the safety zone, or to notify vessels and individuals that they have entered the safety zone and are required to leave.

In accordance with 33 CFR 165.7(a), the COTP will notify the public by all appropriate means that the safety zone will be enforced. Such means of notification will also include, but are not limited to, Broadcast Notice to Mariners. Vessels or persons violating this rule are subject to the penalties set forth in 46 U.S.C. 70036 and 46 U.S.C. 70052. The regulatory text appears at the end of this document.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB). The Coast Guard has determined that this rule is nonsignificant under Executive Order 12866.

This regulatory action determination is based on the size, location and time of year of the safety zone. The temporary safety zone is approximately

1000 feet in width and 2000 feet in length. This safety zone would impact a small, designated area of the Patapsco River for a total of 62 days, but we do not anticipate there will be any vessels that will be unable to conduct business as a result of the safety zone. Excursion vessels and commercial fishing vessels are not impacted by this rulemaking. Excursion vessels do not operate in this area, and commercial fishing vessels are not impacted because the waters in this area are too shallow to accommodate them. Some towing vessels may be impacted, but bridge project personnel have been conducting outreach throughout the project to coordinate with those vessels. Moreover, the Coast Guard would issue Local Notices to Mariners and a Broadcast Notice to Mariners via VHF-FM marine channel 16 about the zone.

B. Impact on Small Entities

The regulatory flexibility analysis provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to rules not subject to notice and comment. As the Coast Guard has, for good cause, waived the notice and comment requirement that would otherwise apply to this rulemaking, the Regulatory Flexibility Act's flexibility analysis provisions do not apply here.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule affects your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the

Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a safety zone lasting 62 total days that would prohibit entry within a portion of the Potomac River. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this

determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.4.

■ 2. Add § 165.T05–0680 to read as follows:

§ 165.T05–0680 Safety Zone; Patapsco River, Francis Scott Key Bridge

(a) *Location.* The following area is a safety zone: The safety zone will cover the following area: all navigable waters of the Patapsco River, encompassed by a line connecting the following points beginning at 39°13.40' N, 076°31.28' W, thence east to 39°13.317' N, 076°31.167' W, thence southwest to 39°13.067' N, 076°31.55' W, thence northwest to 39°13.133' N, 076°31.65' W, and thence northeast to the beginning point, located in the vicinity of Sollers Point. These coordinates are based on datum NAD 83.

(b) *Definitions.* As used in this section—

Captain of the Port (COTP) means the Commander, U.S. Coast Guard, Sector Maryland-National Capital Region.

Designated representative means any Coast Guard commissioned, warrant, or petty officer, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Maryland-National Capital Region (COTP) in the enforcement of the safety zone. The term also includes an employee or contractor of the Maryland Transportation Authority (MDTA) for the sole purposes of designating and establishing safe transit corridors, to permit passage into or through the safety zone, or to notify vessels and individuals that they have entered the safety zone and are required to leave.

Marine equipment means any vessel, barge or other equipment operated by MDTA, or its subcontractors.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, except for marine equipment, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP, MDTA, or the COTP's designated representative. If a vessel or person is notified by the COTP, MDTA, or the COTP's designated representative that they have entered the safety zone without permission, they are required to immediately leave in a safe manner following the directions given.

(2) Mariners requesting to transit any of these safety zone areas must first

contact the MDTA designated representative, the on-site project manager, via Marine Band Radio VHF-FM channels 16. If permission is granted, mariners proceed at their own risk and must strictly observe any and all instructions provided by the COTP, MDTA, or designated representative to the mariner regarding the conditions of entry to and exit from any area of the safety zone. The COTP or the COTP's representative can be contacted by telephone number 410-576-2693 or on Marine Band Radio VHF-FM channel 16 (156.8 MHz).

(3) The Coast Guard will publish a notice in the Fifth Coast Guard District Local Notice to Mariners and issue marine information broadcasts on VHF-

FM marine band radio announcing specific enforcement dates and times.

(d) *Enforcement officials.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by Federal, State, and local agencies.

(e) *Enforcement period.* This section will be enforced from 12:01 a.m. on August 15, 2025, to 11:59 p.m. on October 15, 2025.

Dated: July 23, 2025.

Patrick C. Burkett,

Captain, U.S. Coast Guard, Captain of the Port, Sector Maryland-National Capital Region.

[FR Doc. 2025-14395 Filed 7-29-25; 8:45 am]

BILLING CODE 9110-04-P

Proposed Rules

Federal Register

Vol. 90, No. 144

Wednesday, July 30, 2025

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2025–0366]

RIN 1625–AA87

Security Zone; Base San Juan, San Juan, PR

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to revise the Base San Juan security zone in San Juan Puerto Rico. This action is needed for national security reasons to protect the public and the Coast Guard base from potential subversive acts. This proposed rulemaking would prohibit persons and vessels from being in the security zone extending 120 yards seaward from the water's edge of the Coast Guard Base San Juan unless authorized by the Captain of the Port Sector San Juan or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before August 29, 2025.

ADDRESSES: You may submit comments identified by docket number USCG–2025–0366 using the Federal Decision-Making Portal at <https://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the

SUPPLEMENTARY INFORMATION section for further instructions on submitting comments. This notice of proposed rulemaking with its plain-language, 100-word-or-less proposed rule summary will be available in this same docket.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Lieutenant Commander Carlos M. Ortega-Perez, Waterways Management Division Chief, U.S. Coast Guard; telephone 206–815–

4377, email Carlos.M.Ortega-Perez@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

The Coast Guard docking facilities at Base San Juan in La Puntilla Old San Juan, Puerto Rico are home to several Coast Guard cutters and Coast Guard small boats. In the past, incidents of unknown vessels mooring up to the Coast Guard piers have occurred. In addition, suspected surveillance in the form of photography has been performed by unknown individuals located in close proximity to the Coast Guard base on more than one occasion. These incidents pose a potential threat to national security and may lead to subversive acts against the personnel or equipment located at the Coast Guard base. The Captain of the Port (COTP) Sector San Juan has determined that potential threats associated with the access to Base San Juan of unknown individuals would be a safety concern for anyone within a 120-yard seaward from the water's edge of the Coast Guard Base San Juan.

The proposed rule would make changes to the existing security zone for Coast Guard Base San Juan described in 33 CFR 165.776, by revising the latitudes and longitudes of the current security zone to address the threat to national security by prohibiting all persons and vessels from entering in, transiting through or remaining in a security zone extending 120 yards seaward from the water's edge of the Coast Guard Base San Juan. The Coast Guard may issue security zone regulations under authority in 46 U.S.C. 70051 and 70124.

III. Discussion of Proposed Rule

The COTP Sector San Juan is proposing to amend the current security zone in § 165.776 to correct the latitudes and longitudes that depicts the Coast Guard Base San Juan by extending the zone by 120 yards seaward from the water's edge of the base. No vessel or person would be permitted to enter the

security zone without obtaining permission from the COTP Sector San Juan or a designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This NPRM has not been designated a “significant regulatory action” under section 3(f) of Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on potential threats to national security that may lead to subversive acts against the personnel or equipment located at the Coast Guard base. This rule is not a significant regulatory action because the security zone only extends 120 yards from Base San Juan and does not impede any regular vessel traffic (*i.e.*, cruise ships, ferries, small passenger vessels, etc.). Vessels will be able to transit safely around the zone. If a vessel or person must temporarily transit through the proposed security zone, permission may be requested from the COTP Sector San Juan or a designated representative.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the security

zone may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132 (Federalism), if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the potential effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves an amendment of the current security zone that would prohibit entry within 120 yards seaward from the water's edge of the Coast Guard Base San Juan, reducing the actual security zone to reflects the zone as it appears in the NOAA nautical charts. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision-Making Portal at <https://www.regulations.gov>. To do so, go to <https://www.regulations.gov>, type USCG–2025–0366 in the search box and click “Search.” Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using <https://www.regulations.gov>, call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select “Supporting & Related Material” in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the <https://www.regulations.gov> Frequently Asked Questions web page. Also, if you click on the Dockets tab and then the proposed rule, you should see a “Subscribe” option for email alerts. The option will notify you when comments are posted, or a final rule is published.

We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS’s eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

- 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.4.

- 2. Revise § 165.776 to read as follows:

**§ 165.776 Security Zone; Security Zone;
Base San Juan, San Juan, PR.**

(a) *Location.* The following area is a security zone: All waters from surface to bottom, encompassed by an imaginary line connecting the following points, beginning at Point 1 at 18°27'39" N, 066°06'56" W; then east to Point 2 at 18°27'39" N, 066°06'52" W; then south to Point 3 at 18°27'33" N, 066°06'52" W; then southwest to Point 4 at 18°27'29" N, 066°06'57" W; then west to Point 5 at 18°27'29" N, 066°07'00" W; then northwest to Point 6 at 18°27'37" N, 066°07'10" W; then north to Point 7 at 18°27'46" N, 066°07'11" W; then east back to shore at the northwest end of the CG facility at Point 8 at 18°27'46" N, 066°07'07" W. These coordinates are

based upon North American Datum 1983.

(b) *Definitions.* As used in this section, designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port (COTP) Sector San Juan in the enforcement of the security zone.

(c) *Regulations.* (1) Under the general security zone regulations in subpart D of this part, you may not enter the security zone described in paragraph (a) of this section unless authorized by the COTP Sector San Juan or a designated representative.

(2) To seek permission to enter, contact the COTP Sector San Juan or a

designated representative by telephone at (787) 289–2041, or via VHF–FM radio on channel 16 to request authorization. If authorization is granted, all persons and vessels receiving such authorization must comply with the instructions of the COTP Sector San Juan or a designated representative. Those in the security zone must comply with all lawful orders or directions given to them by the COTP Sector Juan or the designated representative.

Dated: May 20, 2025.

Luis J. Rodríguez,

Captain, U.S. Coast Guard, Captain of the Port Sector San Juan.

[FR Doc. 2025–14394 Filed 7–29–25; 8:45 am]

BILLING CODE 9110–04–P

Notices

Federal Register

Vol. 90, No. 144

Wednesday, July 30, 2025

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Generic Clearance for Questionnaire Pretesting Research

AGENCY: Census Bureau, Department of Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act (PRA) of 1995, invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment on the proposed extension of the Generic Clearance for Questionnaire Pretesting Research, prior to the submission of the information collection request (ICR) to OMB for approval.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before September 29, 2025.

ADDRESSES: Interested persons are invited to submit written comments by email to adrm.pra@census.gov and PRAComments@doc.gov. Please reference "Generic Clearance for Questionnaire Pretesting Research" in the subject line of your comments. You may also submit comments, identified by Docket Number USBC-2025-0008, to the Federal e-Rulemaking Portal: <http://www.regulations.gov>. All comments received are part of the public record. No comments will be posted to <http://www.regulations.gov> for public viewing until after the comment period has closed. Comments will generally be

posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or specific questions related to collection activities should be directed to Jessica Holzberg, Senior Methodologist, Center for Behavioral Science Methods, 301-763-2298, and jessica.holzberg@census.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau plans to request an extension of the current OMB approval to conduct a variety of small-scale questionnaire pretesting activities under this generic clearance. A block of hours will be dedicated to these activities for each of the next three years. OMB will be informed in writing of the purpose and scope of each of these activities, as well as the time frame and the number of burden hours used. The number of hours used will not exceed the number set aside for this purpose.

This research program will be used by the Census Bureau and survey sponsors to improve questionnaires and procedures, reduce respondent burden, and ultimately increase the quality of data collected in the Census Bureau censuses and surveys. The clearance will be used to conduct pretesting of decennial, demographic, and economic census and survey questionnaires prior to fielding them. Pretesting activities will involve one of the following methods for identifying measurement problems with the questionnaire or survey procedure: cognitive interviews, focus groups, respondent debriefing, behavior coding of respondent/interviewer interaction, and split panel tests.

II. Method of Collection

Any of the following methods may be used: mail, telephone, face-to-face; paper-and-pencil, CATI, CAPI, internet, mobile device, or IVR.

III. Data

OMB Control Number: 0607-0725.

Form Number(s): Various.

Type of Review: Regular submission, Request for an Extension, without change of a currently approved collection.

Affected Public: Individuals or households; Business or other for-profit organizations; Farms.

Estimated Number of Respondents: 5,500 per year.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden

Hours: 5,500 hours annually.

Estimated Total Annual Cost to Public: \$0. There is no cost to the respondent other than time to answer the information request.

Respondent's Obligation: Voluntary.

Legal Authority: Data collection for this project is authorized under the authorizing legislation for the questionnaire being tested. This may be Title 13, Sections 131, 141, 161, 181, 182, 193, and 301 for Census Bureau-sponsored surveys, and Title 13, Section 8 for surveys sponsored by other Federal agencies. We do not now know what other titles will be referenced, since we do not know what survey questionnaires will be pretested during the course of the clearance.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that

your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Departmental PRA Compliance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2025–14433 Filed 7–29–25; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Census Bureau

[Docket No. 250725–0129; RTID 0607–XC083]

2030 Census Redistricting Data Program, Commencement of Phase 1: The Block Boundary Suggestion Project

AGENCY: Census Bureau, Department of Commerce.

ACTION: Notice of program.

SUMMARY: This notice announces the commencement of Phase 1 of the 2030 Census Redistricting Data Program: The Block Boundary Suggestion Project. Phase 1 specifically provides states the opportunity to supply the Census Bureau with their suggestions for the 2030 Census tabulation block inventory. Suggestions are made by designating the desirability of linear features for use as 2030 Census tabulation block boundaries. In addition, states have the opportunity to submit to the Census Bureau suggested legal boundary updates. These actions allow states to construct some of the small area geography they need for legislative redistricting. State participation in Phase 1 of the 2030 Census Redistricting Data Program is voluntary.

DATES: Comments on this notice must be received by August 29, 2025.

ADDRESSES: Comments may be submitted by either of the following methods:

Electronic submission: Submit electronic public comments via the Federal eRulemaking Portal.

1. Go to www.regulations.gov and enter Docket Number USBC–2025–0006 in the search field.

2. Click the “Comment Now!” icon and complete the required fields.

3. Enter or attach your comments.

By email: Comments in electronic form may also be sent to rdo@census.gov.

All comments responding to this document will be a matter of public record. Relevant comments will generally be available on the Federal eRulemaking Portal at: <https://www.Regulations.gov>.

The Census Bureau will not accept comments accompanied by a request that part or all the material be treated confidentially for any reason. Therefore, do not submit confidential business information or otherwise sensitive, protected, or personal information, such as account numbers, Social Security numbers, or names of other individuals.

FOR FURTHER INFORMATION CONTACT:

James Whitehorne, Chief of the Census Redistricting and Voting Rights Data Office, U.S. Census Bureau, ADDC/RVDO, Washington, DC 20233, telephone (301) 763–4039.

SUPPLEMENTARY INFORMATION: Under the provisions of Public Law 94–171 (13 U.S.C. 141(c)), the Director of the Census Bureau is required to provide the “officers or public bodies with initial responsibility for legislative apportionment or districting of each state . . .” with the opportunity to specify small geographic areas (e.g., tabulation blocks, voting districts) for which they wish to receive decennial census population totals for the purpose of reapportionment and redistricting.

By April 1 of the year following the census, the Secretary of Commerce is required to furnish the state officials or their designees with population counts for standard geographies such as counties, cities, census blocks, and for state-specified congressional districts, legislative districts, and voting districts.

In accordance with the provisions of 13 U.S.C. 141(c), and on behalf of the Secretary of Commerce, the Director of the Census Bureau announces the commencement of Phase 1 of the 2030 Census Redistricting Data Program. The purpose of this notice is to provide further information on the commencement of Phase 1 of the 2030 Census Redistricting Data Program: The Block Boundary Suggestion Project. Future **Federal Register** notices will address other phases of the 2030 Census Redistricting Data Program.

The 2030 Census Redistricting Data Program was initially announced on July 9, 2024 (89 FR 56287). The Census Bureau received two sets of comments regarding the 2030 Census Redistricting Data Program. One set of comments was determined to be out of scope, and the second set of comments discussed program operations, timing, and past successful activities. Within this set of comments, the first, to send the solicitation for a state non-partisan

liaison letter to the state’s legislative leadership, was implemented. The second comment, to move the timing of the program’s operations from Spring to Fall, was determined to not be feasible for the overall success of the program. This determination was made based on feedback received during the planning phase of the 2030 Census Redistricting Data Program. Finally, the third comment, to solicit statewide geography layers from the commentator’s state GIS coordinator to update Census Bureau geography, was out of scope for the 2030 Census Redistricting Data Program. This recommendation was forwarded to the relevant area of the Census Bureau for consideration.

State participation in the 2030 Census Redistricting Data Program under 13 U.S.C. 141 is voluntary. The 2030 Census Redistricting Data Program is partitioned into several phases, as it was in previous decades. Beginning in late 2025, the program will engage each state regarding their voluntary participation in Phase 1, through their newly designated 2030 Census Redistricting Data Program non-partisan liaison(s). The Census Bureau will make available data from its national geospatial database (MAF/TIGER System), the Geographic Update Partnership Software (GUPS), and the procedures necessary for each state to begin work on Phase 1. States are not required to use the GUPS; however, they are required to provide their Phase 1 submission to the Census Bureau electronically in Census Bureau specified formats. During the submission period, the Census Bureau will provide training in the use of the GUPS and assist the states in understanding the procedures necessary for processing files for their submission. The states will have the opportunity to verify the inclusion of their suggested tabulation block boundary features in the Census Bureau’s MAF/TIGER System as part of Phase 1.

The Census Bureau will continue to communicate with each state to ensure that they are well informed about the benefits of working with the Census Bureau towards a successful 2030 Census. In addition, the Redistricting and Voting Rights Data Office will continue to work with each state to ensure they are prepared to participate in all phases of the 2030 Census Redistricting Data Program. Every state, regardless of their participation in Phase 1, will receive the official redistricting data in Phase 3 of the 2030 Census Redistricting Data Program as required by Public Law 94–171.

Ron Jarmin, Acting Director, Census Bureau, approved the publication of this notice in the **Federal Register**.

Dated: July 25, 2025.

Shannon Wink,

*Program Analyst, Policy Coordination Office,
U.S. Census Bureau.*

[FR Doc. 2025–14408 Filed 7–29–25; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Direct Investment Surveys: BE–577, Quarterly Survey of U.S. Direct Investment Abroad—Transactions of U.S. Reporter With Foreign Affiliate

AGENCY: Bureau of Economic Analysis, Department of Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: Written comments must be submitted on or before September 29, 2025.

ADDRESSES: Interested persons are invited to submit written comments to Amanda Budny, Chief, Direct Transactions and Positions Branch, Bureau of Economic Analysis, U.S. Department of Commerce, by email to Amanda.Budny@bea.gov and PRAComments@doc.gov. Please reference OMB Control Number 0608–0004 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Amanda Budny, Chief, Direct Transactions and Positions Branch, Bureau of Economic Analysis, U.S. Department of Commerce; via phone at (301) 278–

9154; or via email at Amanda.Budny@bea.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Quarterly Survey of U.S. Direct Investment Abroad—Transactions of U.S. Reporter with Foreign Affiliate (Form BE–577) obtains quarterly data on transactions and positions between U.S.-owned foreign business enterprises and their U.S. parents, except certain private funds. The survey is a sample survey that covers all foreign affiliates above a size-exemption level. The sample data are used to derive universe estimates in nonbenchmark years from similar data reported in the BE–10, Benchmark Survey of U.S. Direct Investment Abroad, which is conducted every five years. The data are essential for the preparation of the U.S. international transactions accounts, the national income and product accounts, the input-output accounts, and the international investment position of the United States. The data are needed to measure the size and economic significance of direct investment abroad, measure changes in such investment, and assess its impact on the U.S. and foreign economies.

The Bureau of Economic Analysis (BEA) is proposing a change to the BE–577 survey reporting requirements that will reduce respondent burden and increase the efficiency of data collection.

Description of Changes

The proposed change amends the reporting requirements for the BE–577 survey. Specifically, BEA proposes to increase the valuation threshold in the basic requirement for the survey. Currently, a BE–577 form is required for each (1) directly-owned *foreign affiliate* for which total assets; annual sales or gross operating revenue, excluding sales taxes; or annual net income after provision for *foreign* income taxes was greater than \$60 million (positive or negative) at any time during the *affiliate's* fiscal reporting year and each (2) indirectly-owned *foreign affiliate* that met the \$60 million threshold and had an intercompany receivable or payable balance with the *U.S. reporter* that exceeded \$10 million.

BEA proposes to increase the threshold for filing the BE–577 from \$60 million to \$500 million. BEA has determined that this increased threshold on the BE–577 would be sufficient to collect the information necessary to provide data users with insightful statistics measuring the economic impact of these investments. This proposed change would reduce

respondent burden and the BEA resources needed to collect and process these investments.

II. Method of Collection

Notice of specific reporting requirements, including who is to report, the information to be reported, the manner of reporting, and the time and place of filing reports, will be mailed to potential respondents each quarter. Reports are due 30 days after the close of each calendar or fiscal quarter—45 days if the report is for the final quarter of the respondent's financial reporting year. Reports are required from each U.S. person that has a direct and/or indirect ownership interest of at least 10 percent of the voting stock in an incorporated foreign business enterprise, or an equivalent interest in an unincorporated foreign business enterprise, and that meets the additional conditions detailed in Form BE–577. Certain private funds are exempt from reporting. Entities required to report will be contacted individually by BEA. Entities not contacted by BEA have no reporting responsibilities.

Potential respondents are those U.S. business enterprises that reported owning foreign business enterprises in the 2024 benchmark survey of U.S. direct investment abroad, along with entities that subsequently entered the direct investment universe. The data collected are sample data. Universe estimates are developed from the reported sample data.

BEA offers electronic filing through its eFile system (www.bea.gov/efile) for use in reporting on the BE–577 survey forms. In addition, BEA posts its survey forms and reporting instructions on its website (www.bea.gov/dia).

III. Data

OMB Control Number: 0608–0004.

Form Number: BE–577.

Type of Review: Regular submission, reinstatement without change.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Respondents: 1,500 U.S. parents filing for 12,700 foreign affiliates per quarter, 50,800 annually.

Estimated Time per Response: 1 hour is the average but may vary considerably among respondents because of differences in company structure and complexity.

Estimated Total Annual Burden Hours: 50,800.

Estimated Total Annual Cost to Public: \$0.

Respondent's Obligation: Mandatory.

Legal Authority: International Investment and Trade in Services

Survey Act (P.L. 94–472, 22 U.S.C. 3101–3108, as amended by P.L. 98–573 and P.L. 101–533).

IV. Request for Comments

We are soliciting public comments to permit the Department of Commerce/Bureau of Economic Analysis to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Departmental PRA Compliance Officer, Office of the Under Secretary of Economic Affairs, Commerce Department.

[FR Doc. 2025–14431 Filed 7–29–25; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF050]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Alaska Department of Transportation and Public Facilities Prince William Sound Ferry Terminal Improvement Projects in Cordova, Chenega, and Tatitlek, Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of incidental harassment authorizations.

SUMMARY: In accordance with regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued three incidental harassment authorizations (IHAs) to the Alaska Department of Transportation and Public Facilities (ADOT&PF) for authorization to take marine mammals incidental to the Prince William Sound Ferry Terminal Improvement Projects (PWS Projects) in Cordova, Chenega, and Tatitlek, Alaska.

DATES: These authorizations are effective for one year from the date of notification by the IHA-holders, not to exceed one year from the date of issuance (July 25, 2025).

ADDRESSES: Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: <https://www.fisheries.noaa.gov/action/incidental-take-authorization-alaska-department-transportation-and-public-facilities-prince>. In case of problems accessing these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT: Cara Hotchkin, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

MMPA Background and Determinations

The MMPA prohibits the “take” of marine mammals, with certain exceptions. Among the exceptions is section 101(a)(5)(D) of the MMPA (16 U.S.C. 1361 *et seq.*) which directs the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking by harassment of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and the public has an opportunity to comment on the proposed IHA.

Specifically, NMFS will issue an IHA if it finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other “means of effecting the least [practicable] adverse impact” on the affected species or stocks and their habitat, paying particular attention to

rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to here as “mitigation”). NMFS must also prescribe requirements pertaining to the monitoring and reporting of such takings. The definitions of key terms, such as “take,” “harassment,” and “negligible impact,” can be found in the MMPA and the NMFS’ implementing regulations (see 16 U.S.C. 1362; 50 CFR 216.103).

On June 4, 2025, a notice of NMFS’ proposal to issue three IHAs to ADOT&PF for take of marine mammals incidental to the Prince William Sound Ferry Terminal Improvement Projects (PWS Projects) in Cordova, Chenega, and Tatitlek, Alaska was published in the **Federal Register** (90 FR 23814, June 4, 2025). In that notice, NMFS indicated the estimated numbers, type, and methods of incidental take proposed for each species or stock, as well as the mitigation, monitoring, and reporting measures that would be required should the IHAs be issued. The **Federal Register** notice also included analysis to support NMFS’ preliminary conclusions and determinations that the IHAs, if issued, would satisfy the requirements of section 101(a)(5)(D) of the MMPA for issuance of the IHAs. The **Federal Register** notice included web links to draft IHAs for review, as well as other supporting documents.

No substantive comments were received during the public comment period. There are no changes to the specified activity, the species taken, the proposed numbers, type, or methods of take, or the mitigation, monitoring, or reporting measures in the proposed IHAs notice. No new information that would change any of the preliminary analyses, conclusions, or determinations in the proposed IHAs notice has become available since that notice was published, and therefore, the preliminary analyses, conclusions, and determinations included in the proposed IHAs notice are considered final.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.*, the issuance of three IHAs) with respect to potential impacts on the human environment.

These actions are consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NAO 216–

6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of the proposed IHAs qualifies to be categorically excluded from further NEPA review.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*) requires that each Federal agency ensures that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

NMFS is authorizing take of the Western DPS of Steller sea lions, and of the Mexico DPS of humpback whales, which are listed under the ESA. NMFS Office of Protected Resources has completed a section 7 consultation with the Alaska Regional Office for the issuance of these IHAs. The Alaska Regional Office's biological opinion states that the actions are not likely to jeopardize the continued existence of the listed species.

Authorization

Accordingly, consistent with the requirements of section 101(a)(5)(D) of the MMPA, NMFS has issued three IHAs to ADOT&PF for authorization to take marine mammals incidental to the Prince William Sound Ferry Terminal Improvement Projects (PWS Projects) in Cordova, Chenega, and Tatitlek, Alaska.

Dated: July 25, 2025.

Kimberly Damon-Randall,

*Director, Office of Protected Resources,
National Marine Fisheries Service.*

[FR Doc. 2025-14363 Filed 7-29-25; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XF054]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Terminal 4 Expansion and Redevelopment Project at the Port of Grays Harbor, Washington

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of renewal incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA), as amended, notification is hereby given that NMFS has issued a renewal incidental harassment authorization (IHA) to the Port of Grays Harbor to incidentally harass marine mammals incidental to the Terminal 4 Expansion and Redevelopment Project at the Port of Grays Harbor, Washington.

DATES: This renewal IHA is valid from July 18, 2025 through July 15, 2026.

ADDRESSES: Electronic copies of the original application, renewal request, and supporting documents (including NMFS **Federal Register** notices of the original proposed and final authorizations, and the previous IHA), as well as a list of the references cited in this document, may be obtained online at: <https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act>. In case of problems accessing these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT: Robert Pauline, Office of Protected Resources, NMFS, (301) 427-8401.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the "take" of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are promulgated or, if the taking is limited to harassment, an incidental harassment authorization is issued.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other "means of effecting the least practicable adverse impact" on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to here as "mitigation measures"). NMFS must also prescribe requirements pertaining to monitoring and reporting of such takings. The definition of key terms such as "take," "harassment," and "negligible impact" can be found in the MMPA and NMFS's implementing regulations (see 16 U.S.C. 1362; 50 CFR 216.103).

NMFS' regulations implementing the MMPA at 50 CFR 216.107(e) indicate that IHAs may be renewed for additional periods of time not to exceed 1 year for each reauthorization. In the notice of proposed IHA for the initial IHA, NMFS described the circumstances under which we would consider issuing a renewal for this activity, and requested public comment on a potential renewal under those circumstances. Specifically, on a case-by-case basis, NMFS may issue a one-time 1-year renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical, or nearly identical, activities as described in the Detailed Description of Specified Activities section of the initial IHA issuance notice is planned or (2) the activities as described in the Description of the Specified Activities and Anticipated Impacts section of the initial IHA issuance notice would not be completed by the time the initial IHA expires and a renewal would allow for completion of the activities beyond that described in the **DATES** section of the notice of issuance of the initial IHA, provided all of the following conditions are met:

1. A request for renewal is received no later than 60 days prior to the needed renewal IHA effective date (recognizing that the renewal IHA expiration date cannot extend beyond 1 year from expiration of the initial IHA).

2. The request for renewal must include the following:

- An explanation that the activities to be conducted under the requested renewal IHA are identical to the

activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (e.g., reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take).

- A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

An additional public comment period of 15 days (for a total of 45 days), with direct notice by email, phone, or postal service to commenters on the initial IHA, is provided to allow for any additional comments on the proposed renewal. A description of the renewal process may be found on our website at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-harassment-authorization-renewals>.

History of Request

On June 6, 2024, NMFS issued an IHA to the Port to take marine mammals incidental to the Terminal 4 Expansion and Redevelopment Project at the Port of Grays Harbor, Washington (90 FR 28725, July 1, 2025), effective from July 16, 2024 through July 15, 2025. On April 16, 2025, NMFS received an application for the renewal of that initial IHA. As described in the application for renewal, the activities for which incidental take is requested

are consistent with activities that are covered by the initial authorization but will not be completed prior to its expiration. As required, the applicant also provided a preliminary monitoring report (available at <https://www.fisheries.noaa.gov/action/incidental-take-authorization-ag-processing-incs-port-grays-harbor-terminal-4-expansion-and>) which confirms that the applicant has implemented the required mitigation and monitoring, and which also shows that no impacts of a scale or nature not previously analyzed or authorized have occurred as a result of the activities conducted. The notice of the proposed renewal incidental harassment authorization was published on July 1, 2025 (90 FR 28725).

Description of the Specified Activities and Anticipated Impacts

The purpose of the project is to construct a new export facility at Terminal 4 (T4). The activity includes removal of existing piles and the installation of both temporary and permanent piles of various sizes. Takes of marine mammals by Level A and Level B harassment are expected to occur as a result of noise produced by both impact and vibratory pile driving and vibratory removal. The initial IHA authorized take incidental to in-water construction activities associated with the installation of a new fendering system at Terminal 4A and the installation of a new commodity export facility at Terminal 4B. Ag Processing Inc. has completed the in-water construction activities for the new commodity export facility at Terminal 4B. However, a 1-year renewal of the initial IHA is needed to complete the in-water construction activities associated with the new fendering system at Terminal 4A.

Detailed Description of the Activity

A detailed description of the demolition and construction activities for which take is authorized may be found in the Notices of the Proposed (89 FR 24436, April 8, 2024) and Final (89 FR 48565, June 7, 2024) IHAs for the initial authorization. The location, timing, and nature of the activities, including the types of equipment planned for use, are similar to those described in the previous notices. The renewal IHA is effective for a period not exceeding 1 year from the date of expiration of the initial IHA (July 15, 2025).

The initial IHA authorized take incidental to the in-water pile driving/removal activities shown in tables 1 and 2. The activities in table 1 will be completed under this renewal IHA and the activities in table 2 were completed under the initial IHA. The previously planned impact proofing of 24-inch (60.96 centimeter (cm)) steel pipe piles was not required at Terminal 4B. Since the impact proofing of 24-inch (60.96 cm) steel pipe piles planned for the Terminal 4B commodity export facility portion of the Project was not required, the Port plans to conduct similar impact proofing for the fendering system construction at Terminal 4A under the renewal IHA. With the exception of impact proofing for the new fendering system, there are no new activities or modifications from the originally proposed actions. Pile removal and installation activities will occur during the in-water work window (July 16 through February 15). The most conservative estimate of time required to complete pile installation and removal activities under this renewal is 36 days of intermittent vibratory pile driving/removal and an additional 8 days of impact proofing. The renewal IHA will be effective for a period not exceeding 1 year from the date of expiration of the initial IHA.

TABLE 1—IN-WATER PILE REMOVAL AND INSTALLATION ACTIVITIES UNDER THE RENEWAL IHA FOR THE TERMINAL 4A NEW FENDERING SYSTEM

Pile type and size	Activity	Removal/installation method	Number of piles	Total days of operation	Piles per day	Hours vibratory per day	Impact strikes per day
18-inch (45.72 cm) timber piles	Removal	Vibratory hammer, direct pull.	Up to 50	Up to 12	Up to 10	Up to 5.0.	
18-inch (45.72 cm) steel pipe pile	Installation	Vibratory hammer	Up to 15	Up to 6	Up to 6	Up to 3.0.	
24-to-30-inch (60.96–76.2 cm) steel pipe pile.	Installation	Vibratory hammer	Up to 24	Up to 18	Up to 6	Up to 6.0.	
24-inch (60.96 cm) steel pipe pile	Installation	Impact proof	Up to 24	Up to 8	Up to 4		2,000

TABLE 2—IN-WATER PILE REMOVAL AND INSTALLATION COMPLETED FOR NEW AGP COMMODITY EXPORT FACILITY AT TERMINAL 4B UNDER THE INITIAL IHA

Pile type and size	Activity	Installation/removal method	Number of piles	Total days of operation	Piles per day	Hours vibratory per day	Impact strikes per day
12-inch (30.48 cm) steel H sections ..	Removal	Vibratory hammer or direct pull.	Up to 6	Up to 3	Up to 3	Up to 1.5.	
16.5-inch (41.91 cm) concrete octagonal pile.	Removal	Vibratory hammer, direct pull.	Up to 27	Up to 9	Up to 8	Up to 8.	
36-inch (91.44 cm) steel pipe pile	Installation	Vibratory	Up to 50	Up to 24	Up to 4	Up to 8.	
24-inch (60.96 cm) steel pipe pile	Installation	* Impact proof	Up to 24	Up to 6	Up to 4	Up to 2,400.	
		Vibratory and impact hammer.		Up to 10		Up to 6.	
		* Impact proof		Up to 2			Up to 2,000.
12-inch (30.48 cm) steel H-piles	Installation	Vibratory hammer	Up to 6	Up to 3	Up to 3	Up to 1.5.	
24-inch (60.96 cm) steel pipe pile	Installation	Vibratory hammer	Up to 24	Up to 6	Up to 8	Up to 4.	
24-inch (60.96 cm) steel pipe pile	Removal	Vibratory hammer	Up to 24	Up to 6	Up to 8	Up to 4.	

* The planned impact proofing of 36-in and 24-in steel pipe pile was not required. Impact proofing of 24-inch steel piles has been added to work under the renewal IHA and has been applied to pile installation activities in table 1.

Description of Marine Mammals

A description of the marine mammals in the area of the activities for which take has been authorized, including information on abundance, status, distribution, and hearing, may be found in the Notices of the Proposed IHA for the initial authorization (89 FR 24436, April 8, 2024). NMFS has reviewed the monitoring data from the initial IHA, recent draft Stock Assessment Reports, information on relevant Unusual Mortality Events, and other scientific literature, and determined there is no new information that affects which species or stocks have the potential to be affected or the pertinent information in the Description of the Marine Mammals in the Area of Specified Activities contained in the supporting documents for the initial IHA (89 FR 24436, April 8, 2024). Note that the abundance estimate for the Oregon/Washington coastal stock of harbor seal has been updated to 22,549 from 24,731 animals based on more recent best available information (Pearson *et al.* 2024), but this does not impact estimated take numbers under the renewal IHA or influence the findings made in support of the initial IHA.

Potential Effects on Marine Mammals and their Habitat

A description of the potential effects of the specified activity on marine mammals and their habitat for the

activities for which incidental take is authorized here may be found in the notices of the proposed IHA for the initial authorization (89 FR 24436, April 8, 2024). NMFS has reviewed the monitoring data from the initial IHA, recent draft Stock Assessment Reports, information on relevant Unusual Mortality Events, and other scientific literature, and determined that there is no new information that affects our initial analysis of impacts on marine mammals and their habitat.

Estimated Take

A detailed description of the methods used to estimate take for the specified activity are found in the notices of the proposed and final IHAs for the initial authorization (89 FR 24436, April 8, 2024; 89 FR 48565, June 7, 2024). Specifically, the action area and marine mammal density and occurrence data applicable to this authorization remain unchanged from the initial and modified IHA. Similarly, source levels, type of activity, methods of take, and types of take remain unchanged from the initial IHA. However, there are changes to the estimated Level A harassment zones based on the 2024 Updated Technical Guidance, further discussed below. The estimated number of authorized takes is based on the subset of activities to be completed under this renewal IHA and, therefore, represents a proportion of the initial authorized takes. These takes reflect the

estimated remaining number of days of work and number of piles to be driven. Estimated take by Level A and Level B harassment for the renewal IHA was calculated using the same methodology as in the initial proposed and final IHAs (89 FR 24436, April 8, 2024; 89 FR 48565, June 7, 2024).

On October 24, 2024 NMFS published (89 FR 84872) its final Updated Technical Guidance (<https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance-other-acoustic-tools>) which includes updated thresholds and weighting functions to inform auditory injury estimates and is replacing the 2018 Technical Guidance referenced in the notices of the proposed and final IHAs for the initial authorization (89 FR 24436, April 8, 2024; 89 FR 48565, June 7, 2024). In consideration of the best available science, NMFS conducted calculations using the Updated Technical Guidance and NMFS optional user spreadsheet, using the source levels and spreadsheet inputs provided in the notices for the proposed and final IHAs (89 FR 24436, April 8, 2024; 89 FR 48565, June 7, 2024), for the purpose of understanding how Level A harassment (auditory injury) zones might change from the initial IHA. The updated marine mammal hearing groups and updated thresholds can be found in tables 3 and 4.

TABLE 3—MARINE MAMMAL HEARING GROUPS
[NMFS, 2024]

Hearing group	Generalized hearing range*
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 36 kHz.
High-frequency (HF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
Very High-frequency (VHF) cetaceans (true porpoises, <i>Kogia</i> , river dolphins, Cephalorhynchid, <i>Lagenorhynchus cruciger</i> & <i>L. australis</i>).	200 Hz to 165 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	40 Hz to 90 kHz.

TABLE 3—MARINE MAMMAL HEARING GROUPS—Continued
[NMFS, 2024]

Hearing group	Generalized hearing range*
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 68 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.*, all species within the group), where individual species' hearing ranges may not be as broad. Generalized hearing range chosen based on ~65-dB threshold from composite audiogram, previous analysis in NMFS, 2018, and/or data from Southall *et al.*, 2007; Southall *et al.*, 2019. Additionally, animals are able to detect very loud sounds above and below that "generalized" hearing range. Hz = Hertz. kHz = kilohertz.

TABLE 4—ONSET OF AUDITORY INJURY (AUD INJ) (NMFS, 2024)

Hearing group	AUD INJ Onset Thresholds* (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	Cell 1: $L_{p,0-pk,flat}$: 222 dB; $L_{E,p,LF,24h}$: 183 dB	Cell 2: $L_{E,p,LF,24h}$: 197 dB.
High-Frequency (HF) Cetaceans	Cell 3: $L_{p,0-pk,flat}$: 230 dB; $L_{E,p,HF,24h}$: 193 dB	Cell 4: $L_{E,p,HF,24h}$: 201 dB.
Very High-Frequency (VHF) Cetaceans	Cell 5: $L_{p,0-pk,flat}$: 202 dB; $L_{E,p,VHF,24h}$: 159 dB	Cell 6: $L_{E,p,VHF,24h}$: 181 dB.
Phocid Pinnipeds (PW)	Cell 7: $L_{p,0-pk,flat}$: 223 dB; $L_{E,p,PW,24h}$: 183 dB	Cell 8: $L_{E,p,PW,24h}$: 195 dB.
(Underwater)		
Otariid Pinnipeds (OW)	Cell 9: $L_{p,0-pk,flat}$: 230 dB; $L_{E,p,OW,24h}$: 185 dB	Cell 10: $L_{E,p,OW,24h}$: 199
(Underwater)		dB.

* Dual metric thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating AUD INJ onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds are recommended for consideration.

Note: Peak sound pressure level ($L_{p,0-pk}$) has a reference value of 1 μ Pa, and weighted cumulative sound exposure level ($L_{E,p}$) has a reference value of 1 μ Pa²s. In this table, thresholds are abbreviated to be more reflective of International Organization for Standardization standards (ISO, 2017). The subscript "flat" is being included to indicate peak sound pressure are flat weighted or unweighted within the generalized hearing range of marine mammals (*i.e.*, 7 Hz to 165 kHz). The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, HF, and VHF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The weighted cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.*, varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these thresholds will be exceeded.

The inputs contained in the 2018 Technical Guidance user spreadsheet for the initial IHA are identical to those utilized in the 2024 Technical Guidance user spreadsheet. However, the

estimated Level A harassment isopleths have increased in some cases when the updated 2024 Technical Guidance is used as shown in table 5. The Port changed the shutdown zones

accordingly and consistent with the intent of the measures prescribed through the initial IHA, as discussed in *Description of Mitigation, Monitoring and Reporting Measures* section.

TABLE 5—LEVEL A HARASSMENT ISOPLETHS USING 2024 UPDATED TECHNICAL GUIDANCE AND 2018 TECHNICAL GUIDANCE (METERS)

Pile type and size	Activity	Removal/installation method	Harbor seal		Sea lion		Harbor porpoise	
			2024	2018	2024	2018	2024	2018
Up to 18-inch (45.72 cm) timber piles	Removal	Vibratory hammer	41	15	14	1	26	35
Up to 18-inch (45.72 cm) steel pipe pile	Installation	Vibratory hammer	16	6	5	1	10	13
24-to-30-inch (60.96–76.2 cm) steel pipe pile	Installation	Vibratory hammer	29	10	10	1	18	25
Up to 24-inch (60.96 cm) steel pipe pile	Installation	Impact Proof	259	157	97	12	452	349

A detailed description of the methods and inputs used to estimate take for the specified activity are found in the Notices of the Proposed and/or Final IHAs (89 FR 24436, April 8, 2024; 89 FR 48565, June 7, 2024) for the initial authorization. Specifically, the source levels, days of operation, and marine mammal density/occurrence data

applicable to this authorization remain unchanged from the previously issued IHA. The sizes of the estimated Level A harassment zones have changed in some cases as shown in table 5 and these are reflected in tables 6 through 11. The stocks taken, methods of take, and types of take remain unchanged from the previously issued IHA. The estimated

number of takes for the renewal IHA was calculated by adding the individual takes associated with each of the activities listed in table 5. Tables 6–11 show calculated take numbers by Level A (where authorized) and Level B harassment.

TABLE 6—CALCULATED TAKE OF HARBOR PORPOISE BY LEVEL B HARASSMENT

Pile type	Harbor porpoise density per km ²	Days of pile driving	Level B area (km ²)	Shutdown area (km ²)	Level B take estimate
24-to-30-inch (60.96–76.2 cm) steel pipe piles—vibratory (installation)	0.467	18	4.95	0.023	41.42
24-inch (60.96 cm) steel piles, permanent—impact (installation)	0.467	8	0.46	0.05	1.53
18-inch (45.72 cm) steel pipe piles (installation) vibratory ..	0.467	6	4.3	0.014	12.01
18-inch (45.72 cm) creosote timber piles—Vibratory (removal)	0.467	12	7.4	0.034	41.28
Total					96.2

TABLE 7—CALCULATED TAKE OF HARBOR PORPOISE BY LEVEL A HARASSMENT

Pile type	Harbor porpoise density per km ²	Days of pile driving	Level A area (km ²)	Shutdown area (km ²)	Level A take estimate
24-to-30-inch (60.96–76.2 cm) steel pipe piles—vibratory (installation)	0.467	18	0.008	0.023	0.00
24-inch (60.96 cm) steel piles, permanent—impact (installation)	0.467	8	0.44	0.047	1.47
18-inch (45.72 cm) steel pipe piles (installation) vibratory ..	0.467	6	0.009	0.014	0.00
18-inch (45.72 cm) creosote timber piles—Vibratory (removal)	0.467	12	0.025	0.034	0.00
Total					1.5

The Port requested and NMFS has Level B harassment takes of harbor authorized 2 Level A harassment and 94 porpoise.

TABLE 8—CALCULATED TAKE OF STELLER SEA LION BY LEVEL B HARASSMENT

Pile type	Stellar Sea lion density per km ²	Days of pile driving	Level B area (km ²)	Shutdown area (km ²)	Level B take estimate
24-to-30-inch (60.96–76.2 cm) steel pipe piles—vibratory (installation)	0.1993	18	4.95	0.009	17.73
24-inch (60.96 cm) steel piles, permanent—impact (installation)	0.1993	8	0.46	0.047	0.66
18-inch (45.72 cm) steel pipe piles (installation) vibratory ..	0.1993	6	4.3	0.009	5.13
18-inch (45.72 cm) creosote timber piles—Vibratory (removal)	0.1993	12	7.4	0.009	17.68
Total					41.2

The Port requested and NMFS has Level B harassment. No take by Level A authorized 42 takes of Steller sea lion by harassment is anticipated or authorized.

TABLE 9—CALCULATED TAKE OF CALIFORNIA SEA LION BY LEVEL B HARASSMENT

Pile type	California sea lion density per km ²	Days of pile driving	Level B area (km ²)	Shutdown area (km ²)	Level B take estimate
24-to-30-inch (60.96–76.2 cm) steel pipe piles—vibratory (installation)	0.6493	18	4.95	0.009	57.75
24-inch (60.96 cm) steel piles, permanent—impact (installation)	0.6493	8	0.46	0.047	2.15
18-inch (45.72 cm) steel pipe piles (installation) vibratory ..	0.6493	6	4.3	0.009	16.72
18-inch (45.72 cm) creosote timber piles—Vibratory (removal)	0.6493	12	7.4	0.009	57.59

TABLE 9—CALCULATED TAKE OF CALIFORNIA SEA LION BY LEVEL B HARASSMENT—Continued

Pile type	California sea lion density per km ²	Days of pile driving	Level B area (km ²)	Shutdown area (km ²)	Level B take estimate
Total					134.2

The Port requested and NMFS has authorized 134 takes of California sea lion by Level B harassment. No take by

Level A harassment is anticipated or authorized.

TABLE 10—CALCULATED TAKE OF HARBOR SEAL BY LEVEL B HARASSMENT

Pile type	Harbor seal density per km ²	Days of pile driving	Level B area (km ²)	Shutdown area (km ²)	Level B take estimate
24-to-30-inch (60.96–76.2 cm) steel pipe piles—vibratory (installation)	30.8	18	4.95	0.009	2,739.29
24-inch (60.96 cm) steel piles, permanent—impact (installation)	30.85	8	0.46	0.05	101.19
18-inch (45.72 cm) steel pipe piles (installation) vibratory ..	30.85	6	4.3	0.009	794.26
18-inch (45.72 cm) creosote timber piles—Vibratory (removal)	30.85	12	7.4	0.014	2,734.30
Total					6,369.0

TABLE 11—CALCULATED TAKE OF HARBOR SEAL BY LEVEL A HARASSMENT

Pile type	Harbor seal density per km ²	Days of pile driving	Level A area (km ²)	Shutdown area (km ²)	Level A take estimate
24-to-30-inch (60.96–76.2 cm) steel pipe piles—vibratory (installation)	30.85	18	0.013	0.009	2.22
24-inch (60.96 cm) steel piles, permanent—impact (installation)	30.85	8	0.174	0.05	30.60
18-inch (45.72 cm) steel pipe piles (installation) vibratory ..	30.85	6	0.015	0.009	1.11
18-inch (45.72 cm) creosote timber piles—Vibratory (removal)	30.85	12	0.041	0.014	10.00
Total					43.9

The Port requested and NMFS has authorized 44 Level A harassment takes

and 6,325 Level B harassment takes of harbor seal.

The total number of takes authorized under the renewal IHA for all species by

Level A and Level B harassment as well as the percentage of each stock are shown in table 12.

TABLE 12—SUMMARY OF MARINE MAMMAL TAKES BY SPECIES AND PERCENTAGE OF STOCK TAKEN

Common name	Scientific name	Stock	Level A harassment	Level B harassment	Stock abundance	Percent of stock (%)
Harbor porpoise	<i>Phocoena phocoena</i>	Northern Oregon/ Washington Coast.	2	94	22,074	<0.01
Steller sea lion	<i>Eumetopias jubatus</i>	Eastern U.S.		42	36,308	<0.01
California sea lion	<i>Zalophus californianus</i>	U.S.		135	257,606	<0.01
Harbor seal	<i>Phoca vitulina</i>	OR/WA coast stock.	44	6,325	* 22,549	28.2

* This is likely an underestimate of total abundance since it only includes data for the Washington portion of the Oregon-Washington Coastal Stock (Pearson *et al.*, 2024).

Description of Mitigation, Monitoring and Reporting Measures

The mitigation, monitoring, and reporting measures included as requirements in this renewal IHA are similar to those included in the **Federal Register** notice announcing the issuance of the initial IHA (89 FR 48565, June 7, 2024), and the discussion of the least practicable adverse impact included in that document and the Notice of the Proposed IHA (89 FR 24436, April 8, 2024) remain accurate. The following measures are planned for this renewal:

- The Port must employ NMFS-approved protected Species Observers (PSOs) and establish monitoring locations to the maximum extent possible based on the required number of PSOs, required monitoring locations, and environmental conditions;
- Monitoring must take place from 30 minutes prior to initiation of pile driving activity (*i.e.*, pre-start clearance monitoring) through 30 minutes post-completion of pile driving activity;
- Pre-start clearance monitoring must be conducted during periods of

visibility sufficient for the lead PSO to determine that the shutdown zones are clear of marine mammals;

- If a marine mammal is observed entering or within the shutdown zones pile driving activity must be delayed or halted;
- If pile driving is delayed or halted due to the presence of a marine mammal, the activity may not commence or resume until either the animal has voluntarily exited and been visually confirmed beyond the shutdown;
- Soft start techniques must be used when impact pile driving;
- A bubble curtain must be used during impact pile driving;
- Pile driving activity must be halted upon observation of either a species for which incidental take is not authorized or a species for which incidental take has been authorized but the authorized number of takes has been met, entering or within the harassment zone;
- The Port must shut down construction operations if a marine mammal comes within 10 m of construction activity to avoid direct

physical interaction with marine mammals;

- The Port must submit a draft marine mammal monitoring report to NMFS within 90 days after the completion of pile driving activities or 60 calendar days prior to the requested issuance of any subsequent IHA for construction activity at the same location, whichever comes first. A final report must be prepared and submitted within 30 calendar days following receipt of any NMFS comments on the draft report; and
- All injured or dead marine mammals must be reported to the Office of Protected Resources and to the West Coast regional stranding network.

Consistent with the mitigation required through the initial IHA, shutdown zones under the renewal IHA are based on the largest Level A harassment zone for each pile size/type and driving method, as updated using the draft 2024 Technical Guidance rather than the 2018 Technical Guidance. These zones are shown in table 13.

TABLE 13—SHUTDOWN AND MONITORING ZONES (METERS)

Pile type	Shutdown zone			Monitoring zone
	Very high-frequency cetaceans *	Phocid pinnipeds	Otariid pinnipeds	
Impact				
24-inch (60.96 cm) steel piles, permanent (installation)	100	100	** 100 (10)	465
Vibratory				
24-to-30-inch (60.96–76.2 cm) steel pipe piles (installation)	25	10	10	3,985
18-inch (45.72 cm) steel pipe piles (installation)	15	10	10	3,415
18-inch (45.72 cm) creosote timber piles (removal)	35	15	** 15 (10)	6,310

* In the 2018 guidance and initial IHA, VHF cetaceans were referred to as HF (high-frequency) cetaceans.
** Represents change from Initial 2024–2025 IHA. Initial zones in parentheses.

The monitoring zones in the renewal IHA are identical to those found in the initial proposed and final IHAs (89 FR 24436, April 8, 2024; 89 FR 48565, June 7, 2024). Most of the Level A harassment zones remain unchanged from the initial proposed and final IHAs. However, the Level A harassment zone for Otariids during impact installation of 24-inch (60.96 cm) steel piles increased from 12 m to 97 m so the shutdown zone was increased to 100 m. Vibratory removal of 18-in creosote timber piles for Otariids increased from 1 m to 14 m so the shutdown zone was increased to 15 m from the previous 10 m minimum.

Comments and Responses

A notice of NMFS’ proposal to issue a renewal IHA to the Port was published in the **Federal Register** on July 1, 2025 (90 FR 28725FR). That notice either described, or referenced descriptions of, the Port’s activity, the marine mammal species that may be affected by the activity, the anticipated effects on marine mammals and their habitat, estimated amount and manner of take, and proposed mitigation, monitoring and reporting measures. NMFS received no public comments.

Determinations

The Port’s action requires the completion of a subset of pile driving activities that were not completed under the initial IHA. Work at Terminal 4B has

been completed while work at Terminal 4A has yet to begin. The method of taking and effects of the work on Terminal 4A were analyzed in the initial IHA along with Terminal B. Work on both terminals was expected to take 105 days under the initial IHA. The Port estimates that only 44 days of work remain under the renewal IHA. The take estimate for the renewal IHA is based on the activities planned to occur during these remaining days. The renewal take numbers represent a subset of the total take authorized under the initial IHA. In analyzing the effects of the activities for the initial IHA, NMFS determined that the Port’s activities would have a negligible impact on the affected species or stocks and that authorized take numbers of each species or stock were

small relative to the relevant stocks (*e.g.*, less than one-third the abundance of all stocks). The mitigation measures and monitoring and reporting requirements as described above are substantially similar to those required through the initial IHA, although some shutdown zones for Otariids have undergone slight revisions due to the Updated 2024 Technical Guidance. The abundance of a single species (OR/WA coast stock of harbor seals) has also changed since the initial IHA, but none of this new information affects NMFS' determinations supporting issuance of the initial IHA. The piles planned to be driven in the subset of work and any minor changes described above do not affect the least practicable adverse impact determinations.

NMFS has concluded that there is no new information suggesting that our analysis or findings should change from those reached for the initial IHA. Based on the information and analysis contained here and in the referenced documents, NMFS has determined the following: (1) the required mitigation measures will effect the least practicable impact on marine mammal species or stocks and their habitat; (2) the authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine mammals relative to the affected stock abundances; (4) the Port's activities will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action, and; (5) appropriate monitoring and reporting requirements are included.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216-6A, NMFS must review our proposed action (*i.e.*, the issuance of a renewal IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (incidental take authorizations with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216-6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS determined that the issuance of the initial IHA qualified to be categorically

excluded from further NEPA review. NMFS has determined that the application of this categorical exclusion remains appropriate for this renewal IHA.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*) requires that each Federal agency ensure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

No incidental take of ESA-listed species is authorized or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required.

Renewal

NMFS has issued a renewal IHA to the Port of Grays Harbor for the take of marine mammals incidental to conducting construction activities as part of the T4 Expansion and Redevelopment Project at the Port of Grays Harbor, Washington from the date of issuance through July 15, 2026.

Dated: July 25, 2025.

Kimberly Damon-Randall,

*Director, Office of Protected Resources,
National Marine Fisheries Service.*

[FR Doc. 2025-14343 Filed 7-29-25; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XF047]

Fisheries of the Gulf of America; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 100 Data Workshop for Gulf Gray Triggerfish.

SUMMARY: The SEDAR 100 assessment process of Gulf gray triggerfish will consist of a Data Workshop, a series of assessment webinars, and a Review Workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 100 Data Workshop will be held from 9 a.m. on August 19, 2025, until 1 p.m. on August 22, 2025.

ADDRESSES:

Meeting address: The SEDAR 100 Data Workshop will be held at the Hilton Tampa Airport Westshore, 2225 N Lois Avenue, Tampa, FL 33607. Plenary sessions held during the workshop will be live streamed for listening purposes only. Registration is available <https://sedarweb.org>.

The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571-4366. Email: Julie.neer@safmc.net.

SUPPLEMENTARY INFORMATION: The Gulf, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with the National Marine Fisheries Service and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data/Assessment Workshop, and (2) a series of webinars. The product of the Data and Assessment Workshops is a report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses, and describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. Participants for SEDAR Workshops are appointed by the Gulf, South Atlantic, and Caribbean Fishery Management Councils and National Marine Fisheries Service Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the Data Workshop are as follows:

An assessment data set and associated documentation will be developed

during the workshop. Participants will evaluate proposed data and select appropriate sources for providing information on topics such as life history characteristics, catch statistics, discard estimates, length and age composition, and fishery dependent and fishery independent measures of stock abundance.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 28, 2025.

Key Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2025-14435 Filed 7-29-25; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. Department of Energy.

ACTION: Notice of request for comments.

SUMMARY: The Department of Energy (DOE) invites public comments on a proposed collection of information that DOE is developing for submission to the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995.

DATES: Comments regarding this proposed information collection must be received on or before September 29, 2025. If you anticipate any difficulty in submitting comments within that period, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section as soon as possible.

ADDRESSES: Written comments may be sent to Jeremy Simpson, 1000

Independence Avenue SW, Washington, DC 20585, or by email at Jeremy.simpson@ee.doe.gov.

FOR FURTHER INFORMATION CONTACT: Jeremy Simpson, Office of Integrated Strategies, (240) 446-0003, Jeremy.simpson@ee.doe.gov.

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

This information collection request contains:

(1) *OMB No.:* 1910-NEW;

(2) *Information Collection Request*

Title: EERE Small Businesses and Startups Impact Evaluation Data Collection.

(3) *Type of Request:* New.

(4) *Purpose:* The information collected through this effort is needed as an input to an evaluation study that will produce an analysis of the impact EERE's funding has had on small businesses between 2008 and 2024. The results of this evaluation study will be used by DOE leadership to understand the impact to date and opportunities for improvement in financial awards provided to small businesses. Respondents to this data collection effort will small businesses and startup companies that have applied for financial assistance, SBIR/STTR grants and prize funding from EERE between 2008 and 2024, and will include both award recipients and applicants who did not receive funding. This is planned to be a one-time data collection effort.

(5) *Annual Estimated Number of Respondents:* 9,000;

(6) *Annual Estimated Number of Total Responses:* 9,000;

(7) *Annual Estimated Number of Burden Hours:* 13,500;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* \$751,275.

Statutory Authority: Foundations for Evidence-based Policymaking Act of 2018 (Pub. L. 115-435; Jan. 14, 2019).

Signing Authority

This document of the Department of Energy was signed on July 25, 2025, by

Lou Hrkman, Principal Deputy Assistant Secretary of the Office of Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC on July 25, 2025.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2025-14353 Filed 7-29-25; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Nevada

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an in-person/virtual meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Nevada. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, September 10, 2025; 4-8:45 p.m. PDT.

ADDRESSES: Molasky Corporate Center, 15th Floor Conference Room, 100 North City Parkway, Las Vegas, Nevada 89106. This meeting will be held in-person at the Molasky Corporate Center and virtually. To receive the virtual access information, please contact the Nevada Site Specific Advisory Board (NSSAB) Administrator at the telephone number or email listed below at least two days prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Barbara Ulmer, NSSAB Administrator, NSSAB Office, by phone: 702-523-0894 or email: nssab@emcbc.doe.gov.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to provide advice and recommendations concerning the following EM site-specific issues: clean-up activities and environmental restoration; waste and nuclear materials

management and disposition; excess facilities; future land use and long-term stewardship. The Board may also be asked to provide advice and recommendations on other EM program components. The Board also provides an avenue to fulfill public participation requirements outlined in the National Environmental Policy Act (NEPA), the Comprehensive Environmental Response, Compensation, and Liability Act (CERLA), the Resource Conservation and Recovery Act (RCRA), Federal Facility Agreements, Consent Orders, Consent Decrees and Settlement Agreements.

Tentative Agenda: (agenda topics are subject to change; please contact the NSSAB Administrator for the most current agenda).

- Public Comment Period
- Update from Deputy Designated Federal Officer
- Update from National Nuclear Security Administration/Nevada Field Office
- Updates from NSSAB Liaisons
- Presentations to the Board
- Board Business
- Board Leadership Elections
- Fiscal Year 2026 Work Plan Development.

Public Participation: The meeting is open to the public and public comment can be given orally or in writing. Fifteen minutes are allocated during the meeting for public comment and those wishing to make oral comment will be given a minimum of two minutes to speak. Written comments received at least two working days prior to the meeting will be provided to the members and included in the meeting minutes. Written comments received within two working days after the meeting will be included in the minutes. For additional information on public comment and to submit written comment, please contact the NSSAB Administrator. The EM SSAB, Nevada, welcomes the attendance of the public at its meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact the NSSAB Administrator at least seven days in advance of the meeting.

Meeting conduct: The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Questioning of board members or presenters by the public is not permitted.

Minutes: Minutes will be available at the following website: <https://www.nnss.gov/nssab/nssab-meetings/>.

Signing Authority: This document of the Department of Energy was signed on July 25, 2025, by David Borak, Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC on July 25, 2025.

Jennifer Hartzell,

*Alternate Federal Register Liaison Officer,
U.S. Department of Energy.*

[FR Doc. 2025–14349 Filed 7–29–25; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collection Proposed Extension

AGENCY: U.S. Energy Information Administration (EIA), Department of Energy (DOE).

ACTION: Notice and request for comments.

SUMMARY: DOE invites public comment on the proposed three-year extension, without change, to the Form FE–746R, “Natural Gas Imports and Exports,” as required under the Paperwork Reduction Act of 1995. This information collection request supports DOE’s Office of Fossil Energy and Carbon Management (FECM) in gathering critical information on the U.S. trade in natural gas, including liquefied natural gas (LNG). The data are used to monitor natural gas trade, assess the adequacy of U.S. energy resources to meet near and longer term domestic demands, and support various market and regulatory analyses done by FECM.

DATES: DOE must receive all comments on this proposed information collection no later than September 29, 2025. If you anticipate any difficulties in submitting your comments by the deadline, contact the person listed in the **ADDRESSES** section of this notice as soon as possible.

ADDRESSES: You may submit comments, identified by OMB control 1901–0294, by email at tu.tran@hq.doe.gov. Include

the OMB control number listed in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Tu Tran, (202) 235–5873, tu.tran@hq.doe.gov. The forms and instructions are available on DOE’s website at <https://www.energy.gov/fecm/articles/fe-746-data-collection-omb-clearance-process>.

SUPPLEMENTARY INFORMATION: This information collection request contains:

- (1) *OMB No.:* 1901–0294.
- (2) *Information Collection Request Title:* Natural Gas Imports and Exports.
- (3) *Type of Request:* Three-year extension without change.

(4) *Purpose:* The Form FE–746R Natural Gas Imports and Exports collect information on the imports and exports of natural gas, including LNG, under the Natural Gas Act (NGA) (15 U.S.C. 717b).

The Federal Energy Administration Act of 1974 (15 U.S.C. 761 *et seq.*) and the DOE Organization Act (42 U.S.C. 7101 *et seq.*) require DOE to carry out a centralized, comprehensive, and unified energy information program. This program collects, evaluates, assembles, analyzes, and disseminates information on energy resource reserves, production, demand, technology, and related economic and statistical information.

Under section 3 of the NGA, DOE is authorized to regulate natural gas imports and exports, including LNG. To carry out DOE’s statutory responsibilities, FECM (through its delegated authority) implements regulations (10 CFR part 590) that require any person seeking to import or export natural gas to file an application requesting authorization. The application requires information on the scope and nature of the proposed import/export activity. Additionally, once an importer or exporter receives an authorization from DOE under the NGA, the authorization holder is required to submit monthly reports of all import and/or export transactions on Form FE–746–R.

Form FE–746R has different reporting formats, corresponding to different import and export activities. Generally, however, Form FE–746–R requires the reporting of the following information for the authorized imports or exports on a monthly basis: name of importer/exporter; country of origin/destination; international point of entry/exit; name of supplier; volume; price; transporters; U.S. geographic market(s) served; and duration of supply contract. More information about the Form FE–746R reporting requirements is available at: <https://www.energy.gov/fecm/guidelines-filing-monthly-reports>.

Both EIA and FECM use the information provided by authorization holders on Form FE-746R to assess the adequacy of energy resources to meet near and longer term domestic demands, and FECM also uses it in the management of its natural gas regulatory program. Specifically, data collected on Form FE-746R are published in FECM's *U.S. Natural Gas Imports and Exports Monthly Report*, and in EIA's official statistics on U.S. natural gas supply and disposition. In addition, the data are used to monitor the North American natural gas trade, which, in turn, enables the Federal government to perform market and regulatory analyses; improve the capability of industry and the government to respond to any future energy-related supply problems; and keep the general public informed of international natural gas trade.

(5) *Annual Estimated Number of Respondents*: 396.

(6) *Annual Estimated Number of Total Responses*: 4,752.

(7) *Annual Estimated Number of Burden Hours*: 14,256.

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden*: The cost of the burden hours is estimated to be \$1,354,177. DOE estimates that respondents will have no additional costs associated with the surveys other than the burden hours and the maintenance of the information during the normal course of business.

Comments are invited on whether: (a) The proposed collection of information is necessary for the proper performance of agency functions, including whether the information will have a practical utility; (b) DOE's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used, is accurate; (c) DOE can improve the quality, utility, and clarity of the information it will collect; and (d) DOE can minimize the burden of the collection of information on respondents, such as automated collection techniques or other forms of information technology.

Statutory Authority: 15 U.S.C. 772(b) and 42 U.S.C. 7101 *et seq.*, 15 U.S.C. 717b.

Signed in Washington, DC, on July 28, 2025.

Samson A. Adeshiyan,

Director, Office of Statistical Methods and Research, U. S. Energy Information Administration.

[FR Doc. 2025-14401 Filed 7-29-25; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG25-409-000.

Applicants: Crossroads Solar, LLC.

Description: Crossroads Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 7/25/25.

Accession Number: 20250725-5041.

Comment Date: 5 p.m. ET 8/15/25.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL25-105-000.

Applicants: Ameren Illinois Company.

Description: Petition for Declaratory Order of Ameren Illinois Company.

Filed Date: 7/24/25.

Accession Number: 20250724-5153.

Comment Date: 5 p.m. ET 8/25/25.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER24-506-003.

Applicants: Viridon Mid-Atlantic LLC.

Description: Compliance filing: Compliance Filing to be effective 2/5/2024.

Filed Date: 7/25/25.

Accession Number: 20250725-5128.

Comment Date: 5 p.m. ET 8/15/25.

Docket Numbers: ER25-2970-000.

Applicants: Dusty Rose Wind, LLC.

Description: § 205(d) Rate Filing: Application for Market-Based Rate Authorization—Dusty Rose Wind, LLC to be effective 9/23/2025.

Filed Date: 7/24/25.

Accession Number: 20250724-5145.

Comment Date: 5 p.m. ET 8/14/25.

Docket Numbers: ER25-2971-000.

Applicants: Keystone Appalachian Transmission Company.

Description: § 205(d) Rate Filing: KATCO submits Amended ECSA SA No. 7174 to be effective 9/24/2025.

Filed Date: 7/25/25.

Accession Number: 20250725-5010.

Comment Date: 5 p.m. ET 8/15/25.

Docket Numbers: ER25-2972-000.

Applicants: Jersey Central Power & Light Company.

Description: § 205(d) Rate Filing: JCPL submits Borderline Svc Agmt SA No. 7365 to be effective 9/24/2025.

Filed Date: 7/25/25.

Accession Number: 20250725-5012.

Comment Date: 5 p.m. ET 8/15/25.

Docket Numbers: ER25-2973-000.

Applicants: American Transmission Systems, Incorporated.

Description: § 205(d) Rate Filing: ATSI submits Amended Construction Agmts SA Nos. 7183, 6939 to be effective 9/24/2025.

Filed Date: 7/25/25.

Accession Number: 20250725-5024.

Comment Date: 5 p.m. ET 8/15/25.

Docket Numbers: ER25-2974-000.

Applicants: Crossroads Solar, LLC.

Description: § 205(d) Rate Filing: Application for Market-Based Rate Authority to be effective 9/24/2025.

Filed Date: 7/25/25.

Accession Number: 20250725-5034.

Comment Date: 5 p.m. ET 8/15/25.

Docket Numbers: ER25-2975-000.

Applicants: Central Maine Power Company.

Description: § 205(d) Rate Filing: Amendment to Wholesale Distribution Access Tariff to be effective 9/1/2025.

Filed Date: 7/25/25.

Accession Number: 20250725-5076.

Comment Date: 5 p.m. ET 8/15/25.

Docket Numbers: ER25-2976-000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to ISA, SA No. 7087; Queue No. AF1-062 to be effective 9/24/2025.

Filed Date: 7/25/25.

Accession Number: 20250725-5084.

Comment Date: 5 p.m. ET 8/15/25.

Docket Numbers: ER25-2977-000.

Applicants: Mount Storm Wind LLC.

Description: Compliance filing: Notice of Succession and Request for Waiver to be effective 7/8/2025.

Filed Date: 7/25/25.

Accession Number: 20250725-5087.

Comment Date: 5 p.m. ET 8/15/25.

Docket Numbers: ER25-2978-000.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: Tariff Amendment: Alabama Power Company submits tariff filing per 35.15: Flint River Solar (Flint Solar Project) LGIA Termination Filing to be effective 7/25/2025.

Filed Date: 7/25/25.

Accession Number: 20250725-5091.

Comment Date: 5 p.m. ET 8/15/25.

Docket Numbers: ER25-2979-000.

Applicants: Mount Storm Wind LLC.

Description: Compliance filing: Notice of Succession and Request for Waiver to be effective 7/8/2025.

Filed Date: 7/25/25.

Accession Number: 20250725-5092.

Comment Date: 5 p.m. ET 8/15/25.

Docket Numbers: ER25-2980-000.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: Tariff Amendment: Alabama Power Company submits tariff filing per 35.15: Oris Development (AL B Solar + Storage) LGIA Termination Filing to be effective 7/25/2025.

Filed Date: 7/25/25.

Accession Number: 20250725–5093.

Comment Date: 5 p.m. ET 8/15/25.

Docket Numbers: ER25–2981–000.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: Tariff Amendment: Alabama Power Company submits tariff filing per 35.15: NextEra Energy Resources (Lawrence Creek Solar) LGIA Termination Filing to be effective 7/25/2025.

Filed Date: 7/25/25.

Accession Number: 20250725–5098.

Comment Date: 5 p.m. ET 8/15/25.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, community organization, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or OPP@ferc.gov.

Dated: July 25, 2025.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2025–14403 Filed 7–29–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings in Existing Proceedings

Docket Numbers: RP24–1106–005.

Applicants: Adelphia Gateway, LLC.

Description: Compliance filing: Adelphia Gateway Unopposed Motion to place Interim Settlement Rates into Effect to be effective 7/1/2025.

Filed Date: 7/25/25.

Accession Number: 20250725–5081.

Comment Date: 5 p.m. ET 8/6/25.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, community organization, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or OPP@ferc.gov.

Dated: July 25, 2025.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2025–14406 Filed 7–29–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 77–324]

Pacific Gas & Electric Company; Notice of Application for Temporary Flow Modification Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Application for Temporary Variance of Flow Requirements.

b. *Project No:* 77–324.

c. *Date Filed:* May 1, 2025; supplemented July 16, 2025.

d. *Applicant:* Pacific Gas & Electric Company.

e. *Name of Project:* Potter Valley Hydroelectric Project.

f. *Location:* The project is located on the Eel River and East Fork of the Russian River in Lake and Mendocino counties, California. The project occupies federal lands managed by the U.S. Forest Service.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Chadwick McCready, Pacific Gas and Electric Company, 300 Lakeside Drive, Oakland, CA 94612, (530) 685–5710.

i. *FERC Contact:* Katherine Schmidt, katherine.schmidt@ferc.gov, (415) 369–3348.

j. *Cooperating agencies:* With this notice, the Commission is inviting federal, state, local, and Tribal agencies with jurisdiction and/or special expertise with respect to environmental issues affected by the proposal, that wish to cooperate in the preparation of any environmental document, if applicable, to follow the instructions for filing such requests described in item k below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of any environmental document cannot also intervene. See 94 FERC ¶ 61,076 (2001).

k. *Deadline for filing comments, motions to intervene, and protests:* August 25, 2025.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://>

www.ferc.gov/docs-filing/ecomment.asp. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. The first page of any filing should include the docket number P-77-324. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

1. *Description of Request:* The licensee requests a temporary variance of its minimum flow requirements. Specifically, the licensee requests to reduce minimum flows in the East Branch Russian River to 20 cubic feet per second (cfs) from November 1, 2025 to November 30, 2025, so that it can inspect, replace, and repair the upper and lower wood stave penstocks that transport water from the Eel River to the Potter Valley Powerhouse. Normally during this period, the licensee would be required to maintain at least 35 cfs at compliance gauge E-16 in the East Branch Russian River pursuant to Article 52, in addition to other contracted water deliveries. While the repair work on the staves is occurring, the licensee proposes to reroute and deliver reduced flows into a small seasonal creek that also connects to the East Branch Russian River near the powerhouse. This variance request cannot be combined with the earlier variance request, filed February 14, 2025, because the seasonal creek has limited capacity and cannot convey the full volume of flows required during the preceding variance when both Article 52 minimum flows and contracted delivery flows are combined. A temporary staff gage will be installed in

the seasonal creek to monitor flow releases during the variance.

m. *Locations of the Application:* This filing may be viewed on the Commission's website at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1-866-208-3676 or email FERCOnlineSupport@ferc.gov, for TTY, call (202) 502-8659. Agencies may obtain copies of the application directly from the applicant.

n. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

o. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

p. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

q. The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, community organizations, Tribal members, and others access

publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Dated: July 25, 2025.

Carlos D. Clay,
Deputy Secretary.

[FR Doc. 2025-14404 Filed 7-29-25; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2020-0720; FRL-8329-03-OCSPP]

Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA); Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA or Agency) is seeking public comment to inform its reconsideration of the Toxic Substances Control Act (TSCA) regulation for perchloroethylene (PCE). As promulgated in December 2024, the PCE risk management action addressed the unreasonable risk of injury to health presented by PCE under its conditions of use by requiring various workplace exposure controls, prohibiting certain industrial and commercial uses, and preventing consumer access to the chemical, among other provisions. This request for public comment follows the filing of several legal challenges to the rule in 2025, and EPA's subsequent determination that the PCE regulation under TSCA should be reconsidered through further rulemaking. EPA intends to consider information received in response to this public comment solicitation, and other reasonably available information, to inform the development of any proposed rule to amend the PCE regulation as appropriate.

DATES: Comments must be received on or before August 29, 2025.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0720, online at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting

and visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

Technical information: Peter Deck, Existing Chemical Risk Management Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0488; email address: PCE.TSCA@epa.gov.

General information: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action is directed to the public in general and may be of particular interest to those involved in the manufacture (including import), processing, distribution, use, and disposal of PCE or products containing PCE, related industry trade organizations, non-governmental organizations with an interest in human and environmental health, state and local governments, Tribal Nations, and/or those interested in the assessment or management of risks involving chemical substances and mixtures regulated under TSCA. As such, the Agency has not attempted to describe all the specific entities that this action might apply to. If you need help determining applicability, consult the technical contact listed **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if the Agency determines through a TSCA section 6(b) risk evaluation that the manufacture, processing, distribution in commerce, use or disposal of a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must by rule apply one or more requirements listed in TSCA section 6(a)(1)–(7) to the extent necessary so that the chemical substance or mixture no longer presents such risk.

C. What action is the Agency taking?

On December 18, 2024, EPA released the final risk management rule for PCE titled “Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA)” (89 FR 103560, December 18, 2024) (FRL–8329–01–OCSPP) (hereinafter “PCE final rule”).

Following its publication, EPA received several petitions for review related to the rule. These petitions for review were consolidated in the U.S. Court of Appeals for the Fifth Circuit. The Court granted a temporary abeyance in the litigation through August 21, 2025.

On May 12, 2025, EPA filed a declaration with the Court advising that the Agency intends to reconsider the PCE final rule through further rulemaking. In that declaration, the Agency expressed its intent to solicit early stakeholder input. EPA is now soliciting early stakeholder input regarding its intended reconsideration of the rule. EPA invites public comment on requirements and implementation of the PCE final rule (89 FR 103560), particularly on the topics described in Unit II. The information received in response to this notice will inform EPA's considerations of these provisions.

This review is being done in accordance with applicable law, Executive Orders, and Administration policies, including Executive Order 14219 “Ensuring Lawful Governance and Implementing the President's ‘Department of Government Efficiency’ Deregulatory Initiative” (90 FR 10583, February 19, 2025) and EPA's Powering the Great American Comeback Initiative Pillar I: Clean Air, Land, and Water for Every American.

D. What should I consider as I prepare my comments?

1. Submitting CBI

Do not submit CBI to EPA through <https://www.regulations.gov> or email. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR parts 2 and 703, as applicable.

2. Tips for Preparing Your Comments

When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. Request for Comment

EPA invites public comment on all aspects of the PCE final rule, including but not limited to any existing or anticipated implementation issues associated with the final rule requirements, experiences with the PCE final rule since it went into effect, and whether the Agency should consider additional or alternative measures or

approaches to address the unreasonable risk presented by PCE under the conditions of use. Input on the following is of particular interest to EPA:

- The Existing Chemical Exposure Limit (ECEL) of 0.14 parts per million (ppm) as an 8-hour time weighted average (8-hr TWA) promulgated in the PCE final rule as part of the Workplace Chemical Protection Program (WCPP) (see 40 CFR 751.603 and 751.607(b)), including whether the use of a different exposure limit would be more appropriate to inform risk management. Different exposure limits might include but are not limited to: the acute non-cancer exposure limit of 0.50 ppm (8-hr TWA) and the lifetime cancer exposure limit of 0.47 ppm (8-hr TWA) as presented in the Existing Chemical Exposure Limit (ECEL) for Occupational Use of Perchloroethylene Memo available at <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0720-0043>.

- Conditions of use the Agency could contemplate subjecting to a WCPP as opposed to imposing a prohibition. Information such as workplace controls currently in place or other information demonstrating how regulated parties could mitigate the unreasonable risk of PCE for the condition of use would be most helpful to the Agency.

- The use of PCE in industrial dry cleaning processes including workplace controls that reduce exposure to PCE and the performance of alternatives to PCE in these operations.

To the extent possible, the Agency asks commenters to please cite and provide any public data related to or that supports comments provided, and to the extent permissible, describe and provide any supporting data that is not publicly available.

Authority: 15 U.S.C. 2605.

Dated: July 25, 2025.

Nancy B. Beck,

*Principal Deputy Assistant Administrator,
Office of Chemical Safety and Pollution Prevention.*

[FR Doc. 2025–14429 Filed 7–29–25; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

[OMB No. 3064–0001;–0189]

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request

AGENCY: Federal Deposit Insurance Corporation FDIC.

ACTION: Notice and request for comment.

SUMMARY: The Federal Deposit Insurance Corporation (FDIC), as part of its obligations under the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to take this opportunity to comment on the renewal of the existing information collection described below (OMB Control No. 3064–0001 and –0189).

DATES: Comments must be submitted on or before September 29, 2025.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *Agency website:* <https://www.fdic.gov/resources/regulations/federal-register-publications/>.

- *Email:* comments@fdic.gov. Include the name and number of the collection in the subject line of the message.

- *Mail:* Robert Meiers, Regulatory Counsel, MB–3013, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street NW building (located on F Street NW), on business days between 7 a.m. and 5 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and

Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Robert Meiers, Regulatory Attorney, Romeiers@fdic.gov, MB–3013, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: Proposal to renew the following currently approved collection of information:

1. *Title:* Interagency Charter and Federal Deposit Insurance Application.

OMB Number: 3064–0001.

Form Number: 6200–05.

Affected Public: Banks or savings associations wishing to become FDIC-insured depository institutions.

Burden Estimate:

SUMMARY OF ESTIMATED ANNUAL BURDEN [OMB No. 3064–0001]

Information Collection (IC) (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Average time per response (HH:MM)	Annual burden (hours)
1. Interagency Charter and Federal Deposit Insurance Application, Form 6200–05 (Mandatory).	Reporting (On Occasion).	21	1	125:00	2,625
Total Annual Burden (Hours)					2,625

Source: FDIC.

General Description of Collection: The Federal Deposit Insurance Act requires financial institutions to apply to the FDIC to obtain deposit insurance. This collection provides the FDIC with the information needed to evaluate the applications. There is no change in the method or substance of the collection.

The increase in burden hours is the result of economic fluctuation. In particular, the number of respondents has increased while the hours per response and frequency of responses have remained the same.

2. *Title:* Stress Testing Recordkeeping and Reporting.

OMB Number: 3064–0189.

Form Number: None.

Affected Public: Insured State nonmember banks and State savings associations.

Burden Estimate:

SUMMARY OF ESTIMATED ANNUAL BURDEN [OMB No. 3064–0189]

Information Collection (IC) (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Average time per response (HH:MM)	Annual burden (Hours)
1. Annual Stress Test Reporting Template and Documentation for covered banks with total consolidated assets of \$250 billion or more, 12 CFR 325.6 (Mandatory).	Reporting (Biennial) ..	1	0.667	240:00	240
2. Methodologies and Practices for covered banks with total consolidated assets of \$250 billion or more, 12 CFR 325.5 (Mandatory).	Recordkeeping (Biennial).	1	0.667	640:00	640
3. Publication—covered banks with total consolidated assets of \$250 billion or more, 12 CFR 325.7 (Mandatory).	Third-Party Disclosure (Biennial).	1	0.667	160:00	160
4. Documentation of Assumptions, Uncertainties and Limitations for FDIC-supervised IDIs with total consolidated assets of \$10 billion or more, 2009 Interagency Guidance (Voluntary).	Recordkeeping (Annual).	48	1	40:00	1,920
5. Summary of Test Results for FDIC-supervised IDIs with total consolidated assets of \$10 billion or more, 2009 Interagency Guidance (Voluntary).	Recordkeeping (Annual).	48	1	40:00	1,920
6. Policies and Procedures for FDIC-supervised IDIs with total consolidated assets of \$10 billion or more, 2009 Interagency Guidance (Voluntary).	Recordkeeping (Annual).	9	1	180:00	1,620

SUMMARY OF ESTIMATED ANNUAL BURDEN—Continued
[OMB No. 3064–0189]

Information Collection (IC) (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Average time per response (HH:MM)	Annual burden (Hours)
Total Annual Burden (hours)					6,500

Source: FDIC.

General Description of Collection: The FDIC has issued a rule requiring periodic stress testing by FDIC-supervised institutions having more than \$250 billion in total assets, consistent with changes made by section 401 of the Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA). Section 165(i)(2) of the Dodd-Frank Act requires each primary Federal regulator to issue consistent and comparable regulations to (1) ensure that certain financial companies conduct stress tests; (2) establish the form and content of the required reports of such stress tests, and (3) require companies to publish a summary of the stress test results. As originally enacted, section 165(i)(2)(C) applied to all IDIs with average total consolidated assets of \$10 billion or greater, required such IDIs to conduct annual stress tests, and required the use of three scenarios: baseline, adverse, and severely adverse. Consistent with the requirements of section 165(i)(2)(C), as originally enacted, the FDIC published its final rule implementing section 165(i)(2) on October 15, 2012. The requirements under 12 CFR part 325 applied to FDIC-supervised IDIs with average total consolidated assets of \$10 billion or greater. The EGRRCPA, enacted on May 24, 2018, amended certain aspects of the company-run stress-testing requirements in section 165(i)(2) of the Dodd-Frank Act. The EGRRCPA amendments to the section 165(i)(2) stress testing requirements became effective eighteen months after enactment.

The aspects of 12 CFR part 325 that constitute an information collection are those that require a banking organization to (1) file stress test reports to be filed periodically with the FDIC and the Board of Governors of the Federal Reserve System (the Board) in the time, manner, and form specified by the FDIC (12 CFR 325.6); (2) establish and maintain a system of controls, oversight, and documentation, including policies and procedures that describe the covered bank's stress test practices and methodologies, as well as processes for updating such bank's stress test practices, as well as specific

calculations that must be made by the banking organization during its stress tests (12 CFR 325.5); and (3) publish a summary of the results of its stress tests (12 CFR 325.7).

On May 17, 2012, the FDIC, the Office of the Comptroller of the Currency, and the Board published the 2012 Interagency Guidance on the use of stress testing as a means to better understand the range of a banking organization's potential risk exposures. The guidance is intended for IDIs with total consolidated assets of more than \$10 billion and provides an overview of how a banking organization should structure its stress testing activities to ensure they fit into the banking organization's overall risk management program. The purpose of the guidance is to outline broad principles for a satisfactory stress testing framework and describe the manner in which stress testing should be used, that is as an integral component of risk management applicable at various levels of aggregation within a banking organization as well as a tool for capital and liquidity planning. The 2012 Interagency Guidance recommends that IDIs stress test in coordination with their "overall strategy and annual planning cycles" and assess and review their stress testing frameworks at least once a year to ensure that stress testing coverage is comprehensive, tests are relevant and current, methodologies are sound, and results are properly considered.

The aspects of the 2012 Interagency Guidance that constitute an information collection are the provisions that state a banking organization should (1) have a stress testing framework that includes clearly defined objectives, well designed scenarios tailored to the banking organization's business and risks, well documented assumptions, conceptually sound methodologies to assess potential impact on the banking organization's financial condition (section II); (2) maintain an internal summary of test results to document at a high level the range of its stress testing activities and outcomes, as well as proposed follow-up actions (section III); and (3) have policies and procedures for a stress

testing framework (section VI). There has been no change in the substance or methodology of this information collection. The 774 hour increase in total estimated annual burden from 5,726 hours in 2023 to 6,500 hours currently is due to the doubling of annual responses to ICs 1–3 and the increased number of respondents to IC 6 and is attenuated by the decreased number of respondents to ICs 4 and 5.

Request for Comment

Comments are invited on (a) whether the collections of information are necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collections, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collections of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on July 28, 2025.

Debra A. Decker,

Executive Secretary.

[FR Doc. 2025–14399 Filed 7–29–25; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage de novo, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has

determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than August 29, 2025.

A. *Federal Reserve Bank of Boston* (Prabal Chakrabarti, Executive Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02210-2204. Comments can also be sent electronically to BOS.SRC.Applications.Comments@bos.frb.org:

1. *Hometown Financial Group MHC and Hometown Financial Group, Inc., both of Easthampton, Massachusetts*; to merge with 15 Beach MHC and CFSB Bancorp Inc., respectively, and thereby acquire Colonial Federal Savings Bank, all of Quincy, Massachusetts, and thereby engage in operating a savings association pursuant to section 225.28(b)(4)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System.

Erin Cayce,

Assistant Secretary of the Board.

[FR Doc. 2025-14400 Filed 7-29-25; 8:45 am]

BILLING CODE P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Senior Executive Service Performance Review Board

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Notice.

SUMMARY: This notice announces the appointment of the members of the Senior Executive Service Performance Review Board for the Federal Retirement Thrift Investment Board. The purpose of the Performance Review Board is to make written recommendations on each executive's annual summary ratings, performance-based pay adjustment, and performance awards to the appointing authority.

DATES: This notice is applicable on July 30, 2025.

FOR FURTHER INFORMATION CONTACT: Kelly Powell, HR Specialist, at 202-942-1681.

SUPPLEMENTARY INFORMATION: Title 5, U.S. Code, 4314(c)(4), requires that the appointment of Performance Review Board members be published in the **Federal Register** before Board service commences. The following persons will serve on the Federal Retirement Thrift Investment Board's Performance Review Board which will review initial summary ratings to ensure the ratings are consistent with established performance requirements, reflect meaningful distinctions among senior executives based on their relative performance and organizational results and provide recommendations for ratings, awards, and pay adjustments in a fair and equitable manner: Thomas Brandt, Gisile Goethe, James Kaplan, and Sean McCaffrey.

Dharmesh Vashee,

General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 2025-14389 Filed 7-29-25; 8:45 am]

BILLING CODE 6760-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-5542-N]

Medicare Program; Alternative Payment Model (APM) Incentive Payment Advisory for Clinicians—Request for Current Billing Information for Qualifying APM Participants

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This advisory is to alert certain clinicians who are qualifying Alternative Payment Model (APM) participants (QPs) and have earned an APM incentive payment that CMS does not have the current information needed to disburse the payment. This advisory provides information to QPs on how to update their Medicare billing information so that CMS can disburse APM incentive payments.

DATES: August 29, 2025.

FOR FURTHER INFORMATION CONTACT: Tanya Dorm, (410) 786-2216.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare Quality Payment Program, an eligible clinician who participates in an Advanced Alternative Payment Model (APM) and meets or exceeds the applicable payment amount or patient count thresholds for a performance period is a qualifying APM participant (QP) for that year. For payment years 2019 through 2026, which respectively correspond to the QP performance periods for 2017 through 2024, an eligible clinician who attains QP status for a year earns a lump sum APM incentive payment that is paid in the payment year. For payment years 2019 through 2024, the amount of the APM incentive payment is equal to 5 percent of the estimated aggregate paid amounts for covered professional services furnished by the QP during the calendar year immediately preceding the payment year. For the 2023 performance year and 2025 payment year Congress, via section 4111 of the Consolidated Appropriations Act, 2023 (Pub. L. 117-328), reduced the APM incentive payment from 5 percent to 3.5 percent. For the 2024 performance year and 2026 payment year the APM incentive payment is reduced from 3.5 percent to 1.88 percent.

II. Provisions of the Advisory

The Centers for Medicare & Medicaid Services (CMS) has identified those eligible clinicians who attained QP status in the 2023 performance period and earned a 3.5 percent APM incentive payment for the 2025 payment year based on aggregate paid amounts for the covered professional services they furnished in the calendar year (CY) 2024 base period.

When the 2025 APM incentive payments were processed, CMS was unable to identify the taxpayer identification number (TIN) or TINs associated with some QPs and therefore was unable to disburse the payments. To successfully issue the APM incentive payment for the 2025 payment year, CMS is requesting assistance identifying current Medicare billing information for these under 42 CFR 414.1450(c)(8), if we have not identified any TIN associated with the QP to which we can make the APM Incentive Payment, we will attempt to contact the QP via a public notice to request their Medicare payment information.

CMS has compiled a list of QPs for whom we were unable to identify any associated TIN to which we can make the APM incentive payment. These QPs, and any others who anticipated receiving an APM Incentive Payment but have not, should follow the instructions to provide CMS with updated Medicare billing information at the following web address: <https://qpp-cm-prodcontent.s3.amazonaws.com/uploads/3369/2025%20QP%20Notice%20for%20APM%20Incentive%20Payment.zip>.

If you have any questions concerning submission of information through the QPP website, please contact the Quality Payment Program Help Desk at 1-866-288-8292.

In accordance with 42 CFR 414.1450(c)(8), all information must be received by September 1, 2025. After that date, any claim to an APM incentive payment for the 2025 payment period based on an eligible clinician's QP status for the 2023 QP performance period will be forfeited. To facilitate payment, please include all required documentation as specified in the previous link. If CMS is still unable to process the APM incentive payment based on the Medicare billing information received in response to this advisory, the submitter will not be notified.

CMS will hold all timely submitted information and process the remaining 2025 APM incentive payments simultaneously as soon as possible after the deadline. It may take up to 3 months

to complete the validation and verification process before these APM incentive payments are disbursed.

III. Collection of Information Requirements

This advisory is intended to alert certain QPs that CMS is requesting assistance identifying current Medicare billing information so that we can disburse APM incentive payments. This request for follow-up information is exempt from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) as specified under implementing regulation 5 CFR 1320.3(h)(9) with regard to the clarification of responses.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Mehmet Oz, having reviewed and approved this document, authorizes Chyana Woodyard, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodyard,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2025-14434 Filed 7-29-25; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-2359]

Food Safety Modernization Act Voluntary Qualified Importer Program User Fee Rate for Fiscal Year 2026

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fiscal year (FY) 2026 annual fee rate for importers approved to participate in the Voluntary Qualified Importer Program (VQIP) that is authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). This fee is effective on August 1, 2025, and will remain in effect through September 30, 2026.

FOR FURTHER INFORMATION CONTACT: For questions related to FSMA program fees: FSMAFeeStaff@fda.hhs.gov. For questions related to this notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240-

402-4989; or the User Fees Support Staff at UFSS@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 806 of the FD&C Act (21 U.S.C. 384b) directs FDA to establish a program to provide for the expedited review and importation of food offered for importation by importers who have voluntarily agreed to participate in such program, and a process, consistent with section 808 of the FD&C Act (21 U.S.C. 384d), for the issuance of a facility certification to accompany a food offered for importation by importers participating in VQIP.

Section 743 of the FD&C Act (21 U.S.C. 379j-31) authorizes FDA to assess and collect fees from each importer participating in VQIP to cover FDA's costs of administering the program. Each fiscal year, fees are to be established based on an estimate of 100 percent of the costs for the year (section 743(b)(2)(A)(iii) of the FD&C Act). The fee rates must be published in a **Federal Register** notice not later than 60 days before the start of each fiscal year (section 743(b)(1) of the FD&C Act). After FDA approves a VQIP application, the user fee is to be paid before October 1, the start of the VQIP fiscal year, to begin receiving benefits for that VQIP fiscal year.

The FY 2026 VQIP user fee will support benefits from October 1, 2025, through September 30, 2026.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2026

FDA estimates 100 percent of its costs for each activity to establish fee rates for FY 2026 (see section 743(b)(2)(A) of the FD&C Act).

A. Estimating the Full Cost per Direct Work Hour in FY 2026

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered “hours worked” for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an FDA-wide total cost per FTE requires three primary cost elements: payroll, non-payroll, and rent.

We used an average of past year cost elements to predict the FY 2026 cost.

The FY 2026 FDA-wide average cost for payroll (salaries and benefits) is \$225,917; non-payroll—including equipment, supplies, IT, general and administrative overhead—is \$116,581; and rent, including cost allocation analysis and adjustments for other rent and rent-related costs, is \$24,627 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2026 average fully supported cost to \$367,125 (total includes rounding) per FTE, excluding travel costs. FDA will use this base unit fee in determining the hourly fee rate for VQIP fees for FY 2026 before including

domestic or foreign travel costs as applicable for the activity.

To calculate an hourly rate, we divide the FY 2026 average fully supported cost of \$367,125 per FTE by the average number of supported direct FDA work hours in FY 2024—the last FY for which data are available. See table 1.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2024

Total number of hours in a paid staff year	2,080
Less:	
11 paid holidays	– 88
20 days of annual leave	– 160
10 days of sick leave	– 80
12.5 days of training	– 100
22 days of general administration	– 176
26.5 days of travel	– 212
2 hours of meetings per week	– 104
Net Supported Direct FDA Work Hours Available for Assignments	1,160

Dividing the average fully supported FTE cost in FY 2026 (\$367,125) by the total number of supported direct work hours available for assignment in FY 2024 (1,160) results in an average fully supported cost of \$316 (rounded to the nearest dollar), excluding inspection travel costs, per supported direct work hour in FY 2026.

B. Adjusting FY 2024 Travel Costs for Inflation To Estimate FY 2025 Travel Costs

To adjust the hourly rate for FY 2026, FDA estimates the cost of inflation in each year for FYs 2025 and 2026. FDA uses the method prescribed for estimating inflationary costs under the Prescription Drug User Fee Act (PDUFA) provisions of the FD&C Act (section 736(c)(1) of the FD&C Act (21 U.S.C. 379h(c)(1))), the statutory method for inflation adjustment in the FD&C Act that FDA has used consistently. FDA previously determined the FY 2025 inflation rate to be 4.1167 percent; this rate was published in the FY 2025 PDUFA user fee rates notice in the **Federal Register** (July 31, 2024, 89 FR 61474). Using the method set forth in section 736(c)(1) of the FD&C Act, FDA calculated an inflation rate of 4.1167 percent for FY 2025 and 5.0313 percent for FY 2026, and FDA intends to use these inflation rates to make inflation adjustments for FY 2026.

In FY 2024, FDA’s Office of Regulatory Affairs (ORA) spent a total of \$7,498,059 for domestic regulatory inspection travel costs and General Services Administration Vehicle costs related to FDA’s Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM)

field activities programs. The total ORA domestic travel costs spent is then divided by the 7,851 CFSAN and CVM domestic inspections, which averages a total of \$955 per inspection. These inspections average 45.09 hours per inspection. Dividing \$955 per inspection by 45.09 hours per inspection results in a total and an additional cost of \$21 (rounded to the nearest dollar) per hour spent for domestic inspection travel costs in FY 2024. To adjust for the \$21 per hour additional domestic cost inflation increases for FY 2025 and FY 2026, FDA multiplies the FY 2025 PDUFA inflation rate adjustor (1.041167) by the FY 2026 PDUFA inflation rate adjustor (1.050313) times the \$21 additional domestic cost, which results in an estimated cost of \$23 (rounded to the nearest dollar) per paid hour in addition to \$316 for a total of \$339 per paid hour (\$316 plus \$23) for each direct hour of work requiring domestic inspection travel. FDA will use these rates in charging fees in FY 2026 when domestic travel is required.

In FY 2024, ORA spent a total of \$3,209,026 on 487 foreign inspection trips related to FDA’s CFSAN and CVM field activities programs, which averaged a total of \$6,589 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing \$6,589 per trip by 120 hours per trip results in a total and an additional cost of \$55 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2024. To adjust \$55 for inflationary increases in FY 2025 and FY 2026, FDA multiplies it by the same inflation factors mentioned previously in this

document (1.041167 and 1.050313), which results in an estimated cost of \$60 (rounded to the nearest dollar) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2026 when foreign travel is required.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2026

Fee category	Fee rates for FY 2026
Hourly rate without travel	\$316
Hourly rate if domestic travel is required	339
Hourly rate if foreign travel is required	376

III. Fees for Importers Approved To Participate in the Voluntary Qualified Importer Program Under Section 743 of the FD&C Act

FDA assesses fees for VQIP annually. Table 3 provides an overview of the fees for FY 2026.

TABLE 3—FSMA VQIP USER FEE SCHEDULE FOR FY 2026

Fee category	Fee rates for FY 2026
VQIP User Fee	\$9,620

Section 743 of the FD&C Act requires that each importer participating in VQIP pay a fee to cover FDA’s costs of administering the program. This fee represents the estimated average cost of the work FDA performs in reviewing and evaluating a VQIP importer. At this

time, FDA is not offering an adjusted fee for small businesses. As required by section 743(b)(2)(B)(iii) of the FD&C Act, FDA published guidelines in consideration of the burden of the VQIP fee on small businesses and provided for a period of public comment on the guidelines (80 FR 32136, June 5, 2015). While we received some comments, the comments did not address the questions posed (that is, how a small business fee reduction should be structured, what percentage of fee reduction would be appropriate, or what alternative structures FDA might consider to indirectly reduce fees for small businesses by charging different fee amounts to different VQIP participants). Consistent with section 743(b)(2)(B)(iii) of the FD&C Act, if we determine to provide for a small business fee reduction, we will adjust the fee schedule for small businesses only through notice and comment rulemaking.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. These estimates represent FDA's current thinking, and as the program evolves, FDA will reconsider the estimated hours. We estimate that it would take, on average, 39 person-hours to review a new VQIP application (including communication provided through the VQIP Importer's Help Desk), 28 person-hours to review a returning VQIP application (including communication provided through the VQIP Importer's Help Desk), 16 person-hours for an onsite performance evaluation of a domestic VQIP importer (including travel and other steps necessary for a fully supported FTE to complete and document an onsite assessment), and 34 person-hours for an onsite performance evaluation of a foreign VQIP importer (including travel and other steps necessary for a fully supported FTE to complete and document an onsite assessment).

Based on updated data, FDA anticipates that there may be up to seven returning VQIP applicants and up to two new applicants this fiscal year. FDA employees are likely to review new VQIP applications from their worksites, so we use the fully supported FTE hourly rate excluding travel, \$316/hour, to calculate the portion of the user fee attributable to those activities: $\$316/\text{hour} \times (39 \text{ hours}) = \$12,324$. FDA employees are likely to review returning VQIP applications from their worksites, so we use the fully supported FTE hourly rate excluding travel, \$316/hour, to calculate the portion of the user fee

attributable to those activities: $\$316/\text{hour} \times (28 \text{ hours}) = \$8,848$.

FDA employees may conduct a VQIP inspection to verify the eligibility criteria and full implementation of the food safety and food defense systems established in the Quality Assurance Program. For FY 2026, FDA does not anticipate conducting dedicated VQIP inspections and will instead use existing inspection programs (such as the Foreign Supplier Verification Program and Hazard Analysis and Critical Control Point regulations) for program participants.

FDA employees are likely to prepare for and report on the performance evaluation of a domestic VQIP importer at an FTE's worksite, so we use the fully supported FTE hourly rate excluding travel, \$316/hour, to calculate the portion of the user fee attributable to those activities: $\$316/\text{hour} \times (8 \text{ hours}) = \$2,528$. For the portion of the fee covering onsite evaluation of a domestic VQIP importer, we use the fully supported FTE hourly rate for work requiring domestic travel, \$339/hour, to calculate the portion of the user fee attributable to those activities: $\$339/\text{hour} \times 8 \text{ hours}$ (*i.e.*, one fully supported FTE $\times$ (1 day onsite $\times$ 8 hours)) = \$2,712. Therefore, the total cost of conducting the domestic performance evaluation of a VQIP importer is determined to be $\$2,528 + \$2,712 = \$5,240$.

Coordination of the onsite performance evaluation of a foreign VQIP importer is estimated to take place at an FTE's worksite, so we use the fully supported FTE hourly rate excluding travel, \$316/hour, to calculate the portion of the user fee attributable to those activities: $\$316/\text{hour} \times (10 \text{ hours}) = \$3,160$. For the portion of the fee covering onsite evaluation of a foreign VQIP importer, we use the fully supported FTE hourly rate for work requiring foreign travel, \$376/hour, to calculate the portion of the user fee attributable to those activities: $\$376/\text{hour} \times 24 \text{ hours}$ (*i.e.*, one fully supported FTE $\times$ ((2 travel days $\times$ 8 hours) + (1 day onsite $\times$ 8 hours))) = \$9,024. Therefore, the total cost of conducting the foreign performance evaluation of a VQIP importer is determined to be $\$3,160 + \$9,024 = \$12,184$.

Therefore, the estimated average cost of the work FDA performs in total for approving an application for a VQIP importer in FY 2026 based on these figures would be $(\$12,324 \times \frac{2}{9}) + (\$8,848 \times \frac{7}{9}) = \$9,620$.

IV. How must the fee be paid?

Section 743(a)(1)(C) of the FD&C Act requires FDA to assess and collect user

fees from each importer participating in VQIP. An invoice will be sent to VQIP importers approved to participate in the program. Payment are to be made before October 1, 2025, to be eligible for VQIP participation for the benefit year beginning October 1, 2025. FDA will not refund the VQIP user fee for any reason.

The payments are to be made in U.S. currency drawn on a U.S. bank by electronic check, credit card, or wire transfer. The preferred payment method is online using an electronic check (via the U.S. Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. (*Note:* only full payments are accepted. No partial payments can be made online.) Once you have found your invoice, select "Pay Now" to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available only for balances less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments are to be made using U.S. bank accounts as well as U.S. credit cards.

When paying by wire transfer, the invoice number should be included; without the invoice number the payment may not be applied. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, the fee should be added to the payment to ensure that the invoice is paid in full. For international wire transfers, please inquire with the financial institutions prior to submitting the payment. Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33.

The tax identification number of FDA is 53-0196965.

V. What are the consequences of not paying this fee?

The consequences of not paying these fees are outlined in Section J of our Guidance for Industry, "FDA's Voluntary Qualified Importer Program" (November 2024) (available at <https://www.fda.gov/media/92196/download>). If the user fee is not paid before October 1, a VQIP importer will not be eligible to participate in VQIP. For the first year a VQIP application is approved, if the user fee is not paid before October 1, 2025, you are not eligible to participate

in VQIP. If you subsequently pay the user fee, FDA will begin your benefits after we receive the full payment. The user fee may not be paid after December 31, 2025. For a subsequent year, if you do not pay the user fee before October 1, FDA will send a Notice of Intent to Revoke your participation in VQIP. If you do not pay the user fee within 30 days of the date of the Notice of Intent to Revoke, we will revoke your participation in VQIP.

Dated: July 25, 2025.
Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
[FR Doc. 2025–14407 Filed 7–29–25; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2245]

Prescription Drug User Fee Rates for Fiscal Year 2026

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the rates for prescription drug user fees for fiscal year (FY) 2026. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2022 (PDUFA VII), authorizes FDA to collect application fees for certain applications for the review of human drug and biological products and prescription drug program fees for certain approved products. This notice establishes the fee rates for FY 2026.

DATES: These fees apply to the period from October 1, 2025, through September 30, 2026.

FOR FURTHER INFORMATION CONTACT: For more information on prescription drug fees, visit FDA’s website at: <https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee>

amendments. For questions relating to this notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–4989; or the User Fees Support Staff at UFSS@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h) establish two different kinds of user fees. Fees are assessed as follows: (1) application fees are assessed on certain types of applications for the review of human drug and biological products and (2) prescription drug program fees are assessed on certain approved products (section 736(a) of the FD&C Act). The statute also includes conditions under which such fees may be waived or reduced (section 736(d) of the FD&C Act), or under which fee exceptions, refunds, or exemptions apply (sections 736(a)(1)(C) through (H), 736(a)(2)(B) through (C), and 736(k) of the FD&C Act).

For FY 2023 through FY 2027, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA VII. The base revenue amount for FY 2026 is \$1,434,377,467. The FY 2026 base revenue amount is adjusted for (1) inflation, (2) strategic hiring and retention, and for (3) the resource capacity needs for the process for the review of human drug applications (the capacity planning adjustment (CPA)). This amount is further adjusted to include the additional dollar amount as specified in the statute (see section 736(b)(1)(G) of the FD&C Act) to provide for additional full-time equivalent (FTE) ¹ positions to support PDUFA VII initiatives. If applicable, an operating reserve adjustment is added to provide sufficient operating reserves of carryover user fees. The amount from the preceding adjustments is then adjusted to provide for additional direct costs to fund PDUFA VII initiatives. Fee amounts are to be established each year so that revenues from application fees provide 20 percent of the total revenue, and prescription drug program fees

provide 80 percent of the total revenue (see section 736(b)(2) of the FD&C Act). This document provides fee rates for FY 2026 for an application requiring covered clinical data ² (\$4,682,003), for an application not requiring covered clinical data (\$2,341,002), and for the prescription drug program fee (\$442,213). These fees are effective on October 1, 2025, and will remain in effect through September 30, 2026. For applications that are submitted on or after October 1, 2025, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2026

The base revenue amount for FY 2026 is \$1,434,377,467 (see section 736(b)(1)(A) and (b)(3) of the FD&C Act). This amount is prior to any adjustments made for inflation, the strategic hiring and retention adjustment, CPA, additional dollar amount, operating reserve adjustment (if applicable), and additional direct costs (see section 736(b)(1) of the FD&C Act).

A. FY 2026 Statutory Fee Revenue Adjustments for Inflation

PDUFA VII specifies that the \$1,434,377,467 is to be adjusted for inflation increases for FY 2026 using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 736(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs is the average annual percent change in the cost of all PC&B paid per FTE positions at FDA for the first 3 of the preceding 4 fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of the process for the review of human drug applications for the first 3 of the preceding 4 fiscal years (see section 736(c)(1)(A) and (B)(i) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified fiscal years, provides the percent changes from the previous fiscal years, and provides the average percent changes over the first 3 of the 4 fiscal years preceding FY 2026. The 3-year average is 5.4494 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGES

	2022	2023	2024	3-year average
Total PC&B	\$3,165,477,000	\$3,436,513,000	\$3,791,729,000	
Total FTEs	18,474	18,729	19,687	
PC&B per FTE	\$171,348	\$183,486	\$192,601	

¹ Full-time equivalents refer to a paid staff year, rather than a count of individual employees.

² As used herein, “covered clinical data” is “clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness [that] are required for approval” (see section 736(a)(1)(A) of the FD&C Act).

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGES—Continued

	2022	2023	2024	3-year average
Percent Change from Previous Year	4.2967%	7.0838%	4.9677%	5.4494%

The statute specifies that this 5.4494 percent be multiplied by the proportion of PC&B costs to the total FDA costs of

the process for the review of human drug applications. Table 2 shows the PC&B and the total obligations for the

process for the review of human drug applications for the first 3 of the preceding 4 fiscal years.

TABLE 2—PC&B AS A PERCENT OF TOTAL COST OF THE PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS

	2022	2023	2024	3-year average
Total PC&B (proportion of costs)	\$931,302,114	\$1,040,590,183	\$1,139,962,844	
Total Costs	\$1,480,601,875	\$1,686,733,841	\$1,772,198,497	
PC&B percent	62.9002%	61.6926%	64.3248%	62.9725%

The payroll adjustment is 5.4494 percent from table 1 multiplied by 62.9725 percent from table 2 resulting in 3.4316 percent.

The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban

consumers (Washington-Arlington-Alexandria, DC-VA-MD-WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of the process for the review of human drug

applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years (see section 736(c)(1)(A) and (B)(ii)). Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Arlington-Alexandria area.³

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

	2022	2023	2024	3-year average
Annual CPI	296.117	305.317	315.186	
Annual Percent Change	6.6212%	3.1069%	3.2324%	4.3202%

The statute specifies that this 4.3202 percent be multiplied by the proportion of all costs other than PC&B to total costs of the process for the review of human drug applications obligated. Because 62.9725 percent was obligated for PC&B (as shown in table 2), 37.0275 percent is the portion of costs other than PC&B (100 percent minus 62.9725

percent equals 37.0275 percent). The non-payroll adjustment is 4.3202 percent times 37.0275 percent, or 1.5997 percent.

Next, we add the payroll adjustment (3.4316 percent) to the non-payroll adjustment (1.5997 percent), for a total inflation adjustment of 5.0313 percent (rounded) for FY 2026.

We then multiply the base revenue amount for FY 2026 (\$1,434,377,467) by 5.0313 percent, which produces an inflation adjustment amount of \$72,167,833. Adding this amount to the base revenue amount yields an inflation-adjusted base revenue amount of \$1,506,545,300.

TABLE 4—BASE REVENUE AMOUNT AND SECTION 736(c)(1) ADJUSTMENT AMOUNT

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	\$1,434,377,467
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	72,167,833
Revenue Amount after Adjustments in sections 736(c)(1) of the FD&C Act	1,506,545,300

B. FY 2026 Strategic Hiring and Retention Adjustment

For each fiscal year, after the annual base revenue established in section II is

adjusted for inflation in accordance with section II.A, the statute directs FDA to further increase the fee revenue and fees to support strategic hiring and

retention. For FY 2026, this amount is \$4,000,000 (see section 736(c)(2)(A) of the FD&C Act).

TABLE 5—BASE REVENUE AMOUNT AND SECTION 736(c)(1) THROUGH (2) ADJUSTMENT AMOUNTS

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	\$1,434,377,467

³ The data are published by the Bureau of Labor Statistics and can be found on its website at: [https://](https://data.bls.gov/pdq/SurveyOutputServlet?data_)

data.bls.gov/pdq/SurveyOutputServlet?data_

[tool=dropmap&series_id=CUURS35ASA0, CUUSS35ASA0.](https://data.bls.gov/pdq/SurveyOutputServlet?data_)

TABLE 5—BASE REVENUE AMOUNT AND SECTION 736(c)(1) THROUGH (2) ADJUSTMENT AMOUNTS—Continued

Fee	Amount
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	72,167,833
Strategic Hiring and Retention Adjustment (section 736(c)(2) of the FD&C Act)	4,000,000
Revenue Amount after Adjustments in sections 736(c)(1) and (2) of the FD&C Act	1,510,545,300

C. FY 2026 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after the base revenue amount for FY 2026 of \$1,434,377,467 has been adjusted as described in sections II.A and II.B, this amount shall be further adjusted to reflect changes in the resource capacity needs for the process of human drug application reviews (see section 736(c)(3) of the FD&C Act). Following a process agreed upon by FDA and industry during PDUFA VI reauthorization discussions and subsequently required in statute, FDA established a new CPA methodology and first applied it in the setting of FY 2021 fees. The establishment of this methodology is described in the **Federal Register** of August 3, 2020 (85 FR 46651). This methodology includes a continuous, iterative improvement approach, under which the Agency intends to refine its data and estimates for the core review activities to improve their accuracy over time. An adjustment for workload has been a critical aspect of the PDUFA program since PDUFA III in FY 2003 as it enables the program to adjust to shifts in review workload

resulting from industry submissions to the Agency. The annual adjustment process allows greater accuracy than would be expected if workload adjustments were fixed at the start of the reauthorization period. The CPA is an evolution of the PDUFA workload adjuster and was implemented through a process agreed to by FDA and industry during PDUFA VI. The CPA builds on the concepts of the workload adjuster but realizes enhancements including the use of leading indicators of workload, use of full-time reporting data, the introduction of a managerial adjustment process as an internal check on the reasonableness of any adjustment, outputs measured in full-time equivalent employees, and the incorporation of adjustments into the base revenue amounts to ensure sustainability of payroll to support any new hires.

The CPA methodology includes four steps:

1. *Forecast workload volumes:* predictive models estimate the volume of workload for the upcoming FY.
2. *Forecast the resource needs:* forecast algorithms are generated utilizing time reporting data. These

algorithms estimate the required demand in FTEs for direct review-related effort. This is then compared to current available resources for the direct review related workload.

3. *A managerial adjustment to assess the resource forecast in the context of additional internal factors:* program leadership examines operational, financial, and resourcing data to assess whether FDA will be able to utilize additional funds during the FY, and whether the funds are required to support additional review capacity. FTE amounts are adjusted, if needed.

4. *Convert the FTE need to dollars:* utilizing FDA’s fully loaded FTE cost model, the final feasible FTEs are converted to an equivalent dollar amount.

FDA calculated workload models for the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) in the Fall of 2024.

Table 6 summarizes the forecasted workload volumes for CDER in FY 2026 based on predictive models, as well as historical actuals from FY 2024 for comparison.

TABLE 6—CDER ACTUAL FY 2024 WORKLOAD VOLUMES AND PREDICTED FY 2026 WORKLOAD VOLUMES

Workload category	FY 2024 Actuals	FY 2026 Predictions
Efficacy Supplements	257	241
Labeling Supplements	1,047	996
Manufacturing Supplements	2,463	2,574
NDA/BLA ¹ Original	115	127
PDUFA Industry Meetings (including WROs ²)	4,028	3,843
Active Commercial INDs ³	10,015	10,758
Annual Reports ⁴	3,518	3,659
PMR/PMC-Related Documents ⁴	1,770	1,583
Active REMS Programs ^{4 5}	25	25

¹ New drug applications (NDA)/biological license applications (BLA).

² Written responses only (WROs).

³ For purpose of the CPA, this is defined as an active commercial investigational new drug (IND) for which a document has been received in the past 18 months.

⁴ Represents activities related to the review of materials submitted to the application file after approval.

⁵ Represents the percentage of active risk evaluation and management strategy (REMS) programs proportional to Center and User Fee by total number of qualifying products with the exclusion of the Opioid Shared System.

Table 7 summarizes the forecasted workload volumes for CDER in FY 2026

based on predictive models, as well as

the corresponding historical actuals from 2024 for comparison.

TABLE 7—CBER ACTUAL FY 2024 WORKLOAD VOLUMES AND PREDICTED FY 2026 WORKLOAD VOLUMES

Workload category	FY 2024 Actuals	FY 2026 Predictions
Efficacy Supplements	24	23
Labeling Supplements	61	61
Manufacturing Supplements	833	869
NDA/BLA ¹ Original	12	13
PDUFA Industry Meetings (including WROs ²)	923	1,011
Active Commercial INDs ³	1,873	2,104
Annual Reports ⁴	311	315
PMR/PMC-Related Documents ⁴	188	156
Active REMS Programs ^{4 5}	2	2

¹ New drug applications (NDA)/biological license applications (BLA).

² Written responses only (WROs).

³ For purpose of the CPA, this is defined as an active commercial investigational new drug (IND) for which a document has been received in the past 18 months.

⁴ Represents activities related to the review of materials submitted to the application file after approval.

⁵ Represents the percentage of active REMS programs proportional to Center and User Fee by total number of qualifying products with the exclusion of the Opioid Shared System.

FDA anticipates that any FTE gains could be funded through the expected FY 2026 collections amount without

further adjustment from the CPA. As such, FDA determined that in FY 2026 the PDUFA fee amounts do not need

adjustment from the CPA to provide funds for the program.

TABLE 8—FY 2026 PDUFA CPA

Center	FY 2026 PDUFA CPA
CDER	\$0
CBER	0
Total	0

TABLE 9—BASE REVENUE AMOUNT AND SECTION 736(c)(1) THROUGH (3) ADJUSTMENT AMOUNTS

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	\$1,434,377,467
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	72,167,833
Strategic Hiring and Retention Adjustment (section 736(c)(2) of the FD&C Act)	4,000,000
Capacity Planning Adjustment (section 736(c)(3) of the FD&C Act)	0
Revenue Amount after Adjustments in sections 736(c)(1), (2), and (3) of the FD&C Act	1,510,545,300

D. FY 2026 Statutory Fee Revenue Adjustments for Additional Dollar Amounts

PDUFA VII provides an additional dollar amount for each of the 5 fiscal

years covered by PDUFA VII for additional FTEs to support enhancements outlined in the PDUFA VII commitment letter. The additional dollar amount for FY 2026 as outlined

in statute is \$4,864,860 (see section 736(b)(1)(G)(iv) of the FD&C Act). This amount will be added to the total FY 2026 PDUFA VII revenue amount.

TABLE 10—BASE REVENUE AMOUNT AND SECTION 736(c)(1) THROUGH (3) ADJUSTMENT AMOUNTS

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	\$1,434,377,467
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	72,167,833
Strategic Hiring and Retention Adjustment (section 736(c)(2) of the FD&C Act)	4,000,000
Capacity Planning Adjustment (section 736(c)(3) of the FD&C Act)	0
Additional Dollar Amounts Adjustment (section 736(b)(1)(G) of the FD&C Act)	4,864,860
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), and (3) of the FD&C Act	1,515,410,160

E. FY 2026 Statutory Fee Revenue Adjustments for Operating Reserve

PDUFA VII provides for an operating reserve adjustment that may result in an increase or decrease in fee revenue and

fees for a given FY (see section 736(c)(4) of the FD&C Act). For FY 2026, FDA is required to further increase fee revenue and fees if an adjustment is necessary to provide for at least 10 weeks of

operating reserves of carryover user fees (see section 736(c)(4)(A)(iii) of the FD&C Act). If FDA has carryover balances of user fees in excess of 14 weeks of operating reserves, FDA is required to

decrease fee revenue and fees to provide for not more than 14 weeks of operating reserves of carryover user fees (see section 736(c)(4)(B) of the FD&C Act).

To determine the dollar amounts for the 10-week and 14-week operating reserve thresholds, the adjustments (inflation, strategic hiring and retention, capacity planning, and additional dollar amount) discussed in sections II.A, II.B, II.C, and II.D are applied to the FY 2026 base revenue (see section 736(c)(4)(A) of the FD&C Act), resulting in

\$1,515,410,160. This amount is then divided by 52 to generate the 1-week operating amount of \$29,142,503. The 1-week operating amount is then multiplied by 10 and 14. This results in a 10-week threshold amount of \$291,425,030 and a 14-week threshold amount of \$407,995,042.

To determine the FY 2025 end-of-year operating reserves of carryover user fees, the Agency assessed the operating reserve of carryover fees at the end of June 2025 and forecasted collections

and obligations in the fourth quarter of FY 2025 combined. This provides an estimated end-of-year FY 2025 operating reserve of carryover user fees of \$299,623,185, which equates to 10.28 weeks of operations.⁴

Because the estimated FY 2025 end-of-year operating reserves of carryover user fees are within the 10-week and 14-week thresholds, FDA will not increase or reduce the FY 2026 fees or fee revenue under the statutory provision for operating reserve adjustments.

TABLE 11—BASE REVENUE AMOUNT AND SECTION 736(c)(1) THROUGH (4) ADJUSTMENT AMOUNTS

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	\$1,434,377,467
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	72,167,833
Strategic Hiring and Retention Adjustment (section 736(c)(2) of the FD&C Act)	4,000,000
Capacity Planning Adjustment (section 736(c)(3) of the FD&C Act)	0
Additional Dollar Amounts Adjustment (section 736(b)(1)(G) of the FD&C Act)	4,864,860
Operating Reserve Adjustment (section 736(c)(4) of the FD&C Act)	0
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), (3), and (4) of the FD&C Act	1,515,410,160

F. FY 2026 Statutory Fee Revenue Adjustments for Additional Direct Cost

PDUFA VII specifies that an additional direct cost of \$40,627,674 is to be added to the total FY 2026 PDUFA

revenue amount (see section 736(c)(5)(ii) of the FD&C Act). With respect to target revenue for FY 2026, adding the additional direct cost amount of \$40,627,674 to the inflation, strategic hiring and retention, CPA,

additional dollar amount, and operating reserve adjustment results in the total revenue amount of \$1,556,038,000 (rounded to the nearest thousand dollars).

TABLE 12—TOTAL ESTIMATED ADJUSTED REVENUE AMOUNT

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	\$1,434,377,467
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	72,167,833
Strategic Hiring and Retention Adjustment (section 736(c)(2)(B) of the FD&C Act)	4,000,000
Capacity Planning Adjustment (section 736(c)(3) of the FD&C Act)	0
Additional Dollar Amounts Adjustment (section 736(b)(1)(G) of the FD&C Act)	4,864,860
Operating Reserve Adjustment (section 736(c)(4) of the FD&C Act)	0
Additional Direct Cost Adjustment (section 736(c)(5) of the FD&C Act)	40,627,674
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), (3), (4), and (5) of the FD&C Act	1,556,037,834
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), (3), (4), and (5) of the FD&C Act (rounded to the nearest thousand)	1,556,038,000

III. Application Fee Calculations

A. Application Fee Revenues and Application Fees

Application fees will be set to generate 20 percent of the total revenue amount, amounting to \$311,207,600 in FY 2026.

B. Estimate of the Number of Fee-Paying Applications and Setting the Application Fees

FDA has estimated the total number of fee-paying full application

equivalents (FAEs) it expects to receive during the next fiscal year by averaging the number of fee-paying FAEs received in the ten most recently completed fiscal years. For FY 2026 fee setting, the 10 relevant fiscal years are FY 2015–2024. Prior year FAE totals are updated annually to reflect refunds and waivers processed after the close of the fiscal year.⁵

In estimating the number of fee-paying FAEs, an application requiring covered clinical data⁶ counts as one FAE. An application not requiring

covered clinical data counts as one-half of an FAE. An application that is withdrawn before filing, or refused for filing, counts as one-fourth of an FAE if the applicant initially paid a full application fee, or one-eighth of an FAE if the applicant initially paid one-half of the full application fee amount.

As table 13 shows, the average number of fee-paying FAEs received annually in FY 2015 through FY 2024 is 66.469. FDA will set fees for FY 2026 based on this estimate as the number of

⁴ For purposes of the operating reserve adjustment under PDUFA VII, the operating reserve of carryover user fees includes only user fee funds that are available for obligation. FDA excludes from the operating reserve of carryover user fee funds that were collected prior to 2010 and that are held

by FDA, but which are considered unavailable for obligation due to lack of an appropriation (\$78,850,995).

⁵ In the PDUFA fee setting FRNs for FYs 2023 and 2024, this adjustment for refunds was erroneously

excluded, resulting in an overstatement of the historical FAE data.

⁶ As defined in section 736(a)(1)(A)(i) of the FD&C Act.

full application equivalents that will be subject to fees.

TABLE 13—FEE-PAYING FAES

	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	10-year average
Fee-Paying FAEs	81.956	70.483	79.750	68.875	80.000	56.750	78.875	45.125	49.500	53.375	66.469

Note: Prior year FAE totals are updated annually to reflect refunds and waivers processed after the close of the fiscal year.

The FY 2026 application fee is estimated by dividing the average number of full applications that paid fees from FY 2015 through FY 2024, 66.469, into the fee revenue amount to be derived from application fees in FY 2026, \$311,207,600. The result is a fee of \$4,682,003 per full application requiring clinical data, and \$2,341,002 per application not requiring clinical data.

IV. Fee Calculation for Prescription Drug Program Fees

PDUFA VII assesses prescription drug program fees for certain prescription drug products. Program fees will be set to generate 80 percent of the total target revenue, amounting to \$1,244,830,400 in FY 2026.

An applicant will not be assessed more than five program fees for a FY for prescription drug products identified in a single approved NDA or BLA (see section 736(a)(2)(C) of the FD&C Act). Applicants are assessed a program fee for a FY for user fee eligible prescription drug products identified in a human drug application approved as of October 1 of such FY. Additionally, applicants are assessed a program fee for a product that is not a prescription drug product on October 1 because it is included in the discontinued section of the Orange Book or the CDER/CBER Billable Biologics List on that date, if the product becomes a fee-eligible prescription drug product during the FY.

FDA estimates 2,971 program fees will be invoiced in FY 2026 before factoring in waivers, refunds, exceptions, and exemptions. FDA approximates that there will be 97 waivers and refunds granted. Additionally, FDA approximates that another 59 program fees will be exempted in FY 2026 based on the orphan drug exemption in section 736(k) of the FD&C Act.

FDA estimates 2,815 program fees in FY 2026, after allowing for an estimated 156 waivers and reductions, including the orphan drug exemptions, excepted and exempted fee-liable products. The FY 2026 prescription drug program fee rate is calculated by dividing the adjusted total revenue from program

fees (\$1,244,830,400) by the estimated 2815 program fees, resulting in a FY 2026 program fee of \$442,213 (rounded to the nearest dollar).

V. Fee Schedule for FY 2026

The fee rates for FY 2026 are displayed in table 14.

TABLE 14—FEE SCHEDULE FOR FY 2026

Fee category	Fee rates for FY 2026
Application:	
Requiring clinical data	\$4,682,003
Not requiring clinical data	2,341,002
Program	442,213

VI. Fee Payment Options and Procedures

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application subject to fees under PDUFA VII that is submitted on or after October 1, 2025. To pay, complete the Prescription Drug User Fee Cover Sheet, available at https://userfees.fda.gov/OA_HTML/pdufaCacdLogin.jsp, and generate a user fee identification (ID) number. Payment must be made in U.S. currency by electronic check or wire transfer.⁷ The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express).

FDA has partnered with the U.S. Department of the Treasury to use *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on FDA's website after completing the Prescription Drug User Fee Cover Sheet and generating the user fee ID number. Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay> (Note: only full payments are accepted. No partial payments can be made online). Once an

invoice is located, "Pay Now" should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be included, which could result in FDA not filing an application and other penalties. Note: the originating financial institution may charge a wire transfer fee, especially for international wire transfers. Applicable wire transfer fees must be included with payment to ensure fees are paid in full. Questions about wire transfer fees should be addressed to the financial institution. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53-0196965.

B. Prescription Drug Program Fees

FDA will issue invoices and payment instructions for FY 2026 program fees under the new fee schedule in August 2025. Under section 736(a)(2)(A)(i) of the FD&C Act, prescription drug program fees are due on October 1, 2025.

FDA will issue invoices in December 2026 for products that qualify for FY 2026 program fee assessments after the October 2025 billing.

C. Fee Waivers and Refunds

To qualify for consideration for a waiver or reduction under section 736(d) of the FD&C Act, an exemption under section 736(k) of the FD&C Act, or the return of an application or program fee paid under section 736 of the FD&C Act, including if the fee is claimed to have been paid in error, a person must submit to FDA a written request justifying such waiver,

⁷ See "Change in Federal Payment and Collection Options" announcement published in the **Federal Register** on June 27, 2025 (90 FR 27639).

reduction, exemption or return not later than 180 days after such fee is due (section 736(i) of the FD&C Act). A request submitted under this paragraph must include any legal authorities under which the request is made.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14413 Filed 7–29–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2273]

Biosimilar User Fee Rates for Fiscal Year 2026

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the rates for biosimilar user fees for fiscal year (FY) 2026. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Biosimilar User Fee Amendments of 2022 (BsUFA III), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development; review of certain applications for approval of biosimilar biological products; and each biosimilar biological product approved in a biosimilar biological product application. BsUFA III directs FDA to establish, before the beginning of each fiscal year, the amount of initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application and program fees for such year.

DATES: These fees apply to the period from October 1, 2025, through September 30, 2026.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–4989, and the User Fees Support Staff at UFSS@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744G, 744H, and 744I of the FD&C Act (21 U.S.C. 379j–51, 379j–52, and 379j–53), as amended by BsUFA III, authorize the collection of fees for

biosimilar biological products. Under section 744H(a)(1)(A) of the FD&C Act, the initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application or within 7 calendar days after FDA grants the first BPD meeting, whichever occurs first. A sponsor who has paid the initial BPD fee is considered to be participating in FDA's BPD program for that product.

Under section 744H(a)(1)(B) of the FD&C Act, once a sponsor has paid the initial BPD fee for a product, the annual BPD fee is assessed beginning with the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits a marketing application for the product that is accepted for filing, the sponsor discontinues participation in FDA's BPD program for the product, or the sponsor has been administratively removed from the BPD program for the product.

Under section 744H(a)(1)(D) of the FD&C Act, if a sponsor has discontinued participation in FDA's BPD program or has been administratively removed from the BPD program for a product and wants to reengage with FDA on development of the product, the sponsor must pay all annual BPD fees previously assessed for such product and still owed, and a reactivation fee to resume participation in the program. The sponsor must pay the reactivation fee by the earlier of the following dates: (1) no later than 7 calendar days after FDA grants the sponsor's request for a BPD meeting for that product or (2) upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product. The sponsor will be assessed an annual BPD fee beginning in the next fiscal year after payment of the reactivation fee.

BsUFA III also authorizes fees for certain biosimilar biological product applications and for each biosimilar biological product identified in an approved biosimilar biological product application (section 744H(a)(2) and (3) of the FD&C Act). Under certain conditions, FDA will grant a small business a waiver of the biosimilar biological product application fee (section 744H(d)(1) of the FD&C Act).

For FY 2023 through FY 2027, the base revenue amounts for the total revenues from all BsUFA fees are established by BsUFA III. For FY 2026, the base revenue amount is the FY 2025 total revenue amount excluding any

operating reserve adjustment, which equates to the amount of \$56,011,943. The FY 2026 base revenue amount is to be adjusted by the inflation adjustment, strategic hiring and retention adjustment, capacity planning adjustment (CPA), operating reserve adjustment, and the additional dollar amount. Each of these adjustments will be discussed in the sections below.

This document provides fee rates for FY 2026 for the initial and annual BPD fee (\$10,000), for the reactivation fee (\$20,000), for an application requiring clinical data (\$1,200,794) for an application not requiring clinical data (\$600,397) and for the program fee (\$209,097). These fees are effective on October 1, 2025, and will remain in effect through September 30, 2026. For applications that are submitted on or after October 1, 2025, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2026

The base revenue amount for FY 2026 is \$56,011,943 prior to adjustments for inflation, strategic hiring and retention, capacity planning, operating reserves, and the additional dollar amount (see section 744H(b) and (c) of the FD&C Act).

A. FY 2026 Statutory Fee Revenue Adjustments for Inflation

BsUFA III specifies that the \$56,011,943 is to be adjusted for inflation increases for FY 2026 using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 744H(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs shall be the average annual percent change in the cost of all PC&B paid per full-time equivalent (FTE¹) positions at FDA for the first 3 of the preceding 4 fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of the process for the review of biosimilar biological product applications for the first 3 of the preceding 4 fiscal years (see section 744H(c)(1)(B) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified fiscal years and provides the percent changes from the previous fiscal years and the average percent changes over the first 3 of the 4 fiscal years preceding FY 2026. The 3-year average is 5.4494 percent.

¹ Full-time equivalents refer to a paid staff year, rather than a count of individual employees.

TABLE 1—FDA PC&B EACH YEAR AND PERCENT CHANGES

	2022	2023	2024	3-Year average
Total PC&B	\$3,165,477,000	\$3,436,513,000	\$3,791,729,000	
Total FTE	18,474	18,729	19,687	
PC&B per FTE	171,348	183,486	192,601	
Percent Change from Previous Year	4.2967%	7.0838%	4.9677%	5.4494%

The statute specifies that this 5.4494 percent be multiplied by the proportion of PC&B costs to the total FDA costs of the process for the review of biosimilar

biological product applications. Table 2 shows the PC&B and the total obligations for the process for the review of biosimilar biological product

applications for the first 3 of the preceding 4 fiscal years.

TABLE 2—PC&B AS A PERCENT OF TOTAL COST OF THE PROCESS FOR THE REVIEW OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS

	2022	2023	2024	3-Year average
Total PC&B (proportion of costs)	\$34,065,826	\$45,893,774	\$55,198,837	
Total Costs	68,521,689	86,101,288	91,066,972	
PC&B percent	49.7154%	53.3021%	60.6135%	54.5437%

The payroll adjustment is 5.4494 percent from table 1 multiplied by 54.5437 percent (or 2.9723 percent).

The statute specifies that the portion of the inflation adjustment for nonpayroll costs is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban

consumers (Washington-Arlington-Alexandria, DC-VA-MD-WV; not seasonally adjusted; all items; annual index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of the process for the review of biosimilar

biological product applications for the first 3 years of the preceding 4 fiscal years (see section 744H(c)(1)(B) of the FD&C Act). Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Arlington-Alexandria area.²

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

Fiscal year	2022	2023	2024	3-Year average
Annual CPI	296.117	305.317	315.186	
Annual Percent Change	6.6212%	3.1069%	3.2324%	4.3202%

The statute specifies that this 4.3202 percent be multiplied by the proportion of all costs other than PC&B to total costs of the process for the review of biosimilar biological product applications obligated. Since 54.5437 percent was obligated for PC&B (as shown in table 2), 45.4563 percent is the portion of costs other than PC&B (100 percent minus 54.5437 percent equals 45.4563 percent). The non-payroll adjustment is 4.3202 percent times 45.4563 percent, 1.9638 percent.

Next, we add the payroll adjustment (2.9723 percent) to the nonpayroll adjustment (1.9638 percent), for a total inflation adjustment of 4.9361 percent (rounded) for FY 2026.

We then multiply the base revenue amount for FY 2026 (\$56,011,943) by the inflation adjustment percentage (4.9361 percent), yielding an inflation

adjustment of \$2,764,806. Adding this amount yields an inflation-adjusted amount of \$58,776,749.

B. Strategic Hiring and Retention Adjustment

The statute specifies that for each fiscal year, after the annual base revenue is adjusted for inflation, FDA shall further increase the fee revenue and fees by the strategic hiring and retention adjustment, which is \$150,000 for FY 2026 (see section 744H(c)(2) of the FD&C Act).

C. FY 2026 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that the fee revenue and fees shall be further adjusted to reflect changes in the resource capacity needs for the process for the review of biosimilar biological

product applications (see section 744H(c)(3) of the FD&C Act). Following a process agreed upon by FDA and industry during BsUFA II reauthorization discussions and subsequently required in statute, FDA established the capacity planning adjustment methodology and first applied it in the setting of FY 2021 fees. The establishment of this methodology is described in the **Federal Register** at 85 FR 47220. This methodology includes a continuous, iterative improvement approach, under which the Agency intends to refine its data and estimates for the core review activities to improve their accuracy over time.

The CPA methodology consists of four steps:

1. Forecast workload volumes: predictive models estimate the volume of workload for the upcoming FY.

² The data are published by the Bureau of Labor Statistics and can be found on its website at: [https://](https://data.bls.gov/pdq/SurveyOutputServlet?data_)

data.bls.gov/pdq/SurveyOutputServlet?data_

[tool=dropmap&series_id=CUURS35ASA0, CUUSS35ASA0.](https://data.bls.gov/pdq/SurveyOutputServlet?data_)

2. Forecast the resource needs: forecast algorithms are generated utilizing time reporting data. These algorithms estimate the required demand in FTEs for direct review-related effort. This is then compared to current available resources for the direct review-related workload.

3. A managerial adjustment to assess the resource forecast in the context of additional internal factors: program leadership examines operational, financial, and resourcing data to assess whether FDA will be able to utilize additional funds during the fiscal year and whether the funds are required to support additional review capacity. FTE amounts are adjusted, if needed.

4. Convert the FTE need to dollars: utilizing FDA's fully loaded FTE cost model, the final feasible FTEs are converted to an equivalent dollar amount.
- Table 4 summarizes the forecasted workload volumes for BsUFA III in FY 2026 based on predictive models, as well as historical actuals from FY 2024 for comparison.

TABLE 4—BSUFA III ACTUAL FY 2024 WORKLOAD VOLUMES & PREDICTED FY 2026 WORKLOAD VOLUMES

Workload category	FY 2024 actuals	FY 2026 predictions
Original Biosimilar Supplements ¹	49	53
Manufacturing Supplements	128	123
Biosimilar Biological Product Applications	19	17
BsUFA Industry Meetings (BIA, BPD Type 1–4)	162	159
Participating BPD Programs	123	150
Annual Reports ²	54	58
PMR/PMC-Related Documents ²	38	23
Active REMS Programs ^{2,3}	1	1

¹ Includes Supplements with Clinical Data and Labeling Supplements.

² Represents activities related to the review of materials submitted to the application file after approval.

³ Represents the number of Active REMS Programs proportional to Center and User Fee by total number of qualifying products with the exclusion of the Opioid Shared System.

FDA anticipates that any FTE gains could be funded through the expected FY 2026 collections amount without further adjustment from the CPA. As such, FDA determined that in FY 2026 the BsUFA fee amounts do not need

adjustment from the CPA to provide funds for the program.

D. FY 2026 Additional Dollar Amount

For FY 2023 and FY 2024, BsUFA III provided an additional dollar amount for additional FTE for the biosimilar

biological product review program to support enhancements outlined in the BsUFA III Commitment Letter. For FY 2025, FY 2026, and FY 2027, no additional amount is specified in statute.

TABLE 5—BASE REVENUE AMOUNT AND ADJUSTMENTS PRIOR TO OPERATIVE RESERVE ADJUSTMENT

Fee	Amount
Base Revenue Amount (Section 744H(b)–(c) of the FD&C Act)	\$56,011,943
Inflation Adjustment (Section 744H(c)(1) of the FD&C Act)	2,764,806
Strategic Hiring and Retention Adjustment (Section 744H(c)(2) of the FD&C Act)	150,000
Capacity Planning Adjustment (Section 744H(c)(3) of the FD&C Act)	0
Additional Dollar Amount	0
Cumulative Revenue Amount Prior to Operative Reserve Adjustment	58,926,749

E. FY 2026 Statutory Fee Revenue Adjustments for Operating Reserve

BsUFA III sets forth an operating reserve adjustment to the fee revenue and fees. Specifically, for FY 2026, the statute directs FDA: (1) to increase the fee revenue and fees if such an adjustment is necessary to provide for at least 10 weeks of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications and (2) if FDA has carryover balances for such process in excess of 21 weeks of such operating reserves, to decrease such fee revenue and fees to provide for not more than 21 weeks of such operating reserves (see section 744H(c)(4) of the FD&C Act).

To calculate the 10-week and 21-week threshold amounts for the FY 2026 operating reserve adjustment, the

estimated adjusted revenue amount (*i.e.*, the base revenue amount and adjustments prior to the operating reserve adjustment), \$58,926,749 is divided by 52, resulting in a \$1,133,207 cost of operation for 1 week (rounded to the nearest dollar). The 1-week value (\$1,133,207) is then multiplied by 10 weeks to generate the 10-week operating reserve threshold amount for FY 2026 of \$11,332,067. The 1-week value is multiplied by 21 to generate the 21-week operating reserve threshold amount for FY 2026 of \$23,797,341.

To calculate the estimated operating reserve of carryover user fees at the end of FY 2025, FDA estimated the operating reserves of carryover fees at the end of June 2025. The balance of operating reserves of carryover fees at the end of June 2025 is combined with

the forecasted collections and obligations for the remainder of FY 2025 to generate a full year estimate for FY 2025. The estimated operating reserve of carryover user fees at the end of FY 2025 is \$26,883,182.

The estimated operating reserve of carryover user fees at the end of FY 2025 of \$26,883,182 is above the 21-week threshold allowable operating reserve of carryover user fees for FY 2026 of \$23,797,341. As such, FDA is applying a downward operating reserve adjustment of \$3,085,841 (rounded to the nearest dollar), an amount equivalent to a reduction of approximately 2.72 weeks of operations, to bring the operating reserve of carryover user fees to \$23,797,341 or 21 weeks of operations at the start of FY 2026. With this operating reserve

adjustment, the estimated adjusted revenue amount of \$58,926,749 will be

lowered by \$3,085,841, yielding the FY 2026 target revenue amount of

\$55,841,000 (rounded to the nearest thousand), summarized below.

TABLE 6—TOTAL ESTIMATED ADJUSTED REVENUE AMOUNT

Fee	Amount
Base Revenue Amount (Section 744H(b)–(c) of the FD&C Act)	\$56,011,943
Inflation Adjustment (Section 744H(c)(1) of the FD&C Act)	2,764,806
Strategic Hiring and Retention Adjustment (Section 744H(c)(2) of the FD&C Act)	150,000
Capacity Planning Adjustment (Section 744H(c)(3) of the FD&C Act)	0
Additional Dollar Amount	0
Operating Reserve Adjustment	(3,085,841)
Total Revenue Amount in sections 744H(b)–(c), 744H(c)(1), (2), (3) of the FD&C Act	55,840,908
Total Revenue Amount in sections 744H(b)–(c), 744H(c)(1), (2), (3) of the FD&C Act (rounded to the nearest thousand dollars)	55,841,000

III. Fee Amounts for FY 2026

Under section 744H(b)(2)(A) of the FD&C Act, FDA must determine the percentage of the total revenue amount for a fiscal year to be derived from: (1) initial and annual BPD fees, and reactivation fees; (2) biosimilar biological product application fees; and (3) biosimilar biological product program fees. As described above, a downward operating reserve adjustment is required for FY 2026. The operating reserve adjustment in subsequent years may not be as large. As such, the target revenue in FY 2026 may be lower than in prior or future years, and thereby the fee amounts may also be lower than in prior or future years.

A. Application Fees

To calculate the biosimilar biological product application fee, FDA estimated the number of full application equivalents (FAEs) that will be submitted in FY 2026. A filed original 351(k) BLA with clinical data counts as one FAE. A filed original 351(k) BLA without clinical data counts as one-half of an FAE. An original 351(k) BLA that is refused to file (RTF) or withdrawn before filing (WD), counts as one-fourth of an FAE if the application required clinical data, or one-eighth of an FAE if the application did not require clinical data. After an original 351(k) BLA has been RTF or WD, the applicant has the option of resubmitting. For user fee purposes, these resubmitted original 351(k) BLAs are equivalent to original 351(k) BLA submissions. Filed original 351(k) BLA resubmissions are charged the full amount for an application with clinical data (one FAE) or without clinical data (one-half FAE). Additionally, a filed original 351(k) BLA with or without clinical data that is granted a small business waiver (SBW) from the application fee counts as zero FAE.

As discussed in II.C above, FDA estimates that 17 original 351(k) BLAs will be submitted in FY 2026. Based on

recent years' data regarding SBWs, original 351(k) BLAs with or without clinical data, original 351(k) BLAs that are RTF or WD, and considering that some of these applications may be resubmitted in the same fiscal year, it is assumed that the 17 submissions will equate to 16 FAEs.

For FY 2026 the biosimilar biological product application fee for applications requiring clinical data is \$1,200,794. Applications not requiring clinical data pay half that fee, or \$600,397. This is estimated to provide a total of \$19,212,704 representing 34 percent (rounded to the nearest whole number) of the FY 2026 target revenue amount.

B. Biosimilar Biological Product Program Fee

Under BsUFA III, FDA assesses biosimilar biological product program fees ("program fees"). An applicant in a biosimilar biological product application shall not be assessed more than five program fees for a fiscal year for biosimilar biological products identified in a single biosimilar biological product application (see section 744H(a)(3)(D) of the FD&C Act). Applicants are assessed a program fee for a fiscal year for biosimilar biological products that are identified in a biosimilar biological product application approved as of October 1 of such fiscal year; that may be dispensed only under prescription pursuant to section 503(b) of the FD&C Act; and that, as of October 1 of such fiscal year, do not appear on a list developed and maintained by FDA of discontinued biosimilar biological products. An approved biosimilar biological product that appears on the list of discontinued biosimilar biological products as of October 1 of a fiscal year would also be assessed the program fee if it is removed from the discontinued list during the fiscal year and the other statutory criteria for fee assessment are satisfied (see section 744H(a)(3)(E)(iii) of the FD&C Act).

Based on available information, FDA estimates that 168 program fees will be invoiced for FY 2026. For products invoiced in the FY 2026 regular billing cycle, FDA anticipates that zero program fees will be refunded.

For FY 2026, the biosimilar biological product program fee is \$209,097. This is estimated to provide a total of \$35,128,296, representing 63 percent (rounded to the nearest whole number) of the FY 2026 target revenue amount.

C. Initial and Annual BPD Fees, and Reactivation Fees

To estimate the number of BPD fees to be paid in FY 2026, FDA must consider the number of new BPD programs, the number of current BPD programs, and the number of BPD programs that will be reactivated. These estimates provide information that, when aggregated, allows FDA to set BPD fees (initial BPD fees, annual BPD fees, reactivation fees).

FDA analyzed available data to estimate the total number of BPD programs for FY 2026. In FY 2026, FDA estimates approximately 30 new BPD programs, no reactivations (a single reactivation is weighted as two BPD fees), and approximately 120 BPD programs to pay the annual BPD fee, yielding a rounded total estimated equivalent of 150 BPD fees to be collected in FY 2026. The remainder of the target revenue of \$1,500,000 or 3 percent is to be collected from the BPD fees. Dividing this amount by the estimated 150 BPD fees to be paid equals an initial BPD and annual BPD fee amount of \$10,000 (rounded to the nearest dollar). The reactivation fee is set at twice the initial/annual BPD amount at \$20,000 (rounded to the nearest dollar).

IV. Fee Schedule for FY 2026

The fee rates for FY 2026 are displayed in table 7.

TABLE 7—FEE SCHEDULE FOR FY 2026

Fee category	Fee rates for FY 2026
Initial BPD	\$10,000
Annual BPD	10,000
Reactivation	20,000
Applications:	
Requiring Clinical Data	1,200,794
Not Requiring Clinical Data	600,397
Program Fee	209,097

V. Fee Payment Options and Procedures

A. Initial BPD, Reactivation, and Application Fees

The fees established in the new fee schedule apply to FY 2026, *i.e.*, the period from October 1, 2025, through September 30, 2026. The initial BPD fee for a product is due when the sponsor submits an IND that FDA determines is intended to support a biosimilar biological product application for the product or within 7 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. Sponsors who have discontinued participation in the BPD program for a product or have been administratively removed from the BPD program for a product, and seek to resume participation in the BPD program for the product must pay all annual BPD fees previously assessed for such product and still owed and the reactivation fee by the earlier of the following dates: no later than 7 calendar days after FDA grants the sponsor's request for a BPD meeting for that product, or upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product.

The application fee for a biosimilar biological product is due upon submission of the application (see section 744H(a)(2)(C) of the FD&C Act).

To make a payment of the initial BPD, reactivation, or application fee, complete the Biosimilar User Fee Cover Sheet, available on FDA's website (<https://www.fda.gov/bsufa>) and https://userfees.fda.gov/OA_HTML/bsufaCAcdLogin.jsp, and generate a user fee identification (ID) number. Payment must be made in U.S. currency by electronic check or wire transfer.³ The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as

eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to use www.pay.gov, a web-based payment application, for online electronic payment. The www.pay.gov feature is available on the FDA website after the user fee ID number is generated. Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay> (Note: only full payments are accepted. No partial payments can be made online). Once you search for your invoice, click "Pay Now" to be redirected to www.pay.gov. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No: 75060099, Routing No: 021030004, SWIFT: FRNYUS33. FDA's tax identification number is 53-0196965.

B. Annual BPD and Program Fees

FDA will issue invoices with payment instructions for FY 2026 annual BPD and program fees under the new fee schedule in August 2025. Under sections 744H(a)(1)(B)(ii) and 744H(a)(3)(B) of the FD&C Act, annual BPD and program fees will be due on October 1, 2025.

If sponsors join the BPD program after the annual BPD invoices have been issued in August 2025, FDA will issue invoices in December 2025 to sponsors subject to fees for FY 2026 that qualify for the annual BPD fee after the August 2025 billing. FDA will issue invoices in December 2026 for any products that qualify for the annual program fee after the August 2025 billing.

C. Waivers and Returns

To qualify for consideration for a small business waiver under section 744H(d) of the FD&C Act, or the return

of any fee paid under section 744H of the FD&C Act, including if the fee is claimed to have been paid in error, a person shall submit to FDA a written request justifying such waiver or return and, except as otherwise specified in section 744H of the FD&C Act, such written request shall be submitted to FDA not later than 180 days after such fee is due. Such written request shall include any legal authorities under which the request is made. See section 744H(h) of the FD&C Act.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-14416 Filed 7-29-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0008]

Arthritis Advisory Committee; Termination

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the termination of the Agency's Arthritis Advisory Committee (Committee) by the Commissioner of Food and Drugs (Commissioner). The Commissioner has determined that it is not necessary to continue to maintain this Committee.

DATES: This Committee will terminate on the date of publication of this notice.

FOR FURTHER INFORMATION CONTACT:

Emily Helms Williams, Director, Advisory Committee Oversight and Management Staff, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3240, Silver Spring, MD 20993, 301-796-3381, Emily.HelmsWilliams@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Arthritis Advisory Committee was established on April 5, 1974 (39 FR 14737-14738), to advise the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use in arthritic conditions, and as required, any other product for which FDA has regulatory responsibility. This Committee has met infrequently in recent years, and FDA has determined that the effort and expense of

³ See "Change in Federal Payment and Collection Options" announcement published in the **Federal Register** on June 27, 2025 (90 FR 27639).

maintaining the Committee is no longer justified. This Committee is therefore terminated, effective on July 30, 2025, in accordance with 21 CFR 14.55. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463) (5 U.S.C. 1001 *et seq.*). Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule announcing the removal of the Arthritis Advisory Committee from the Agency's list of standing advisory committees.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14345 Filed 7–29–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2248]

Generic Drug User Fee Rates for Fiscal Year 2026

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (FD&C Act or statute), as

amended by the Generic Drug User Fee Amendments of 2022 (GDUFA III), authorizes the Food and Drug Administration (FDA, Agency, or we) to assess and collect fees for abbreviated new drug applications (ANDAs); drug master files (DMFs); generic drug active pharmaceutical ingredient (API) facilities, finished dosage form (FDF) facilities, and contract manufacturing organization (CMO) facilities; and generic drug applicant program user fees. In this document, FDA is announcing fiscal year (FY) 2026 rates for GDUFA III fees.

DATES: These fees are effective on October 1, 2025, and will remain in effect through September 30, 2026.

FOR FURTHER INFORMATION CONTACT: For more information on human generic drug fees, visit FDA's website at: <https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments>. For questions relating to this notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240–402–4989; or the User Fees Support Staff at UFSS@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744A and 744B of the FD&C Act (21 U.S.C. 379j–41 and 379j–42), as

amended by GDUFA III, authorize FDA to assess and collect fees associated with human generic drug products. Fees are assessed on: (1) certain types of applications for human generic drug products; (2) certain facilities where APIs and FDFs are produced; (3) certain DMFs associated with human generic drug products; and (4) generic drug applicants who own one or more approved ANDAs (the program fee) (see section 744B(a)(2) through (5) of the FD&C Act). For more information about GDUFA III, please refer to the FDA website (<https://www.fda.gov/gdufa>).

For FY 2026, the generic drug user fee rates are ANDA (\$358,247), DMF (\$102,584), domestic API facility (\$43,549), foreign API facility (\$58,549), domestic FDF facility (\$238,943), foreign FDF facility (\$253,943), domestic CMO facility (\$57,346), foreign CMO facility (\$72,346), large size operation generic drug applicant program (\$1,918,377), medium size operation generic drug applicant program (\$767,351), and small business generic drug applicant program (\$191,838). These fees are effective on October 1, 2025, and will remain in effect through September 30, 2026. The fee rates for FY 2026 are set out in table 1.

TABLE 1—FEE SCHEDULE FOR FY 2026

Fee category	Fee rates for FY 2026
Applications:	
Abbreviated New Drug Application (ANDA)	\$358,247
Drug Master File (DMF)	102,584
Facilities:	
Active Pharmaceutical Ingredient (API)—Domestic	43,549
API—Foreign	58,549
Finished Dosage Form (FDF)—Domestic	238,943
FDF—Foreign	253,943
Contract Manufacturing Organization (CMO)—Domestic	57,346
CMO—Foreign	72,346
GDUFA Program:	
Large size operation generic drug applicant	1,918,377
Medium size operation generic drug applicant	767,351
Small business generic drug applicant	191,838

II. Fee Revenue Amount for FY 2026

Under section 744B(b)(1)(B)(ii) of the FD&C Act, the base revenue amount for FY 2026 for GDUFA III is \$638,961,803. Under section 744B(c)(1) of the FD&C Act, applicable inflation adjustments to base revenue shall be made beginning with FY 2024.

Under section 744B(c)(2) of the FD&C Act, for FY 2026, FDA shall, in addition to the inflation adjustment, apply a capacity planning adjustment to further

adjust, as needed, the fee revenue and fees to reflect changes in the resource capacity needs of FDA for human generic drug activities.

Under section 744B(c)(3) of the FD&C Act, for FY 2026, FDA may, in addition to the inflation and capacity planning adjustments, apply an operating reserve adjustment to further increase the fee revenue and fees if necessary to provide operating reserves of carryover user fees for human generic drug activities for not

more than the number of weeks specified in such section (or as applicable, shall apply such adjustment to decrease the fee revenues and fees to provide for not more than 12 weeks of such operating reserves).

A. Inflation Adjustment

As noted above, the base revenue amount for FY 2026 is \$638,961,803. This is the total revenue amount specified for the prior fiscal year, FY

2025, pursuant to the statute (see section 744B(b)(1)(A) of the FD&C Act).¹ GDUFA III specifies that the \$638,961,803 is to be adjusted for inflation for FY 2026 using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see sections 744B(c)(1)(B) and (C) of the FD&C Act).

The component of the inflation adjustment for PC&B costs shall be the average annual percent change in the cost of all PC&B paid per full-time equivalent (FTE) positions at FDA for the first 3 of the 4 preceding fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of human generic drug activities for the first 3 of

the preceding 4 fiscal years (see section 744B(c)(1)(B) of the FD&C Act). Table 2 summarizes the actual cost and total FTEs for the specified fiscal years and provides the percent change from the previous fiscal year and the average percent change over the first 3 of the 4 fiscal years preceding FY 2026. The 3-year average is 5.4494 percent.

TABLE 2—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE

Fiscal year	2022	2023	2024	3-Year average
Total PC&B	\$3,165,477,000	\$3,436,513,000	\$3,791,729,000	
Total FTEs	18,474	18,729	19,687	
PC&B per FTE	\$171,348	\$183,486	\$192,601	
Percent Change from Previous Year	4.2967%	7.0838%	4.9677%	5.4494%

The statute specifies that this 5.4494 percent should be multiplied by the proportion of PC&B expended for

human generic drug activities for the first 3 of the preceding 4 fiscal years. Table 3 shows the amount of PC&B and

the total amount obligated for human generic drug activities from FY 2022 through FY 2024.

TABLE 3—PC&B AS A PERCENT OF FEE REVENUES SPENT ON HUMAN GENERIC DRUG ACTIVITIES OVER THE LAST 3 YEARS

Fiscal year	2022	2023	2024	3-Year average
PC&B	\$391,922,747	\$441,930,068	\$479,495,256	
Non-PC&B	\$289,479,265	\$301,930,017	\$278,861,828	
Total Costs	\$681,402,012	\$743,860,085	\$758,357,084	
PC&B Percent	57.5171%	59.4104%	63.2282%	60.0519%
Non-PC&B Percent	42.4829%	40.5896%	36.7718%	39.9481%

The payroll adjustment is 5.4494 percent multiplied by 60.0519 percent (or 3.2725 percent). The statute specifies that the portion of the inflation adjustment for non-PC&B costs for FY 2026 is the average annual percent change that occurred in

the Consumer Price Index (CPI) for urban consumers (Washington-Arlington-Alexandria Area, DC–VA–MD–WV; not seasonally adjusted; all items; annual index) for the first 3 of the preceding 4 years of available data multiplied by the proportion of all costs

other than PC&B costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years (see section 744B(c)(1)(C) of the FD&C Act). Table 4 provides the summary data for the percent change in the specified CPI.²

TABLE 4—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

Year	2022	2023	2024	3-Year average
Annual CPI	296.117	305.317	315.186	
Annual Percent Change	6.6212%	3.1069%	3.2324%	4.3202%

To calculate the inflation adjustment for non-pay costs, we multiply the 3-year average percent change in the CPI (4.3202 percent) by the proportion of all costs other than PC&B to total costs of human generic drug activities obligated. Because 60.0519 percent was obligated for PC&B as shown in table 3, 39.9481 percent is the portion of costs other than PC&B. The non-pay adjustment is 4.3202 percent times 39.9481 percent, or 1.7258 percent.

To complete the inflation adjustment for FY 2026, we add the PC&B component (3.2725 percent) to the non-PC&B component (1.7258 percent) for a total inflation adjustment of 4.9983 percent (rounded), and then add 1, making an inflation adjustment multiple of 1.049983. We then multiply the base revenue amount for FY 2026 (\$638,961,803) by 1.049983, yielding an inflation-adjusted amount of \$670,899,031.

B. FY 2026 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after the base revenue amount for FY 2026 of \$638,961,803 has been adjusted for inflation as described in section A above, the resulting amount shall be further adjusted to reflect changes in the resource capacity needs for human generic drug activities (see section 744B(c)(2) of the FD&C Act). Following a process required in the statute, FDA

¹ Under section 744B(b)(1)(B)(ii) of the FD&C Act, the base revenue amount for a fiscal year is equal to the total revenue amount established for the previous fiscal year, not including any adjustments

for such previous fiscal year under section 744B(c)(3).

² The data are published by the Bureau of Labor Statistics and can be found on its website at: https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0, CUUSS35ASA0.

established the capacity planning adjustment (CPA) methodology that is derived from the methodology and recommendations made in the report titled “Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology: Evaluation and Recommendations” as announced in the **Federal Register** of August 3, 2020, and incorporating approaches and attributes determined appropriate by the Agency, except that the workload drivers are limited to those specified in the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027 (GDUFA III Commitment Letter).³ This methodology includes a continuous, iterative improvement approach, under

which the Agency intends to refine its data and estimates for the core review activities to improve the accuracy of its data and estimates over time.⁴

The CPA methodology consists of four steps:

1. *Forecast workload volumes:* predictive models estimate the volume of workload for the upcoming FY.

2. *Forecast the resource needs:* forecast algorithms are generated utilizing time reporting data. These algorithms estimate the required demand in FTEs⁵ for direct review-related effort. This is then compared to current available resources for the direct review-related workload.

3. *A managerial adjustment to assess the resource forecast in the context of additional internal factors:* program

leadership examines operational, financial, and resourcing data to assess whether FDA will be able to utilize additional funds during the fiscal year, and whether the additional funds are required to support additional review capacity. FTE amounts are adjusted, if needed.

4. *Convert the FTE need to dollars:* utilizing FDA’s fully loaded FTE cost model, the final feasible FTEs are converted to an equivalent dollar amount.

Table 5 summarizes the forecasted workload volumes for the Center for Drug Evaluation and Research (CDER) for FY 2026 based on predictive models, as well as historical actuals from FY 2024 for comparison.

TABLE 5—CDER ACTUAL FY 2024 WORKLOAD VOLUMES AND PREDICTED FY 2026 WORKLOAD VOLUMES

Workload driver category	FY 2024 actuals	FY 2026 predictions
ANDA Originals ¹	713	618
ANDA Supplements ²	11,807	11,699
Pre-ANDA Meetings	95	91
Controlled Correspondences ³	3,277	3,092
Suitability Petitions	111	52
ANDA Annual Reports ⁴	13,395	14,499
Active REMS Programs ^{4 5}	53	53

¹ Excludes response to refused to receive (RTR) and Orig-2+. ANDA Original and Resubmissions/Amendments captured in time reporting data.

² Includes changes being effected (CBE) and prior approval supplement (PAS) Manufacturing and Labeling Supplements. PAS exclude response to RTRs, risk evaluation and mitigation strategies (REMS) and Bioequivalence Supplements. ANDA Supplement and Resubmissions/Amendments captured in time reporting data.

³ Includes all requesting controlled correspondences.

⁴ Data represents workload related to resource needs for post-marketing safety activities (developed in alignment with the methodology used in fee-setting under PDUFA (section 736 of the FD&C Act) (21 U.S.C. 379h) and BsUFA (section 744H of the FD&C Act) (21 U.S.C. 379j–52)), as applicable.

⁵ Represents the percentage of Active REMS Programs proportional to Center and User Fee by total number of qualifying products with the exclusion of the Opioid Shared System.

FDA anticipates that any FTE gains could be funded through the expected FY 2026 collections amount without

further adjustment from the CPA. As such, FDA determined that in FY 2026 the GDUFA fee amounts do not need

adjustment from the CPA to provide funds for the program.

TABLE 6—BASE REVENUE AMOUNT AND SECTION 744B(c)(1) AND (2) ADJUSTMENT AMOUNTS

Fee	Amount
Statutory Fee Revenue Base Amount (section 744B(b)(1) of the FD&C Act)	\$638,961,803
Inflation Adjustment (section 744B(c)(1) of the FD&C Act)	31,937,228
Capacity Planning Adjustment (section 744B(c)(2) of the FD&C Act)	0
Revenue Amount after Adjustments in sections 744B(b)(1), 744B(c)(1), and 744B(c)(2) of the FD&C Act	670,899,031

C. FY 2026 Statutory Fee Revenue Adjustments for Operating Reserve

Under section 744B(c)(3) of the FD&C Act, for FY 2026, FDA may, in addition to the inflation and capacity planning adjustments, apply an operating reserve adjustment to further increase the fee

revenue and fees if necessary to provide operating reserves of carryover user fees for human generic drug activities for not more than the number of weeks specified in such section (or as applicable, shall apply such adjustment to decrease the fee revenues and fees to

provide for not more than 12 weeks of such operating reserves).

The upward operating reserve adjustment is discretionary. For FY 2026, FDA may take an adjustment to provide for not more than 10 weeks of operating reserve. If carryover is more than 12 weeks of operating reserve, FDA

³ Section 744B(c)(2)(B) of the FD&C Act; see also section VIII.B.2.e. of the GDUFA III Commitment Letter available at <https://www.fda.gov/media/153631/download>.

⁴ For example, FDA will aim to refine the CPA methodology to reflect a more comprehensive assessment of the applicable workload drivers across the Agency.

⁵ Full-time equivalents refer to a paid staff year, rather than a count of individual employees.

must decrease the fee revenues and fees to provide for not more than 12 weeks of operating reserve. To calculate the 10-week and 12-week threshold amounts for the FY 2026 operating reserve adjustment, the FY 2026 adjusted revenue amount, \$670,899,031 is divided by 52, resulting in a \$12,901,904 cost of operation for 1 week. The 1-week value is then multiplied by 10 weeks to generate the 10-week operating reserve threshold

amount for FY 2026 of \$129,019,040. The 1-week value is multiplied by 12 to generate the 12-week operating reserve threshold amount for FY 2026 of \$154,822,848.

To determine the FY 2025 end-of-year operating reserves of carryover user fees, the Agency assessed the operating reserve of carryover user fees at the end of June 2025 and forecast collections and obligations in the fourth quarter of FY 2025 combined. This provides an

estimated end-of-year FY 2025 operating reserve of carryover user fees of \$126,429,724 which equates to 9.80 weeks of operations. As the estimated end-of-year FY 2025 operating reserve of carryover user fees is just below the 10-week discretionary increase threshold, there will not be an operating reserve adjustment.

Table 7 below summarizes FY 2026 fee revenue.

TABLE 7—TOTAL ESTIMATED ADJUSTED REVENUE AMOUNT

Fee	Amount
Statutory Fee Revenue Base Amount (section 744B(b)(1) of the FD&C Act)	\$638,961,803
Inflation Adjustment (section 744B(c)(1) of the FD&C Act)	31,937,228
Capacity Planning Adjustment (section 744B(c)(2) of the FD&C Act)	0
Operating Reserve Adjustment (section 744B(c)(3) of the FD&C Act)	0
Total Revenue Amount (sections 744B(b)(1), 744B(c)(1), 744B(c)(2) and 744B(c)(3) of the FD&C Act)	670,899,031
Total Revenue Amount (rounded to the nearest thousand dollars) (sections 744B(b)(1), 744B(c)(1), 744B(c)(2) and 744B(c)(3) of the FD&C Act) (rounded to the nearest thousand)	670,899,000

III. ANDA Filing Fee

Under GDUFA III, the FY 2026 ANDA filing fee is owed by each applicant that submits an ANDA on or after October 1, 2025.⁶ This fee is due on the submission date of the ANDA. Section 744B(b)(2)(B) of the FD&C Act specifies that the ANDA fee will make up 33 percent of the \$670,899,000, which is \$221,396,670.

To calculate the ANDA fee, FDA estimated the number of full application equivalents (FAEs) that will be submitted in FY 2026. The submissions are broken down into three categories: new originals (submissions that have not been received by FDA previously), submissions that FDA RTR for reasons other than failure to pay fees, and applications that are resubmitted after an RTR decision for reasons other than failure to pay fees. An ANDA counts as one FAE; however, 75 percent of the fee paid for an ANDA that has been RTR shall be refunded according to GDUFA III if: (1) the ANDA is refused for a cause other than failure to pay fees or (2) the ANDA has been withdrawn prior to receipt (section 744B(a)(3)(D)(i) of the FD&C Act). Therefore, an ANDA that is considered not to have been received by FDA due to reasons other than failure to pay fees or withdrawn prior to receipt counts as one-fourth of an FAE. After an ANDA has been RTR, the applicant has the option of resubmitting. For user fee purposes, these resubmissions are equivalent to new original submissions: ANDA resubmissions are charged the

full amount for an application (one FAE).

As shown in table 5, FDA estimates that 618 new original ANDAs will be submitted and incur filing fees in FY 2026. Not all the new original ANDAs will be received by FDA and some of those not received will be resubmitted in the same fiscal year. After accounting for these factors, FDA expects that the FAE count for ANDAs will be 617.66, rounded to 618 for FY 2026.

The FY 2026 ANDA filing fee is estimated by dividing the number of FAEs that will incur the fee in FY 2026 (618) into the fee revenue amount to be derived from ANDA filing fees in FY 2026 (\$221,396,670). The result, rounded to the nearest dollar, is a fee of \$358,247 per ANDA.

The statute provides that those ANDAs that include information about the production of APIs other than by reference to a DMF will pay an additional fee that is based on the number of such APIs and the number of facilities proposed to produce those ingredients (see section 744B(a)(3)(F) of the FD&C Act). FDA anticipates that this additional fee is unlikely to be assessed often; therefore, FDA has not included projections concerning the amount of this fee in calculating the fees for ANDAs.

IV. DMF Fee

Under GDUFA III, the DMF fee is owed by each person that owns a type II API DMF that is referenced, on or after October 1, 2012, in a generic drug submission by an initial letter of

authorization.⁷ This is a one-time fee for each DMF. This fee is due on the earlier of the date on which the first generic drug submission is submitted that references the associated DMF or the date on which the DMF holder requests the initial completeness assessment. Under section 744B(a)(2)(D)(iii) of the FD&C Act, if a DMF has successfully undergone an initial completeness assessment and the fee is paid, the DMF will be placed on a publicly available list documenting DMFs available for reference.

To calculate the DMF fee, FDA assessed the volume of DMF submissions over time. FDA assessed DMFs from October 1, 2022, to April 30, 2025, and concluded that averaging the number of fee-paying DMFs provided the most accurate model for predicting fee-paying DMFs for FY 2026. The monthly average of paid DMF submissions FDA received from FY 2023 through April 2025 is 27.3. To determine the FY 2026 projected number of fee-paying DMFs, the average of 27.3 DMF submissions is multiplied by 12 months, which results in 327 estimated FY 2026 fee-paying DMFs. FDA is estimating 327 fee-paying DMFs for FY 2026.

The FY 2026 DMF fee is determined by dividing the DMF target revenue by the estimated number of fee-paying DMFs in FY 2026. Section 744B(b)(2)(A) of the FD&C Act specifies that the DMF fees will make up 5 percent of the \$670,899,000, which is \$33,544,950. Dividing the DMF revenue amount

⁶ Section 744B(a)(3) of the FD&C Act.

⁷ Section 744B(a)(2) of the FD&C Act.

(\$33,544,950) by the estimated fee-paying DMFs (327), and rounding to the nearest dollar, yields a DMF fee of \$102,584 for FY 2026.

V. Foreign Facility Fee Differential

Under GDUFA III, the fee for a facility located outside the United States and its territories and possessions shall be \$15,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions.⁸ The basis for this differential is the extra cost incurred by conducting an inspection outside the United States and its territories and possessions.

VI. FDF and CMO Facility Fees

Under GDUFA III, the annual FDF facility fee is owed by each person who owns an FDF facility that is identified in at least one approved generic drug submission owned by that person or its affiliates.⁹ The CMO facility fee is owed by each person who owns an FDF facility that is identified in at least one approved ANDA but is not identified in an approved ANDA held by the owner of that facility or its affiliates.¹⁰ Section 744B(b)(2)(C) of the FD&C Act specifies that the FDF and CMO facility fee revenue will make up 20 percent of the \$670,899,000, which is \$134,179,800.

To calculate the fees, data from FDA's Integrity Services (IS) were utilized as the primary source of facility information for determining the denominators of each facility fee type. IS is the master data steward for all facility information provided in generic drug submissions received by FDA. A facility's reference status in an approved generic drug submission is extracted directly from submission data rather than relying on data from self-identification. This information provided the number of facilities referenced as FDF manufacturers in at least one approved generic drug submission. These findings were compared against facility statuses from FDA's Office of Inspections and Investigations (OI) to exclude facilities that are no longer operational.

Based on these data, the FDF and CMO facility denominators are 153 FDF domestic, 325 FDF foreign, 84 CMO domestic, and 142 CMO foreign facilities for FY 2026.

GDUFA III specifies that the CMO facility fee is to be equal to 24 percent of the FDF facility fee.¹¹ Therefore, to generate the target collection revenue

amount from FDF and CMO facility fees (\$134,179,800), FDA must weight a CMO facility as 24 percent of an FDF facility. FDA set fees based on the estimate of 153 FDF domestic, 325 FDF foreign, 20.16 CMO domestic (84 multiplied by 24 percent), and 34.08 CMO foreign facilities (142 multiplied by 24 percent), which equals 532.24 total weighted FDF and CMO facilities for FY 2026.

To calculate the fee for domestic facilities, FDA first determines the total fee revenue that will result from the foreign facility differential by subtracting the fee revenue resulting from the foreign facility fee differential from the target collection revenue amount (\$134,179,800) as follows: the foreign facility fee differential revenue equals the foreign facility fee differential (\$15,000) multiplied by the number of FDF foreign facilities (325) plus the foreign facility fee differential (\$15,000) multiplied by the number of CMO foreign facilities (142), totaling \$7,005,000. This results in foreign fee differential revenue of \$7,005,000 from the total FDF and CMO facility fee target collection revenue.

Subtracting the foreign facility differential fee revenue (\$7,005,000) from the total FDF and CMO facility target collection revenue (\$134,179,800) results in a remaining facility fee revenue balance of \$127,174,800. To determine the domestic FDF facility fee, FDA divides the \$127,174,800 by the total weighted number of FDF and CMO facilities (532.24), which results in a domestic FDF facility fee of \$238,943. The foreign FDF facility fee is \$15,000 more than the domestic FDF facility fee, or \$253,943.

According to GDUFA III, the domestic CMO fee is calculated as 24 percent of the amount of the domestic FDF facility fee.¹² Therefore, the domestic CMO fee is \$57,346, rounded to the nearest dollar. The foreign CMO fee is calculated as the domestic CMO fee plus the foreign fee differential of \$15,000. Therefore, the foreign CMO fee is \$72,346.

VII. API Facility Fee

Under GDUFA III, the annual API facility fee is owed by each person who owns a facility that is identified in at least one approved generic drug submission in which the facility is approved to produce one or more API or in a Type II API DMF referenced in at least one approved generic drug submission.¹³ Section 744B(b)(2)(D) of the FD&C Act specifies the API facility

fee will make up 6 percent of \$670,899,000 in fee revenue, which is \$40,253,940.

To calculate the API facility fee, data from FDA's IS were utilized as the primary source of facility information for determining the denominator. As stated above, IS is the master data steward for all facility information provided in generic drug submissions received by FDA. A facility's reference status in an approved generic drug submission is extracted directly from submission data rather than relying on data from self-identification. This information provided the number of facilities referenced as API manufacturers in at least one approved generic drug submission. These findings were compared against facility statuses from FDA's OII to exclude facilities that are no longer operational.

Based on these data, the total number of API facilities identified was 707; of that number, 76 were domestic and 631 were foreign facilities. The foreign facility differential is \$15,000. To calculate the fee for domestic facilities, FDA must first subtract the fee revenue that will result from the foreign facility fee differential. FDA takes the foreign facility differential (\$15,000) and multiplies it by the number of foreign facilities (631) to determine the total fee revenue that will result from the foreign facility differential. As a result of this calculation, the foreign fee differential revenue will make up \$9,465,000 of the total API fee revenue. Subtracting the foreign facility differential fee revenue (\$9,465,000) from the total API facility target revenue (\$40,253,940) results in a remaining balance of \$30,788,940. To determine the domestic API facility fee, we divide the \$30,788,940 by the total number of facilities (707), which gives us a domestic API facility fee of \$43,549. The foreign API facility fee is \$15,000 more than the domestic API facility fee, or \$58,549.

VIII. Generic Drug Applicant Program Fee

Under GDUFA III, if a person and its affiliates own at least one but not more than five approved ANDAs on October 1, 2025, the person and its affiliates shall owe a small business generic drug applicant program fee.¹⁴ If a person and its affiliates own at least 6 but not more than 19 approved ANDAs, the person and its affiliates shall owe a medium size operation generic drug applicant program fee.¹⁵ If a person and its

⁸ Section 744B(b)(2)(C) and (D) of the FD&C Act.

⁹ Section 744B(a)(4)(A) of the FD&C Act.

¹⁰ Section 744A(5) and 744B(b)(2)(C) of the FD&C Act.

¹¹ Section 744B(b)(2)(C) of the FD&C Act.

¹² Section 744B(b)(2)(C) of the FD&C Act.

¹³ Section 744B(a)(4)(A)(ii) of the FD&C Act.

¹⁴ Sections 744B(a)(5)(A) and 744B(b)(2)(E)(i) of the FD&C Act.

¹⁵ Id.

affiliates own at least 20 approved ANDAs, the person and its affiliates shall owe a large size operation generic drug applicant program fee.¹⁶ Section 744B(b)(2)(E) of the FD&C Act specifies the GDUFA program fee will make up 36 percent of \$670,899,000 in fee revenue, which is \$241,523,640.

To determine the appropriate number of parent companies for each tier, FDA asked companies to claim their ANDAs and affiliates in the CDER NextGen Portal. The companies were able to confirm relationships currently present in FDA’s records, while also reporting newly approved ANDAs, newly acquired ANDAs, and new affiliations.

In determining the appropriate number of approved ANDAs, FDA has factored in a number of variables that could affect the collection of the target revenue: (1) withdrawals of approved ANDAs by April 1: applicants who have submitted a written request for withdrawal of approval by April 1 of the previous fiscal year;¹⁷ (2) inactive ANDAs: applicants who have not submitted an annual report for one or more of their approved applications within the past 2 years; (3) CBER-

approved ANDAs: applicants and their affiliates with CBER-approved ANDAs are added to CDER’s population of approved ANDAs; (4) Program Fee Arrears List: parent companies that are on the arrears list for any fiscal year; (5) Out of Business companies: parent companies that are no longer in operation; and (6) Tier Adjustment: the frequency of large-tier, medium-tier, and small-tier companies moving to different tiers (or as applicable, dropping out of any tier) after the completion of the program fee methodology and tier determination.

The list of original approved ANDAs from the Generic Drug Review Platform as of April 30, 2025, in addition to CBER’s database, shows 259 applicants in the small business tier, 63 applicants in the medium size tier, and 88 applicants in the large size tier. Factoring in all the variables, we estimate there will be 221 applicants in the small business tier, 57 applicants in the medium size tier, and 81 applicants in the large size tier for FY 2026.

To calculate the GDUFA program fee, GDUFA III provides that large size operation generic drug applicants pay

the full fee, medium size operation applicants pay two-fifths of the full fee, and small business applicants pay one-tenth of the full fee.¹⁸ To generate the target collection revenue amount from GDUFA program fees (\$241,523,640), we must weigh medium and small tiered applicants as a subset of a large size operation generic drug applicant. FDA will set fees based on the weighted estimate of 22.1 applicants in the small business tier (221 multiplied by 10 percent), 22.8 applicants in the medium size tier (57 multiplied by 40 percent), and 81 applicants in the large size tier, arriving at 125.9 total weighted applicants for FY 2026.

To generate the large size operation GDUFA program fee, FDA divides the target revenue amount of \$241,523,640 by 125.9, which equals \$1,918,377. The medium size operation GDUFA program fee is 40 percent of the full fee (\$767,351), and the small business GDUFA program fee is 10 percent of the full fee (\$191,838).

IX. Fee Schedule for FY 2026

The fee rates for FY 2026 are displayed in table 8.

TABLE 8—FEE SCHEDULE FOR FY 2026

Fee category	Fee rates for FY 2026
Applications:	
Abbreviated New Drug Application (ANDA)	\$358,247
Drug Master File (DMF)	102,584
Facilities:	
Active Pharmaceutical Ingredient (API)—Domestic	43,549
API—Foreign	58,549
Finished Dosage Form (FDF)—Domestic	238,943
FDF—Foreign	253,943
Contract Manufacturing Organization (CMO)—Domestic	57,346
CMO—Foreign	72,346
GDUFA Program:	
Large size operation generic drug applicant	1,918,377
Medium size operation generic drug applicant	767,351
Small business generic drug applicant	191,838

X. Fee Payment Options and Procedures

The new fee rates are effective on October 1, 2025, and will remain in effect through September 30, 2026. Under sections 744B(a)(4) and (5) of the FD&C Act, respectively, facility and program fees are generally due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations act providing for the collection and obligation of GDUFA fees for the fiscal year.

To pay the ANDA, DMF, API facility, FDF facility, CMO facility, and GDUFA program fees, complete the Generic Drug User Fee Cover Sheet, available at <https://www.fda.gov/gdufa> and https://userfees.fda.gov/OA_HTML/gdufaCAcdLogin.jsp, and generate a user fee identification (ID) number. Payment must be made in U.S. currency drawn on a U.S. bank by electronic check, credit card, or wire transfer.¹⁹ The preferred payment method is online using electronic check (Automated Clearing House (ACH), also known as

eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after completing the Generic Drug User Fee Cover Sheet and generating the user fee ID number.

Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. (Note: Only full payments are accepted;

¹⁶ Id.
¹⁷ See section 744B(b)(2)(E)(ii) of the FD&C Act.

¹⁸ Section 744B(b)(2)(E)(i) of the FD&C Act.
¹⁹ See “Change in Federal Payment and Collection Options” announcement published in

the **Federal Register** on June 27, 2025 (90 FR 27639).

no partial payments can be made online.) Once an invoice is located, "Pay Now" should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied. If the payment amount is not applied, the invoice amount will be referred to collections. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, account number: 75060099, routing number: 021030004, SWIFT: FRNYUS33. FDA's tax identification number is 53-0196965.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-2488]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2026

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the fee rates and payment procedures for fiscal year (FY) 2026 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Drug User Fee Amendments of 2023 (ADUFA V), authorizes FDA to collect user fees for certain animal drug applications and supplemental animal drug applications, for certain animal drug products, for certain establishments where such

products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2026.

DATES: The application fee rates apply to applications submitted on or after October 1, 2025, and will remain in effect through September 30, 2026.

FOR FURTHER INFORMATION CONTACT: Visit FDA's website at: <https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa>. For general questions, you may also email FDA's Center for Veterinary Medicine (CVM) at: cvmadufa@fda.hhs.gov. For questions relating to this notice: UFFS, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993; or email the User Fee Support Staff at UFSS@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 740(a) of the FD&C Act (21 U.S.C. 379j-12), as amended by ADUFA V, establishes four different types of user fees: (1) fees for certain animal drug applications and supplemental animal drug applications; (2) annual fees for certain animal drug products; (3) annual fees for certain establishments where such products are made; and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions. When certain conditions are met, FDA will waive or reduce fees per section 740(d) of the FD&C Act.

For FYs 2024 through 2028, section 740(b)(1) of the FD&C Act establishes the base revenue amount for each fiscal year. Per section 740(c)(2) and (3) of the FD&C Act, the base revenue amounts established for fiscal years after FY 2024 are subject to adjustment for inflation and workload. Beginning in FY 2025, the annual fee revenue amount is also subject to an operating reserve adjustment to allow FDA to adjust the fee revenue amount to maintain a specified operating reserve of carryover user fees, per section 740(c)(4) of the FD&C Act. FDA may increase the fee revenue amount to maintain a 12-week minimum. If FDA has an excess operating reserve, FDA will decrease the fee revenue amount so that FDA has 22 weeks of operating reserve for FY 2025, 20 weeks for FY 2026, 18 weeks for FY 2027, and 16 weeks for FY 2028.

Per section 740(b)(2) of the FD&C Act, fees for applications, establishments, products, and sponsors are to be established each year by FDA so that the percentages of the total revenue that are derived from each type of user fee will

be as follows: (1) revenue from application fees shall be 20 percent of total fee revenue; (2) revenue from product fees shall be 27 percent of total fee revenue; (3) revenue from establishment fees shall be 26 percent of total fee revenue; and (4) revenue from sponsor fees shall be 27 percent of total fee revenue. The target revenue amounts for each fee category for FY 2026 are as follows: for application fees, the target revenue amount is \$7,230,400; for product fees, the target revenue amount is \$9,761,040; for establishment fees, the target revenue amount is \$9,399,520; and for sponsor fees, the target revenue amount is \$9,761,010.

For FY 2026, the animal drug user fee rates are: (1) \$708,863 for an animal drug application; (2) \$354,431 for a supplemental animal drug application for which safety or effectiveness data are required, for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b), and for an application for conditional approval under section 571 of the FD&C Act (21 U.S.C. 360ccc) for which an animal drug application submitted under section 512(b)(1) of the FD&C Act has been previously approved under section 512(d)(1) of the FD&C Act for another intended use; (3) \$13,463 for the annual product fee; (4) \$200,000 for the annual establishment fee; and (5) \$165,441 for the annual sponsor fee. FDA will issue invoices for FY 2026 product, establishment, and sponsor fees by December 31, 2025, and payment will be due by January 31, 2026. The application fee rates are effective for applications submitted on or after October 1, 2025, and will remain in effect through September 30, 2026. Applications will not be accepted for review until FDA has received full payment of application fees and any other animal drug user fees owed under the ADUFA program.

II. Fee Revenue Amount for FY 2026

A. Statutory Fee Revenue Amounts

Section 740(b)(1) of the FD&C Act specifies that the base fee revenue amount for FY 2026 for all animal drug user fee categories totals \$33,500,000.

B. Inflation Adjustment to Fee Revenue Amount

Section 740(c)(2)(A)(ii) and (iii) of the FD&C Act specifies that the annual fee revenue amount is to be adjusted for inflation increases for FY 2025 and subsequent fiscal years using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs. Section 740(c)(2)(A)(ii) of the FD&C Act

specifies the component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding fiscal years of available data, multiplied by the average proportion of PC&B costs to total FDA

costs for the first 3 of the 4 preceding fiscal years of available data. The data on total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA’s Justification of Estimates for Appropriations Committees.

Table 1 summarizes the total PC&B cost per FTE for the specified fiscal years, provides the percent change from the previous fiscal year, and provides the average percent change over the first 3 of the 4 fiscal years preceding FY 2026. The 3-year average is 5.4494 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENTAGE CHANGE

Fiscal year	2022	2023	2024	3-Year average
Total PC&B	\$3,165,477,000	\$3,436,513,000	\$3,791,729,000	
Total FTEs	18,474	18,729	19,687	
PC&B per FTE	\$171,348	\$183,486	\$192,601	
Percentage Change from Previous Year	4.2967%	7.0838%	4.9677%	5.4494%

Section 740(c)(2)(A)(ii) of the FD&C Act specifies that this 5.4494 percent should be multiplied by the proportion

of PC&B costs to total FDA costs for the first 3 of the preceding 4 fiscal years for which data are available. Table 2 shows

the amount of PC&B and the total amount obligated by FDA for the same 3 fiscal years.

TABLE 2—PC&B AS A PERCENT OF TOTAL COST AT FDA

Fiscal year	2022	2023	2024	3-Year average
Total PC&B	\$3,165,477,000	\$3,436,513,000	\$3,791,729,000	
Total Costs	\$6,251,981,000	\$6,654,058,000	\$6,976,495,000	
PC&B percent	50.6316%	51.6454%	54.3501%	52.2090%

The portion of the inflation adjustment relating to payroll costs is 5.4494 percent multiplied by 52.2090 percent, or 2.8451 percent.

Section 740(c)(2)(A)(iii) of the FD&C Act specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent

change that occurred in the Consumer Price Index (CPI) (Washington-Arlington-Alexandria, DC-VA-MD-WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 years of the preceding 4 years of available data multiplied by the average proportion of all costs other than PC&B

costs to total FDA costs for the first 3 years of the preceding 4 fiscal years. Table 3 provides the summary data for the percent change in the specified CPI for the Washington-Arlington-Alexandria area. The data from the Bureau of Labor Statistics are shown in table 3.¹

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENTAGE CHANGE IN CPI (LESS FOOD AND ENERGY) FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

Fiscal year	2022	2023	2024	3-Year average
Annual CPI	302.608	313.315	324.560	4.1709%
Annual Percent Change	5.3855%	3.5382%	3.5890%	

Section 740(c)(2)(A)(iii) of the FD&C Act specifies to calculate the inflation adjustment for non-payroll costs, we multiply 4.1709 percent by the average proportion of all costs other than PC&B to total FDA costs for the first 3 years of the preceding 4 fiscal years. Since 52.2090 percent was obligated for PC&B as shown in table 2, 47.7910 percent is the portion of costs other than PC&B (100 percent minus the PC&B percentage of 52.2090). The portion of the inflation adjustment relating to non-payroll costs is 4.1709 percent multiplied by 47.7910 percent, or 1.9933 percent.

Next, we add the payroll component (2.8451percent) to the non-payroll component (1.9933 percent), for an inflation adjustment of 4.8384 percent for FY 2026.

Section 740(c)(2)(B) of the FD&C Act provides for the inflation adjustment to be compounded each fiscal year after FY 2025. The inflation adjustment for FY 2026 (4.8384 percent) is compounded by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2025 (1.0393), which equals 1.0896 (rounded) (1.0393 multiplied by 1.048384). We then multiply the base revenue amount for FY 2026

(\$33,500,000) by 1.0896, yielding an inflation adjusted amount of \$36,502,505.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

Section 740(c)(3)(A) of the FD&C Act specifies that the annual fee revenue amounts in ADUFA V for FY 2025 and subsequent fiscal years are subject to adjustment to account for changes in FDA’s review workload. The workload adjustment will be applied to the inflation adjusted fee revenue amount.

To determine whether a workload adjustment applies, per ADUFA V

¹ The data is published by the Bureau of Labor Statistics and can be found on its website at: <https://data.bls.gov/timeseries/CUURS35ASA0L1E>.

commitments FDA calculates the weighted average of the change in the total number of each of the five types of applications and submissions specified in the workload adjustment provision (animal drug applications, supplemental animal drug applications for which data with respect to safety or efficacy are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions) received over the 5-year period that ended on

September 30, 2024 (the base years; 2020 through 2024), and the average number of each of these types of applications and submissions over the most recent 5-year period that ended April 30, 2025.

The results of these calculations are presented in the first two columns of table 4. Column 3 reflects the percent change in workload over the two 5-year periods. Column 4 shows the weighting factor for each type of application/submissions, reflecting how much of the total FDA animal drug review workload

was accounted for by each type of application or submission in the table during the most recent 5 years. Column 5 is the weighted percent change in each category of workload and was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. At the bottom right of the table, the sum of the values in column 5 is calculated, reflecting a total change in workload of negative 3.4253 percent for FY 2025. This is the workload adjuster for FY 2026.

TABLE 4—WORKLOAD ADJUSTER CALCULATION

Application type	Column 1	Column 2	Column 3	Column 4	Column 5
	5-Year average (base years)	Latest 5-year average	Percent change	Weighting factor	Weighted percent change
New Animal Drug Application (NADAs)	12.40	11.40	– 8.0645	0.0408	– 0.3290
Supplemental NADAs With Safety or Efficacy Data	7.20	8.00	11.1111	0.0311	0.3453
Manufacturing Supplements	377.80	351.0	– 7.0937	0.2171	– 1.5398
Investigational Study Submissions	150.40	149.2	– 0.7979	0.5882	– 0.4693
Investigational Protocol Submissions	163.00	144.0	– 11.6564	0.1229	– 1.4324
FY 2026 ADUFA V Workload Adjuster					– 3.4253

Section 740(c)(3)(B) of the FD&C Act specifies that under no circumstances shall the workload adjustment result in fee revenues that are less than the base fee revenues for that fiscal year as adjusted for inflation. Additionally, section 740(c)(3)(A)(ii) states that the workload adjuster must be greater than 3 percent for a second fiscal year within ADUFA V before FDA can add the adjustment to the target revenue. For FY 2026 the workload adjuster is below the 3 percent statute threshold, therefore no workload adjustment shall be applied.

D. Operating Reserve Adjustment to Inflation and Workload Adjusted Fee Revenue Amount

Section 740(c)(4)(A) of the FD&C Act specifies that for FY 2026, after the fee revenue amount established under section 740(b) of the FD&C Act is adjusted for inflation and workload, the Secretary shall increase the fee revenue amount for such fiscal year, if necessary to provide an operating reserve of not less than 12 weeks or decrease the fee revenue amount for such fiscal year, if necessary to provide for not more than 20 weeks of operating reserves.

To determine the dollar amounts for the 12-week and 20-week operating reserve thresholds, we divide the adjusted annual fee revenue amount (\$36,502,505) by 52 weeks to generate a 1-week operating reserve amount of \$701,971. The 1-week operating reserve amount is then multiplied by 12 and 20. This results in a 12-week minimum

threshold of \$8,423,544 and a 20-week maximum threshold of \$14,039,420.

To estimate the FY 2025 end-of-year operating reserve of carryover user fees, the Agency projected the user fee carryover amount at the end of July 2025 using forecasted obligations, collections, and estimated recoveries but not including carryover use fees that have not been appropriated. The operating reserve of carryover user fees is projected to be \$14,390,059 or 20.50 weeks (\$14,390,059 divided by \$701,971).

Because the estimated FY 2025 end-of-year operating reserve of carryover user fees is not below the 12-week threshold amount of \$8,423,544, FDA will not increase the fee revenue amount and fees for FY 2026.

However, because the estimated FY 2025 end-of-year operating reserve of carryover user fees of \$14,390,059 exceeds the 20-week threshold of \$14,039,420, FDA will apply an operating reserve adjustment of \$350,639 to decrease the fee revenue and fees for FY 2026.

With respect to target revenue for FY 2026, subtracting the operating reserve adjustment amount of \$350,639 from the adjusted fee revenue amount of \$36,502,505 results in a total target revenue amount of \$36,152,000 (rounded) for FY 2026.

E. FY 2026 Fee Revenue Amounts

The fee revenue amount for FY 2026 is \$36,152,000. Section 740(b)(2) of the

FD&C Act specifies that this revenue amount is to be divided as follows: 20 percent, or a total of \$7,260,400 is to come from application fees; 27 percent, or a total of \$9,761,040, is to come from product fees; 26 percent, or a total of \$9,399,520 is to come from establishment fees; and 27 percent, or a total of \$9,761,040 is to come from sponsor fees.

III. Animal Drug Application Fee Calculations for FY 2026

A. Application Fee Revenues and Numbers of Fee-Paying Applications

Section 740(a)(1)(A) of the FD&C Act states that each person that submits an animal drug application or a supplemental animal drug application shall be subject to an application fee, with limited exceptions. The term “animal drug application” means an application for approval of any new animal drug submitted under section 512(b)(1) of the FD&C Act or an application for conditional approval of a new animal drug submitted under section 571 of the FD&C Act. A “supplemental animal drug application” is defined as a request to FDA to approve a change in an approved animal drug application, or a request to FDA to approve a change to an application approved under section 512(c)(2) of the FD&C Act for which data with respect to safety or effectiveness are required. Such applications are subject to ADUFA fees,

except those fees may be waived under the circumstances described in section 740(d)(1)(D) and 740(i) of the FD&C Act.

Furthermore, ADUFA V continues to provide an exception from application fees for animal drug applications submitted under section 512(b)(1) of the FD&C Act by a sponsor who previously applied for conditional approval under section 571 of the FD&C Act for the same product and paid an application fee at the time they applied for conditional approval. The purpose of this exception is to prevent sponsors of conditionally approved products from having to pay a second application fee at the time they apply for full approval of their products under section 512(b)(1) of the FD&C Act, provided the sponsor's application for full approval is filed consistent with the timeframes established in section 571(h) of the FD&C Act.

The application fees are to be set so that they will generate \$7,230,400 in fee revenue for FY 2026. The fee for a supplemental animal drug application for which safety or effectiveness data are required, for an animal drug application subject to criteria set forth in section 512(d)(4) of the FD&C Act, and for an application for conditional approval under section 571 of the FD&C Act of a new animal drug for which an animal drug application submitted under section 512(b)(1) of the FD&C Act has been previously approved under section 512(d)(1) for another intended use is to be set at 50 percent of the animal drug application fee.

To set animal drug application fees and supplemental animal drug application fees to realize \$7,230,400, FDA must first make some assumptions about the number of fee-paying applications and supplemental applications the Agency will receive in FY 2026.

The Agency knows the number of applications that have been submitted in previous fiscal years. That number fluctuates annually. In estimating the fee revenue to be generated by animal drug application fees in FY 2026, FDA is assuming that the number of applications for which fees will be paid in FY 2026 will equal the average number of applications over the five most recently completed fiscal years of the ADUFA program (FY 2020 to FY 2024).

Over the 5 most recently completed fiscal years, the average number of animal drug applications subject to the full fee was 5.80. Over this same period, the average number of supplemental applications for which safety or effectiveness data are required, applications subject to the criteria set

forth in section 512(d)(4) of the FD&C Act, and applications for conditional approval of a new animal drug for which a section 512(b)(1) application has been previously approved for another intended use subject to half of the full fee was 8.80.

Based on the previous assumptions, FDA is estimating that it will receive a total of 10.20 fee-paying animal drug applications in FY 2026 (5.80 applications paying a full fee and 8.80 applications paying a half fee).

B. Application Fee Rates for FY 2026

FDA must set the fee rates for FY 2026 so that the estimated 10.20 applications that pay the fee will generate a total of \$7,230,400. To generate this amount, the fee for an animal drug application, rounded to the nearest dollar, will have to be \$708,863, and the fee for a supplemental animal drug application for which safety or effectiveness data are required, for applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act, and for an application for conditional approval under section 571 of the FD&C Act of a new animal drug for which an animal drug application submitted under section 512(b)(1) of the FD&C Act has been previously approved under section 512(d)(1) for another intended use will have to be \$354,431.

IV. Animal Drug Product Fee Calculations for FY 2026

A. Product Fee Revenues and Numbers of Fee-Paying Products

Section 740(a)(2) of the FD&C Act specifies that the animal drug product fee must be paid annually by the person named as the applicant in a new animal drug application or supplemental new animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360) and who had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003. The term "animal drug product" means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the National Drug Code, and for which an animal drug application or a supplemental animal drug application has been approved (see section 739(3) of the FD&C Act). The product fees are to be set so that they will generate \$9,761,040 in fee revenue for FY 2026.

To set animal drug product fees to realize \$9,761,040, FDA must make some assumptions about the number of

products for which these fees will be paid in FY 2026. FDA developed data on all animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who had an animal drug application or a supplemental animal drug application pending after September 1, 2003. As of May 2025, FDA estimates that there are 740 products submitted for listing by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA estimates that a total of 740 products will be subject to this fee in FY 2026.

In estimating the fee revenue to be generated by animal drug product fees in FY 2026, FDA is assuming that 2 percent of the products invoiced, or 15, will not pay fees in FY 2026, due to fee waivers and reductions. FDA has made this estimate at 2 percent this year, based on historical data over the past 5 completed fiscal years of the ADUFA program.

Accordingly, the Agency estimates that a total of 725 (740 minus 15) products will be subject to product fees in FY 2026.

B. Product Fee Rates for FY 2026

FDA must set the fee rates for FY 2026 so that the estimated 725 products for which fees are paid will generate a total of \$9,761,040. To generate this amount will require the fee for an animal drug product, rounded to the nearest dollar, to be \$13,463.

V. Animal Drug Establishment Fee Calculations for FY 2026

A. Establishment Fee Revenues and Numbers of Fee-Paying Establishments

Section 740(a)(3) of the FD&C Act states that the animal drug establishment fee must be paid annually by the person who: (1) owns or operates, directly or through an affiliate, an animal drug establishment; (2) is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act; (3) had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003; and (4) whose establishment engaged in the manufacture of the animal drug product during the fiscal year. An establishment subject to animal drug establishment fees is assessed only one such fee per fiscal year. The term "animal drug establishment" is defined as a foreign or domestic place of business at one general physical

location, consisting of one or more buildings, all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form (see section 739(4) of the FD&C Act). The establishment fees are to be set so that they will generate \$9,399,520 in fee revenue for FY 2026.

To set animal drug establishment fees to realize \$9,399,520, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2026. FDA developed data on all animal drug establishments and matched this to the list of all persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. As of May 2025, FDA estimates that there are a total of 50 establishments owned or operated by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA believes that 50 establishments will be subject to this fee in FY 2026.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2026, FDA is assuming that 6 percent of the establishments invoiced, or three, will not pay fees in FY 2026 due to fee waivers and reductions. FDA has made this estimate at 6 percent this year, based on historical data over the past 5 completed fiscal years.

Accordingly, the Agency estimates that a total of 47 establishments (50

minus 3) will be subject to establishment fees in FY 2026.

B. Establishment Fee Rates for FY 2026

FDA must set the fee rates for FY 2026 so that the fees paid for the estimated 47 establishments will generate a total of \$9,399,520. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest dollar, to be \$200,000.

VI. Animal Drug Sponsor Fee Calculations for FY 2026

A. Sponsor Fee Revenues and Numbers of Fee-Paying Sponsors

The animal drug sponsor fee must be paid annually by each person who: (1) is named as the applicant in an animal drug application, except for an approved application for which all subject products have been removed from listing under section 510 of the FD&C Act, or has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive and (2) had an animal drug application, supplemental animal drug application, or investigational animal drug submission pending at FDA after September 1, 2003 (see sections 739(6) and 740(a)(4) of the FD&C Act). An animal drug sponsor is subject to only one such fee each fiscal year (see § 740(a)(4) of the FD&C Act). The sponsor fees are to be set so that they will generate \$9,761,040 in fee revenue for FY 2026.

To set animal drug sponsor fees to realize \$9,761,040, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2026. FDA developed data on all animal drug sponsors and matched this to the list of all sponsors who had pending submissions and applications after September 1, 2003. As of May 2024, FDA estimates that a total of 189 sponsors will meet this definition in FY 2026.

In estimating the fee revenue to be generated by animal drug sponsor fees in FY 2026, FDA is assuming that 69 percent of the sponsors invoiced, or 130, will not pay sponsor fees in FY 2026 due to fee waivers and reductions. FDA has made this estimate at 69 percent this year, based on historical data over the past 5 completed fiscal years of the ADUFA program.

Accordingly, the Agency estimates that a total of 59 sponsors (189 minus 130) will be subject to and pay sponsor fees in FY 2026.

B. Sponsor Fee Rates for FY 2026

FDA must set the fee rates for FY 2026 so that the estimated 59 sponsors that pay fees will generate a total of \$9,761,040. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest dollar, to be \$165,441.

VII. Fee Schedule for FY 2026

The fee rates for FY 2026 are summarized in table 5.

TABLE 5—FY 2026 FEE RATES

Animal drug user fee category	Fee rate for FY 2026
Animal Drug Application Fees:	
Animal Drug Application	\$708,863
Supplemental Animal Drug Application for Which Safety or Effectiveness Data are Required, Animal Drug Application Subject to the Criteria Set Forth in Section 512(d)(4) of the FD&C Act, or Application for Conditional Approval Under Section 571 of the FD&C Act for Which an Animal Drug Application Submitted Under Section 512(b)(1) of the FD&C Act Has Been Previously Approved Under Section 512(d)(1) for Another Intended Use	354,431
Animal Drug Product Fee	13,463
Animal Drug Establishment Fee ¹	200,000
Animal Drug Sponsor Fee ²	165,441

¹ An animal drug establishment is subject to only one such fee each fiscal year.

² An animal drug sponsor is subject to only one such fee each fiscal year.

VIII. Fee Waiver or Reduction; Exemption From Fees

The types of fee waivers, fee reductions, and exemptions from fees that applied during ADUFA IV still exist in ADUFA V, with one exception. After September 30, 2023, there is no longer an exemption for any person who submits to CVM a supplemental animal drug application relating to a new

animal drug application approved under section 512 of the FD&C Act, solely to add the application number to the labeling of the drug in the manner specified in section 503(w) of the FD&C Act.

Remaining waivers and reductions apply for the following: barriers to innovation; where fees will exceed the cost to review the animal drug

application; if the application is related to certain free-choice medicated feeds; if the application is solely for a MUMS indication; or if the sponsor is a small business submitting its first animal drug application. See section 740(d)(1) of the FD&C Act.

A. Barrier to Innovation Waivers or Fee Reductions

Under section 740(d)(1)(A) of the FD&C Act, an animal drug applicant may qualify for a waiver or reduction of one or more ADUFA fees if the fee would present a significant barrier to innovation because of limited resources available to the applicant or other circumstances. CVM's guidance for industry (GFI) #170, entitled "Animal Drug User Fees and Fee Waivers and Reductions,"² states that the Agency interprets this provision to mean that a waiver or reduction is appropriate when: (1) the product for which the waiver is being requested is innovative, or the requestor is otherwise pursuing innovative animal drug products or technology and (2) the fee would be a significant barrier to the applicant's ability to develop, manufacture, or market the innovative product or technology. Only those applicants that meet both criteria will qualify for a waiver or reduction in user fees under this provision (see GFI #170 at pp. 6–8). For purposes of determining whether the second criterion would be met based on limited financial resources available to the applicant, FDA has determined an applicant with financial resources of less than \$20,000,000 (including the financial resources of the applicant's affiliates), adjusted annually for inflation, has limited resources available. Using the CPI for urban consumers (U.S. city average; not seasonally adjusted; all items; annual index), the inflation-adjusted level for FY 2026 will be \$24,384,000; this level represents the financial resource ceiling that will be used to determine if there are limited resources available to an applicant requesting a Barrier to Innovation waiver on financial grounds for FY 2026. Requests for a waiver must be submitted in writing to FDA each fiscal year not later than 180 days from when the fees are due. A waiver granted on Barrier to Innovation grounds (or any of the other grounds listed in section 740(d)(1) of the FD&C Act) is only valid for one fiscal year. If a sponsor is not granted a waiver, they are liable for the fees.

B. Exemption or Exception From Fees

In addition to the waivers and fee reductions described above, one fee exemption and two exceptions still apply in ADUFA V.

If an animal drug application, supplemental animal drug application,

or investigational submission involves the intentional genomic alteration of an animal that is intended to produce a human medical product, any person who is the named applicant or sponsor of that application or submission will not be subject to sponsor, product, or establishment fees under ADUFA based solely on that application or submission (see section 740(d)(4) of the FD&C Act).

There is an exception from application fees for animal drug applications submitted under section 512(b)(1) of the FD&C Act by a sponsor who previously applied for conditional approval under section 571 of the FD&C Act for the same product and paid an application fee at the time they applied for conditional approval, provided the sponsor has submitted the application under section 512(b)(1) of the FD&C Act within the timeframe specified in section 571(h) of the FD&C Act. There is also an exception from application fees for previously filed applications that were not approved or were withdrawn (without waiver or refund). Both exceptions are detailed in section 740(a)(1)(C) of the FD&C Act.

IX. Procedures for Paying the FY 2026 Fees

A. Application Fees and Payment Instructions

The FY 2026 fee established in the new fee schedule must be paid for an animal drug application or supplement subject to fees under ADUFA V that is submitted on or after October 1, 2025. Payments made to FDA must be made in U.S. currency drawn on a U.S. bank by electronic check, credit card, or wire transfer.³ The preferred method for payments to FDA is online using electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website upon receipt of an invoice or after completing the User Fee Cover Sheet and generating the user fee ID number.

Secure electronic payments to FDA can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. (Note: Only full payments are accepted; no partial payments can be made online.) Once an invoice or cover sheet is located, "Pay Now" should be selected to be redirected to *Pay.gov*. Electronic

payment options are based on the balance due. Payment by credit card is available for balances less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID or invoice number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID or invoice number, the payment may not be applied. If a fee is not paid in full, the fee will be treated as a claim of the U.S. Government (see section 740(h) of the FD&C Act), meaning the invoice balance due amount must be referred to collections. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, account number: 75060099, routing number: 021030004, SWIFT: FRNYUS33. FDA's tax identification number is 53–0196965.

It is important that the fee arrives at the bank at least a day or two before the application arrives at FDA's CVM. FDA records the official application receipt date as the later of the following: the date the application was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Department of the Treasury notifies FDA of receipt of an electronic or wire transfer payment. U.S. Bank and the U.S. Department of the Treasury are required to notify FDA within 1 working day, using the PIN described previously. The tax identification number of FDA is 53–0196965.

B. Application Cover Sheet Procedures

Step One: Create a user account and password. Log on to the ADUFA website at <https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/animal-drug-user-fee-cover-sheet> and, under Application Submission Information, click on "Create ADUFA User Fee Cover Sheet." For security reasons, each firm applying will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two: Create an Animal Drug User Fee Cover Sheet, transmit it to the

² CVM's GFI #170 is located at: <https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052494.pdf>.

³ See "Change in Federal Payment and Collection Options" announcement published in the **Federal Register** on June 27, 2025 (90 FR 27639).

FDA, and print a copy. After logging into your account with your username and password, complete the steps required to create an Animal Drug User Fee Cover Sheet. One cover sheet is needed for each animal drug application or supplement. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to the FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three: Send the payment for your application as described in section IX.A above.

Step Four: Submit your application.

C. Product, Establishment, and Sponsor Fees

By December 31, 2025, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2026 using this fee schedule. Payment will be due by January 31, 2026. FDA will issue invoices in November 2026 for any products, establishments, and sponsors subject to fees for FY 2026 that qualify for fees after the December 2025 billing.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-2355]

Animal Generic Drug User Fee Program Rates and Payment Procedures for Fiscal Year 2026

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the fee rates and payment procedures for fiscal year (FY) 2026 generic new animal drug program user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2023 (AGDUFA IV), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal

drugs (JINADs), and for certain submissions related to JINAD files. This notice establishes the fee rates for FY 2026.

DATES: The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2025, and will remain in effect through September 30, 2026. The fee rates for requests to establish a JINAD file, and for certain submissions to JINAD files established prior to October 1, 2023, are effective on October 1, 2025, and will remain in effect through September 30, 2026.

FOR FURTHER INFORMATION CONTACT: Visit FDA's website at: <https://www.fda.gov/industry/fda-user-fee-programs/animal-generic-drug-user-fee-act-agdufa>. For general questions, email FDA's Center for Veterinary Medicine (CVM) at: cvmagdufa@fda.hhs.gov.

For questions relating to this notice: UFFS, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993; or email the User Fee Support Staff at UFFS@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 741(a) of the FD&C Act (21 U.S.C. 379j-21(a)), establishes four different types of generic new animal drug user fees: (1) fees for certain abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs; and (4) JINAD file fees. When certain conditions are met, section 741(d) of the FD&C Act authorizes FDA to waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication.

Section 741(b)(1) of the FD&C Act establishes a base revenue amount for each fiscal year. Per section 741(c)(2) and (3) of the FD&C Act, the base revenue amounts established for fiscal years after FY 2024 are subject to adjustment for inflation and workload. Beginning FY 2026, the annual fee revenue amounts are also subject to adjustment to reduce workload-based increases by the amount of certain excess collections. Section 741(b) of the FD&C Act establishes fees each year so that the percentage allocations for each of the fee categories is as follows: 20 percent shall be derived from fees for abbreviated applications for a generic new animal drug and JINAD file fees; 40 percent shall be derived from fees for

generic new animal drug products; and 40 percent shall be derived from fees for generic new animal drug sponsors. The target revenue amounts for each fee category for FY 2026 are as follows: for application and/or JINAD file fees, the target revenue amount is \$5,448,200; for product fees, the target revenue amount is \$10,896,400; and for sponsor fees, the target revenue amount is \$10,896,400.

For FY 2026, the AGDUFA rates are: \$137,853 for each abbreviated application for a generic new animal drug other than those subject to the criteria in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); \$68,927 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4) of the FD&C Act; \$50,000 for each JINAD file request or certain submissions to established JINAD files; \$16,119 for each generic new animal drug product; \$261,618 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; \$196,214 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and \$130,809 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2026 product and sponsor fees by December 31, 2025, and payment will be due by January 31, 2026. The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2025, and will remain in effect through September 30, 2026. The fee rate for requests to establish a JINAD file, and for certain submissions to JINAD files established prior to October 1, 2023, is effective on October 1, 2025, and will remain in effect through September 30, 2026.

Applications will not be accepted for review until FDA has received full payment of application fees and any other fees owed under the AGDUFA program. Similarly, a request to establish a JINAD file or a submission to an existing JINAD file will not be accepted for action by FDA until FDA has received full payment of all fees owed under the AGDUFA program.

II. Fee Revenue Amount for FY 2026

A. Statutory Fee Revenue Amounts

Section 741(b)(1) of the FD&C Act specifies that the base fee revenue amount for FY 2026 for all generic animal drug user fee categories totals \$25,000,000.

B. Inflation Adjustment to Fee Revenue Amount

Section 741(c)(2)(A) of the FD&C Act specifies that the annual fee revenue amount is to be adjusted for inflation

increases for FY 2025 and subsequent fiscal years using two separate factors—one for personnel compensation and benefits (PC&B) costs and one for non-PC&B costs.

Section 741(c)(2)(A)(ii) of the FD&C Act specifies the component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B,

per full-time equivalent (FTE) position of FDA, for the first 3 of the preceding 4 fiscal years of available data, multiplied by the average proportion of PC&B costs to total FDA costs for the first 3 of the 4 preceding fiscal years of available data. The data on total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA's

Justification of Estimates for Appropriations Committees.

Table 1 summarizes the total PC&B costs per FTE for the specified fiscal years, provides the percentage change from the previous fiscal year, and provides the average percentage change over the first 3 of the 4 fiscal years preceding FY 2026. The 3-year average is 5.4494 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE

Fiscal year	2022	2023	2024	3-Year average
Total PC&B	\$3,165,477,000	\$3,436,513,000	\$3,791,729,000	
Total FTEs	18,474	18,729	19,687	
PC&B per FTE	\$171,348	\$183,486	\$192,601	
Percent Change from Previous Year	4.2967%	7.0838%	4.9677%	5.4494%.

Section 741(c)(2)(A)(ii) of the FD&C Act specifies that the 5.4494 percent should be multiplied by the average

proportion of PC&B costs to total FDA costs for the first 3 of the preceding 4 fiscal years for which data are available.

Table 2 shows the amount of PC&B and the total costs obligated by FDA for the same 3 fiscal years.

TABLE 2—PC&B AS A PERCENT OF TOTAL COST

Fiscal year	2022	2023	2024	3-Year average
Total PC&B	\$3,165,477,000	\$3,436,513,000	\$3,791,729,000	
Total Costs	\$6,251,981,000	\$6,654,058,000	\$6,976,495,000	
PC&B percent	50.6316%	51.6454%	54.3501%	52.2090%

The portion of the inflation adjustment relating to payroll costs is 5.4494 percent multiplied by 52.2090 percent, or 2.8451 percent.

Section 741(c)(2)(A)(iii) of the FD&C Act specifies that the non-payroll costs adjustment factor is calculated by multiplying the average annual

percentage change that occurred in the Consumer Price Index for Urban Consumers (Washington-Arlington-Alexandria, DC-VA-MD-WV; Not Seasonally Adjusted; All Items Less Food and Energy; Annual Index) for the first 3 years of the preceding 4 years of

available data by the average proportion of all non-PC&B costs to total FDA costs for the first 3 years of the preceding 4 fiscal years. Table 3 provides the summary data for the percentage change in the specified CPI for the Washington-Arlington-Alexandria area.¹

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI (LESS FOOD AND ENERGY) FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

Fiscal year	2022	2023	2024	3-Year average
Annual CPI	302.608	313.315	324.560	
Annual Percent Change	5.3855%	3.5382%	3.5890%	4.1709%

Section 741(c)(2)(A)(iii) of the FD&C Act specifies to calculate the inflation adjustment for non-payroll costs, we multiply 4.1709 percent by the average proportion of all costs other than PC&B to total FDA costs for the first 3 years of the preceding 4 fiscal years. Since 52.2090 percent was obligated for PC&B as shown in table 2, 47.7910 percent is the portion of costs other than PC&B (100 percent minus the PC&B percentage of 52.2090). The portion of the inflation adjustment relating to non-

payroll costs is 4.1709 percent multiplied by 47.7910 percent, or 1.9933 percent.

Next, we add the payroll component (2.8451 percent) to the non-payroll component (1.9933 percent), for an inflation adjustment of 4.8384 percent for FY 2026.

Section 741(c)(2)(B) of the FD&C Act provides for the inflation adjustment to be compounded each fiscal year after FY 2025. The inflation adjustment for FY 2026 (4.8384 percent) is compounded

by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2025 (1.03934), which equals 1.0896 (rounded) (1.0896 × 1.0). We then multiply the base revenue amount for FY 2026 (\$25,000,000) by 1.0896, yielding an inflation adjusted amount of \$27,240,675

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

Section 741(c)(3)(A) of the FD&C Act specifies that fee revenue amounts for

¹ The data is published by the Bureau of Labor Statistics and can be found on its website at: <https://data.bls.gov/timeseries/CUURS35ASA0L1E>.

FY 2025 and subsequent fiscal years are subject to adjustment to account for changes in FDA's review workload. The workload adjustment would be applied to the inflation adjusted fee revenue amount.

To determine whether a workload adjustment applies, per AGDUFA IV commitments FDA calculates the weighted average of the change in the total number of each of the six types of applications and submissions specified in the workload adjustment provision (abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug

study submissions, investigational generic new animal drug protocol submissions, generic investigational new animal drug file requests, and generic investigational new animal drug meeting requests) received over the 5-year period that ended on September 30, 2023 (the base years; 2019 through 2023), and the average number of each of these types of applications and submissions over the most recent 5-year period that ended April 30, 2025.

The results of these calculations are presented in the first two columns of table 4. Column 3 reflects the percent change in workload over the two 5-year periods. Column 4 shows the weighting factor for each type of application/

submission, reflecting how much of the total FDA generic new animal drug review workload was accounted for by each type of application or submission in the table during the most recent 5 years. Column 5 is the weighted percent change in each category of workload and was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. At the bottom right of the table, the sum of the values in column 5 is calculated, reflecting a total change in workload of 1.8988% percent for FY 2026. This is the workload adjuster for FY 2026.

TABLE 4—WORKLOAD ADJUSTER CALCULATION

Application type	Column 1 5-Year average (base years)	Column 2 Latest 5-year average	Column 3 Percent change	Column 4 Weighting factor	Column 5 Weighted percent change
Abbreviated Application for a Generic New Animal Drug (ANADAs)	30.80	30.20	– 1.9481	0.1033	–0.2013
Manufacturing Supplements ANADAs	264.00	269.60	2.1212	0.2429	0.5153
Generic Investigational Study Submissions	166.80	169.60	1.6787	0.4678	0.7853
Generic Investigational Protocol Submissions	50.20	50.80	1.1952	0.0983	0.1175
Generic Investigational New Animal Drug File Requests (JINAD)	47.20	43.60	– 7.6271	0.0167	–0.1273
Generic Investigational New Animal Drug Meeting Requests (JINAD)	29.80	33.20	11.4094	0.0709	0.8094
FY 2026 AGDUFA IV Workload Adjuster					1.8988

Per section 741(c)(3)(C) of the FD&C Act under no circumstances shall the workload adjustment result in fee revenues that are less than the base fee revenues for that fiscal year as adjusted for inflation. For FY 2026 the workload adjustment would not result in fee revenues less than the base fee revenues as adjusted for inflation, therefore a workload adjustment of \$517,110 shall be applied.

Per section 741(c)(3)(B) of the FD&C Act, for each of fiscal years 2026 through 2028, if application of the workload adjustment increases the fee revenue amounts otherwise established for the fiscal year, as adjusted for inflation, such fee revenue increase shall be reduced by the amount of any excess collections for the second preceding fiscal year, up to the amount of such fee revenue increase. The second preceding fiscal year for FY 2026 resulted in excess collections of \$2,776,000, which is higher than the corresponding workload adjustment for FY 2026, and therefore, the workload adjustment is reduced to \$0.

D. FY 2026 Fee Revenue Amounts

AGDUFA IV specifies that the revenue amount of \$27,241,000 (rounded) for FY 2026 is to be divided as follows: 20 percent, or a total of \$5,448,200, is to come from application and/or JINAD file fees; 40 percent, or a total of \$10,896,400, is to come from product fees; and 40 percent, or a total of \$10,896,400 is to come from sponsor fees (See section 741(b) of the FD&C Act).

III. Abbreviated Application Fee and Generic Investigational New Animal Drug (JINAD) File Fee Calculations for FY 2026

A. Fee Revenues and Numbers of Fee-Paying Applications and Submissions

Section 741(a)(1)(A) of the FD&C Act states that each person who submits an abbreviated application for a generic new animal drug shall be subject to an application fee, with limited exceptions. The term “abbreviated application for a generic new animal drug” means an abbreviated application for the approval of any generic new animal drug submitted under section 512(b)(2) of the FD&C Act. FDA will assess fees related to JINAD files under section

741(a)(4)(A)(i) of the FD&C Act when a person submits a request to establish a new JINAD file. FDA will assess a fee under section 741(a)(4)(A)(ii) and (iii) of the FD&C Act for a person's first submission, as described below, to a JINAD file on or after October 1, 2023, where the JINAD file had been established prior to that date. The JINAD file fee is set in accordance with section 741(c)(1)(C) of the FD&C Act at \$50,000. FDA will set the abbreviated application fee so that such fees combined with the JINAD file fees will generate a combined total of \$5,448,200 in fee revenue for FY 2026.

To set fees for abbreviated applications for generic new animal drugs, FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive during FY 2026, the number of requests to establish new JINAD files it will receive during FY 2026, and the number of existing (prior to October 1, 2023) JINAD files to which it will receive submissions during FY 2026.

Regarding the fee for a person's first submission to an existing (prior to October 1, 2023) JINAD file on or after October 1, 2023, FDA intends to assess

a fee only for the first data (or “P”) submission to the Bioequivalence (BE) or Chemistry, Manufacturing, and Controls (CMC) technical sections of the JINAD file. The Agency has selected P submissions to the BE or CMC technical sections as the basis for assessing this fee because P submissions to these sections consistently entail the substantial use of FDA review hours during the phased review process.

The Agency knows the numbers of applications and submissions that have been submitted in previous years. Those numbers fluctuate annually. In estimating the fee revenue to be generated by application and submission fees in FY 2026, FDA is assuming that the number of applications and submissions for which fees will be paid in FY 2026 will equal the average number of applications and submissions over the 5 most recently completed fiscal years of the AGDUFA program (FY 2020–FY 2024).

In addition, under section 741(a)(1)(C)(ii) of the FD&C Act an abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4) of the FD&C Act and submitted on or after October 1, 2013, shall be subject to 50 percent of the fee applicable to all other abbreviated applications for a generic new animal drug.

The average number of original submissions of abbreviated applications for generic new animal drugs over the 5 most recently completed fiscal years is 21.2 applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 4.0 submissions subject to the criteria in section 512(d)(4). Each of the submissions described under section 512(d)(4) of the FD&C Act pays 50 percent of the fee paid by the other applications and will be counted as one half of a fee. Adding all of the applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 50 percent of the number that are subject to such criteria results in a total of 23.2 anticipated full fees.

Based on the previous assumptions, FDA is estimating that it will receive a total of 23.2 fee-paying generic new animal drug applications in FY 2026 (21.2 original applications paying a full fee and 4.0 applications paying a half fee).

For estimating the number of requests to establish a new JINAD file and the number of P submissions to the BE or CMC section of an existing (prior to October 1, 2023) JINAD file the Agency will receive in FY 2026, FDA took the number of new JINAD file requests and P submissions to the BE or CMC section of an existing JINAD file received in FY

2025. The number of requests to establish new JINAD files and P submissions to the BE or CMC section of existing JINAD files during FY 2025 as of June is 45.

Based on the previous assumptions, FDA is estimating that it will receive a total of 45 fee-paying JINAD file submissions in FY 2026 (including both requests to establish new JINAD files and first P submissions to the BE or CMC section of existing (prior to October 1, 2023) JINAD files).

B. Application Fee Rates for FY 2026

FDA must set the fee rates for FY 2026 so that the estimated 23.2 abbreviated application fees and 45 JINAD file fees will generate a total of \$5,448,200. The fee for a new JINAD file request or the first submission to an existing (prior to October 1, 2023) JINAD file is \$50,000 under section 741(c)(1)(C) of the FD&C Act. Therefore, the JINAD fees will generate a total of \$2,250,000. Abbreviated application fees will have to generate a total of \$3,198,200.

To generate this amount, the fee for a generic new animal drug application will be \$137,853 and for those applications that are subject to the criteria set forth in section 512(d)(4) of the FD&C Act, 50 percent of that amount, or \$68,927.

IV. Generic New Animal Drug Product Fee Calculations for FY 2026

A. Product Fee Revenues and Numbers of Fee-Paying Products

The generic new animal drug product fee must be paid annually by the person named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360), and who had an abbreviated application or supplemental abbreviated application for a generic new animal drug product pending at FDA after September 1, 2008 (21 U.S.C. 379j–21(a)(2)). Section 741(k)(6) of FD&C Act defines “generic new animal drug product” as a specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the National Drug Code, and for which an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug has been approved. The product fees are to be set so that they will generate \$10,896,400 in fee revenue for FY 2026.

To set generic new animal drug product fees to realize \$10,896,400, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2026. FDA gathered data on all generic new animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who FDA estimated would have a generic new animal drug application or supplemental abbreviated application pending after September 1, 2008. As of May 2025, FDA estimates that there is a total of 679 products submitted for listing by persons who had an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug pending after September 1, 2008. Based on this, FDA believes that a total of 679 products will be subject to this fee in FY 2026.

Per section 741(d) of the FD&C Act in estimating the fee revenue to be generated by generic new animal drug product fees in FY 2026, FDA is estimating that 0.5 percent of the products invoiced, or 3 products, will not pay fees in FY 2026, due to fee waivers and reductions. FDA has made this estimate at 0.5 percent this year, based on historical data over the past 5 completed fiscal years of the AGDUFA program.

Accordingly, the Agency estimates that a total of 676 (679 minus 3) products will be subject to product fees in FY 2026.

B. Product Fee Rates for FY 2026

FDA must set the fee rates for FY 2026 so that the estimated 676 products for which fees are paid will generate a total of \$10,896,400. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest dollar, to be \$16,119.

V. Generic New Animal Drug Sponsor Fee Calculations for FY 2026

A. Sponsor Fee Revenues and Numbers of Fee-Paying Sponsors

The generic new animal drug sponsor fee must be paid annually by each person who: (1) is named as the applicant in an abbreviated application for a generic new animal drug, except for an approved application for which all subject products have been removed from listing under section 510 of the FD&C Act, or has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive; and (2) had an abbreviated application for a generic new animal drug, supplemental abbreviated

application for a generic new animal drug, or investigational submission for a generic new animal drug pending at FDA after September 1, 2008. See section 741(k)(7) and (a)(3) of the FD&C Act.

Per section 741(a)(3)(C) of the FD&C Act, a generic new animal drug sponsor is subject to only one such fee each fiscal year. Applicants with more than 6 approved abbreviated applications will pay 100 percent of the sponsor fee; applicants with more than 1 and fewer than 7 approved abbreviated applications will pay 75 percent of the sponsor fee; and applicants with 1 or fewer approved abbreviated applications will pay 50 percent of the sponsor fee. The sponsor fees are to be set so that they will generate \$10,896,400 in fee revenue for FY 2026.

To set generic new animal drug sponsor fees to realize \$10,896,400, FDA must make some assumptions about the

number of sponsors who will pay these fees in FY 2026. FDA developed data on all generic new animal drug sponsors and matched this to the list of all sponsors who had pending submissions and applications after September 1, 2008. As of May, 2025, FDA estimates that in FY 2026, 16 sponsors will pay 100 percent fees, 16 sponsors will pay 75 percent fees, and 29 sponsors will pay 50 percent fees. The total of these figures is the equivalent of 42.50 full sponsor fees (16 times 100 percent or 16, plus 16 times 75 percent or 12 plus 29 times 50 percent or 14.5).

FDA estimates that about 2 percent of all of these sponsors, or 0.85, will not pay fees in FY 2026, due to fee waivers and reductions. FDA has made the estimate of the percentage of sponsors that will not pay fees at 2 percent this year, based on historical data over the past 5 completed fiscal years of the

AGDUFA program. See section 741(d) of the FD&C Act.

Accordingly, the Agency estimates that the equivalent of 41.65 full sponsor fees (42.50 minus 0.85) are likely to be paid in FY 2026.

B. Sponsor Fee Rates for FY 2026

FDA must set the fee rates for FY 2026 so that the estimated equivalent of 41.65 full sponsor fees will generate a total of \$10,896,400. To generate this amount will require the 100 percent fee for a generic new animal drug sponsor, rounded to the nearest dollar, to be \$261,618. Accordingly, the fee for those paying 75 percent of the full sponsor fee will be \$196,214, and the fee for those paying 50 percent of the full sponsor fee will be \$130,809.

VI. Fee Schedule for FY 2026

The fee rates for FY 2026 are summarized in table 5.

TABLE 5—FY 2026 FEE RATES

User fee category	Fee rate for FY 2026
Abbreviated Application Fee for Generic New Animal Drug except those subject to the criteria in section 512(d)(4)	\$137,853
Abbreviated Application Fee for Generic New Animal Drug subject to the criteria in section 512(d)(4)	68,927
Generic Investigational New Animal Drug File Fee (JINAD)	50,000
Generic New Animal Drug Product Fee	16,119
100% Generic New Animal Drug Sponsor Fee ¹	261,618
75% Generic New Animal Drug Sponsor Fee ¹	196,214
50% Generic New Animal Drug Sponsor Fee ¹	130,809

¹ An animal drug sponsor is subject to only one fee each fiscal year.

VIII. Fee Waiver or Reduction; Exemption From Fees

Per section 741(d)(1), of the FD&C Act the types of fees waivers and reductions that applied last fiscal year still exist for FY 2026. However, after September 30, 2023, there is no longer an exemption for any person who submits to CVM a supplemental abbreviated application relating to a generic new animal drug approved under section 512 of the FD&C Act, solely to add the application number to the labeling of the drug in the manner specified in section 502(w)(3) of the FD&C Act (21 U.S.C. 352(w)(3)).

Waivers or reductions remain available for abbreviated applications for generic new animal drugs intended solely for a minor use/minor species indication; see section 741(d) of the FD&C Act.

IX. Procedures for Paying the FY 2026 Fees

A. Abbreviated Application Fees, JINAD File Fees, and Payment Instructions

The FY 2026 fees established in the new fee schedule must be paid for the following applications/submissions that

are subject to fees under AGDUFA IV and submitted on or after October 1, 2025: a generic new animal drug application, a submission requesting to establish a JINAD file, or the first BE or CMC submission to a JINAD file that was established prior to October 1, 2023. Payments made to FDA must be made in U.S. currency drawn on a U.S. bank by electronic check, credit card, or wire transfer.² The preferred method for payments to FDA is online using electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website upon receipt of an invoice or after completing the User Fee Cover Sheet and generating the user fee ID number.

Secure electronic payments to FDA can be submitted using the User Fees

Payment Portal at <https://userfees.fda.gov/pay>. (Note: Only full payments are accepted; no partial payments can be made online.) Once an invoice or cover sheet is located, “Pay Now” should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID or invoice number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID or invoice number, the payment may not be applied. If a fee is not paid in full, the fee will be treated as a claim of the U.S. Government (see section 740(h) of the FD&C Act), meaning the invoice balance due amount must be referred to collections. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully

² See “Change in Federal Payment and Collection Options” announcement published in the **Federal Register** on June 27, 2025 (90 FR 27639).

paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, account number: 75060099, routing number: 021030004, SWIFT: FRNYUS33. FDA's tax identification number is 53-0196965.

It is important that the fee arrives at the bank at least a day or two before the abbreviated application or JINAD submission arrives at FDA's CVM. FDA records the official abbreviated application or JINAD submission receipt date as the later of the following: the date the application or submission was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Department of the Treasury notifies FDA of payment. U.S. Bank and the U.S. Department of the Treasury are required to notify FDA within 1 working day, using the PIN described previously.

The tax identification number of FDA is 53-0196965.

B. Application and JINAD File Submission Cover Sheet Procedures

Step One: Create a user account and password. Log onto the AGDUFA website at <https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm> and, under Application Submission Information, click on "Create AGDUFA User Fee Cover Sheet" and follow the directions. For security reasons, each firm submitting an application and/or a JINAD file submission will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two: Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your username and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated application for a generic new animal drug or JINAD file submission. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three: Send the payment for your application or JINAD file submission as described in section IX.A.

Step Four: Submit your application or JINAD file submission.

C. Product and Sponsor Fees

By December 31, 2025, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2026 using this fee schedule. Payment will be due by January 31, 2026. FDA will issue invoices in November 2026 for any products and sponsors subject to fees for FY 2026 that qualify for fees after the December 2025 billing.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-14409 Filed 7-29-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-2030]

Tobacco Products Scientific Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Tobacco Products Scientific Advisory Committee (TPSAC, the Committee). The general function of the Committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on October 7, 2025, from 9:00 a.m. to 4:30 p.m. Eastern Time.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. The public will have the option to participate, and the advisory committee meeting and meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/>

AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.

For those unable to attend in person, the meeting will also be webcast and will be available at the following links:

Live Link: <https://youtube.com/live/MNXGH9aki4I?feature=share>.

Caption Link: <http://upload.youtube.com/closedcaption?cid=jfzr-97fr-a9ax-sxcz-c31k>.

FOR FURTHER INFORMATION CONTACT:

Rachel Jang, PharmD, DFO, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993-0002, 1-877-287-1373, TPSAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On October 7, 2025, the Center for Tobacco Product's TPSAC will convene for one open session, during which the Committee will discuss the renewal of modified risk granted orders issued to Philip Morris Products S.A. for the following products:

- MR0000059: Marlboro Amber HeatSticks
- MR0000060: Marlboro Green Menthol HeatSticks
- MR0000061: Marlboro Blue Menthol HeatSticks
- MR0000133: IQOS 2.4 System Holder and Charger
- MR0000192: IQOS 3.0 System Holder and Charger

Discussion will focus on whether the statutory standards continue to be met.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting and be posted on the FDA's website after the meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at <https://>

www.fda.gov/AdvisoryCommittees/Calendar/default.htm. The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Written submissions may be submitted to the contact person on or before September 25, 2025. Oral presentations from the public will be scheduled between 1:00 p.m. and 2:00 p.m. ET on October 7, 2025. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**) and submit a brief statement describing the general nature of the evidence or arguments they wish to present, the names and email addresses of proposed participants, and whether they would like to present online or in-person, on or before September 11, 2025. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. Similarly, room for interested persons to participate in-person may be limited. If the number of registrants requesting to speak in-person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the advisory committee meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in-person. The contact person will notify interested persons regarding their request to speak by September 15, 2025.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Rachel Jang, PharmD, DFO (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on

public conduct during advisory committee meetings.

For press inquiries, please contact the HHS Press Room at www.hhs.gov/press-room/index.html or 202-690-6343.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform in conjunction with the physical meeting room (see location). This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. No participant will be prejudiced by this waiver, and that the ends of justice will be served by allowing for this modification to FDA's advisory committee meeting procedures.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-14347 Filed 7-29-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-2522]

Medical Device User Fee Rates for Fiscal Year 2026

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2026. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device User Fee Amendments of 2022 (MDUFA V), authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. This notice establishes the fee rates for FY 2026, which apply from October 1, 2025, through September 30, 2026, and provides information on how the fees for FY 2026 were determined, the payment procedures you should follow, and how you may qualify for reduced small business fees.

FOR FURTHER INFORMATION CONTACT: For information on Medical Device User

Fees: <https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa>. For questions relating to the MDUFA Small Business Program, please visit the Center for Devices and Radiological Health's website: <https://www.fda.gov/medical-devices/premarket-submissions/reduced-medical-device-user-fees-small-business-determination-sbd-program>. For questions relating to this notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20903, 240-402-4989; or the User Fee Support Staff at UFSS@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The FD&C Act, as amended by MDUFA V, authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. Section 738 of the FD&C Act (21 U.S.C. 379j) establishes fees for certain medical device applications, submissions, supplements, notices, and requests (for simplicity, this document refers to these collectively as "submissions" or "applications"); for periodic reporting on class III devices; and for the registration of certain establishments.

Under the FD&C Act, the fee rate for each type of submission is set at a specified percentage of the standard fee for a premarket application (a premarket application is a premarket approval application (PMA), a product development protocol (PDP), or a biologics license application (BLA)). The FD&C Act specifies the base fee for a premarket application for each year from FY 2023 through FY 2027; the base fee for a premarket application received by FDA during FY 2026 is \$455,000. From this starting point, this document establishes FY 2026 fee rates for certain types of submissions, and for periodic reporting, by applying criteria specified in the FD&C Act. Under statutorily defined conditions, a qualified applicant may receive a fee waiver or may pay a lower small business fee (see sections 738(a)(3)(B), 738(d) and 738(e) of the FD&C Act). For more information on fee waivers, please see Section IX. Small Business Fee Reductions and Fee Waivers.

The FD&C Act specifies the base fee for establishment registration for each year from FY 2023 through FY 2027; the base fee for an establishment registration in FY 2026 is \$7,575. Each establishment that is registered (or is required to register) with the Secretary of Health and Human Services under

section 510 of the FD&C Act, because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device, is required to pay the annual fee for establishment registration.

II. Total Revenue Amount for FY 2026

The total revenue amount for FY 2026 is \$366,486,300, as set forth in the statute prior to the inflation adjustment (see section 738(b)(3) of the FD&C Act). MDUFA V directs FDA to use the yearly total revenue amount as a starting point to set the standard fee rates for each fee

type. The fee calculations for FY 2026 are described in this document.

Inflation Adjustment

MDUFA specifies that the \$366,486,300 is to be adjusted for inflation increases for FY 2026 using two separate adjustments: one for payroll costs and one for non-payroll costs (see 738(c)(2)). The base inflation adjustment for FY 2026 is the sum of one plus the two separate adjustments and is compounded as specified in the statute (see section 738(c)(2)(C) and 738(c)(2)(B) of the FD&C Act).

The component of the inflation adjustment for payroll costs is the

average annual percent change in the cost of all personnel compensation and benefits (PC&B) paid per full-time equivalent (FTE) position at FDA for the first 3 of the 4 preceding FYs, multiplied by 0.60, or 60 percent (see section 738(c)(2)(C)(i)(I) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified FYs, provides the percent change from the previous fiscal year, and provides the average percent change over the first 3 of the 4 fiscal years preceding FY 2026. The 3-year average is 5.4494 percent (rounded).

TABLE 1—FDA PC&BS EACH YEAR AND PERCENT CHANGE

	FY 2022	FY 2023	FY 2024	3-year average
Total PC&B	\$3,165,477,000	\$3,436,513,000	\$3,791,729,000	
Total FTE	18,474	18,729	19,687	
PC&B per FTE	\$171,348	\$183,486	\$192,601	
Percent change from previous year	4.2967%	7.0838%	4.9677%	5.4494%

The payroll adjustment is 5.4494 percent multiplied by 60 percent, or 3.2696 percent. The statute specifies that the component of the inflation adjustment for non-payroll costs for FY 2026 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Arlington-Alexandria, DC-

VA-MD-WV; Not Seasonally Adjusted; All Items; Annual Index) for the first 3 of the preceding 4 years of available data multiplied by 0.40, or 40 percent (see section 738(c)(2)(C)(i)(II) of the FD&C Act).

Table 2 provides the summary data and the 3-year average percent change in the specified CPI for the Washington-

Arlington-Alexandria area. These data are published by the Bureau of Labor Statistics and can be found on their website under series Id CUURS35ASA0 at: https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0.

TABLE 2—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN WASHINGTON-ARLINGTON-ALEXANDRIA AREA CPI

	2022	2023	2024	3-year average
Annual CPI	296.117	305.317	315.186	
Annual Percent Change	6.6212%	3.1069%	3.2324%	
3-Year Average Percent Change in CPI				4.3202%

The non-payroll adjustment is 4.3202 percent multiplied by 40 percent, or 1.7281 percent. Next, the payroll adjustment (3.2696 percent or 0.032696) is added to the non-payroll adjustment (1.7281 percent or 0.017281), for a total of 4.9977 percent (or 0.049977). To complete the inflation adjustment, 1 (100 percent or 1.0) is added for a total base inflation adjustment of 1.049977 for FY 2026. If the base inflation adjustment for a fiscal year is greater than 1.04, such adjustment shall be considered to be equal to 1.04 (see section 738(c)(2)(C)(ii)(II) of the FD&C Act). The total base inflation adjustment for FY 2026 is 1.04.

MDUFA V provides for this inflation adjustment to be compounded for FY 2023 and each subsequent fiscal year (see section 738(c)(2)(B) of the FD&C Act). To complete the compounded inflation adjustment for FY 2026, the FY

2025 compounded adjustment (1.122491) is multiplied by the FY 2026 base inflation adjustment (1.040000) to reach the applicable inflation adjustment of 1.167391 (rounded) for FY 2026. We then multiply the total revenue amount for FY 2026 (\$366,486,300) by 1.167391, yielding an inflation adjusted total revenue amount of \$427,833,000 (rounded to the nearest thousand dollars).

III. Adjustments to Base Fee Amounts for FY 2026

Under the FD&C Act, all submission fees and the periodic reporting fee are set as a percent of the standard (full) fee for a premarket application (see section 738(a)(2)(A) and (b)(1)).

A. Inflation Adjustment

MDUFA specifies that the base fees of \$455,000 (premarket application) and

\$7,575 (establishment registration) are to be adjusted for FY 2026 using the same methodology as that for the total revenue inflation adjustment in section II (see section 738(c)(2)(D)(i) of the FD&C Act). Multiplying the base fees by the compounded inflation adjustment of 1.167391 yields inflation adjusted base fees of \$531,163 (premarket application) and \$8,843 (establishment registration).

B. Further Adjustments To Generate the Inflation-Adjusted Total Revenue Amount

After the applicable inflation adjustment to fees is done, FDA may increase, if necessary to achieve the inflation adjusted total revenue amount, the base fee amounts on a uniform proportionate basis (see section 738(c)(2)(D)(ii) of the FD&C Act). After this adjustment, if necessary, FDA may further increase the base establishment

registration fees to generate the inflation-adjusted total revenue amount (see section 738(c)(3)).

For FY 2026, further adjustments were required to meet the inflation adjusted total revenue amount of \$427,833,000. After increasing base fees, on a uniform proportionate basis, and further increasing establishment registration fees, this yields inflation adjusted base fees of \$579,272 (premarket application) and \$9,760 (establishment registration).

C. MDUFA V Adjustments Solely to Registration Fees

MDUFA V has three new potential adjustments that will not change the total revenue amount but may impact collections by increasing or decreasing establishment registration base fees only. These adjustments are the performance improvement adjustment, the hiring adjustment, and the operating reserve adjustment.

1. Performance Improvement Adjustment

Beginning with FY 2025, this adjustment allows FDA to collect fees in addition to the total revenue amount in FYs 2025, 2026, and 2027, if the Agency meets certain performance goals in FYs 2023, 2024, and 2025. If applicable, this provision further increases base establishment registration fee amounts to achieve an increase in total fee collections equal to the applicable performance improvement adjustment amount, which is set forth in the statute (see section 738(c)(4)). FDA met the FY 2024 Pre-Submission Written Feedback goal and the FY 2023 De Novo Decision goal, which determine the amount of the performance improvement adjustment for FY 2026.

For FY 2026, the performance improvement adjustment amount is equal to the product of (1) the sum of the pre-submission amount in section 738(c)(4)(B)(i)(II)(bb), \$36,792,200 and the de novo classification request amount in section 738(c)(4)(B)(ii)(I), \$6,323,500 and (2) the applicable inflation adjustment under section 738(c)(2)(B), 1.167391. See section 738(c)(4)(A)(ii). For FY 2026, the performance improvement adjustment is \$50,332,880.

2. Hiring Adjustment

Beginning with FY 2025, this adjustment provides for the reduction of base establishment registration fees in FYs 2025, 2026, and 2027, if specified hiring goals for FYs 2023, 2024, and 2025 are not met by a certain threshold. The hiring adjustment would serve to decrease the base establishment

registration fee amounts, as necessary, to achieve a reduction in total fee collections equal to the hiring adjustment amount, which is set forth in the statute (see section 738(c)(5)).

FDA met the FY 2024 statutory hiring threshold of 38 hires, so establishment registration fees will not need to be lowered by the hiring adjustment amount in FY 2026.

3. Operating Reserve Adjustment

For FYs 2023 to 2027, the operating reserve adjustment requires FDA to decrease base establishment registration fees if the amount of operating reserves of carryover user fees exceeds the “designated amount”, and such reduction is necessary to provide for not more than such designated amount of operating reserves of carryover user fees (see section 738(c)(6)(A)). In making this calculation for FYs 2023 to 2026, a certain amount is excluded from the designated amount and is not subject to the decrease (see section 738(c)(6)(C)). For FY 2026, this excluded amount is \$61,892,215.

The designated amount is equal to the sum of 13 weeks of operating reserves of carryover user fees plus 1 month of operating reserves, as described in 738(c)(8) (see 738(c)(6)(B)).

To determine the 13-week operating reserves of carryover user fees amount, the FY 2026 inflation-adjusted total revenue amount (from section II), \$427,833,000, is added to the inflation-adjusted performance improvement adjustment amount (from section III.C.1), \$50,332,880, resulting in \$478,165,880. This amount is then divided by 52, and then multiplied by 13. The 13-week operating reserve amount for FY 2026 is \$119,541,470.

To determine the 1 month of operating reserves described in section 738(c)(8) of the FD&C Act, the FY 2026 inflation-adjusted total revenue amount of \$427,833,000 is added to the inflation-adjusted performance improvement adjustment amount of \$50,332,880, resulting in \$478,165,880. This amount is then divided by 12. The 1 month of operating reserves for FY 2026 is \$39,847,157.

For FY 2026, the designated amount is equal to the 13-week operating reserve of \$119,541,470 plus the 1 month of operating reserves of \$39,847,157, totaling \$159,388,627.

To determine the FY 2025 end-of-year operating reserves of carryover user fees amount, FDA combined the actual collections and obligations at the end of the third quarter (June 2025) and added the forecasted collections and obligations for the fourth quarter of FY 2025 to generate a full year estimate for

FY 2025. The estimated end-of-year FY 2025 operating reserves of carryover user fees is \$56,152,612 (Note, this amount includes the 1-month reserve).

Note that under MDUFA V, for the purposes of calculating the operating reserve adjustment, this amount does not include user fee funds considered unappropriated (\$26,680,243) or unearned revenue (\$65,193,572). In addition, as noted above, for purposes of the operating reserve adjustment, operating reserves of carryover user fees do not include the estimated \$61,892,215 remaining to spend at the end of FY 2025 from the total of \$118,000,000 intended to support the Total Product Life Cycle Advisory Program Pilot and Third-Party Review programs.

Because the estimated end-of-year FY 2025 MDUFA operating reserves of carryover user fees amount totaling \$56,152,612 does not exceed the FY 2026 designated amount of \$159,388,627 FDA will not decrease the base establishment registration fee amounts for FY 2026 to provide for not more than such designated amount.

As there is a performance improvement adjustment for FY 2026, but no hiring adjustment or operating reserve adjustment, establishment registration fees are increased to achieve an increase in total fee collections for FY 2026 equal to the performance improvement adjustment amount of \$50,332,880. After so increasing establishment registration fees only, this yields fees of \$579,272 (premarket application) and \$11,423 (establishment registration).

IV. Calculation of Fee Rates

As noted in section II, the total revenue amount after the applicable inflation adjustment is \$427,833,000 (rounded to the nearest thousand dollar). As noted in section III, the performance improvement adjustment solely to registration fees for FY 2026 is \$50,332,880. There is no hiring adjustment or operating reserve adjustment for FY 2026.

Table 3A provides fee-paying submission counts, excluding establishment registration, for the last 3 years and the 3-year average. Table 3B provides establishment registration fee-paying submission counts for the most recently completed fiscal year (FY 2024). Historically, FDA has estimated the total number of fee-paying submission counts it expects to receive during the next fiscal year by averaging the number of fee-paying submission counts received in the 3 most recently completed fiscal years; for FY 2026 fee-setting, this would be an average of FY

2022 through FY 2024. FDA received an abnormally high volume of fee-paying establishment registrations due to the COVID–19 pandemic in FY 2020 and FY 2021. The surge in fee-paying establishment registrations has been declining starting in FY 2022, trending

back toward pre-pandemic levels. In an effort to normalize the projected volume of establishment registration submissions for the FY 2026 fee-setting calculation, and more accurately project the associated establishment registration revenue, FDA decided to utilize the

number of establishment registration fee-paying submission counts from FY 2024, after making an adjustment to account for implementation of the small business registration fee waiver for FY 2026.

TABLE 3A—THREE-YEAR AVERAGE OF FEE-PAYING SUBMISSIONS
[Excluding establishment registration]

Application type	FY 2022 Actual	FY 2023 Actual	FY 2024 Actual	3 Yr average
Full Fee applications	18	31	20	23
Small Business	3	3	4	3
Panel-Track Supplements	21	22	26	23
Small Business	1	5	2	3
De Novo Classifications	23	26	26	25
Small Business	53	68	47	56
180-Day Supplements	93	113	127	111
Small Business	31	12	15	19
Real-Time Supplements	140	138	157	145
Small Business	12	28	35	25
510(k)s	2,012	1,943	1,754	1,903
Small Business	1,757	2,031	2,066	1,951
30-Day Notice (Note also includes counts for 135 Day Supplements)	782	825	854	820
Small Business	67	53	62	61
513(g)(21 U.S.C. 360c(g)) Request for Classification Information	93	82	65	80
Small Business	58	59	68	62
Annual Fee for Periodic Reporting	620	657	700	659
Small Business	87	22	32	47

TABLE 3B—FISCAL YEAR 2024 ACTUAL FEE-PAYING
[Establishment registration submissions]

Application type	FY 2024	FY 2026 Estimate for registrations
Establishment Registrations	30,280	30,270

The information in tables 3A and 3B is necessary to estimate the amount of revenue that will be collected based on the fee amounts. Tables 4A and 4B display the FY 2026 base fees set in statute (column one) and the inflation adjusted base fees (per calculations in section III.A.) (column two). Using the inflation adjusted fees, the 3-year average of fee-paying submissions (excluding establishment registration), and the fee-paying establishment registration submissions from FY 2024, collections are projected to total \$389,083,279 which is \$38,749,721 lower than the inflation adjusted total revenue amount (in section II). Accordingly, the next step in the fee setting process is to increase the base fee amounts on a uniform proportionate

basis to generate the inflation adjusted total revenue amounts (see 738(c)(2)(D)(ii) and table 4A, column three).

Applying these further adjusted fee rates to the 3-year average of fee-paying submissions, and the fee-paying establishment registration submissions from FY 2024 results in estimated total fee collections of \$424,326,053 which is still \$3,506,947 lower than the inflation adjusted total revenue amount (in Section II). The next step in the fee setting process, after the adjustment in (2)(D) is done, is to increase the base establishment registration fee amount as necessary for total fee collections to generate the inflation adjusted total revenue amount, as adjusted under paragraph (2) (see 738(c)(3)).

Accordingly, the base establishment registration fee was increased by \$116 for an establishment registration fee rate of \$9,760 (see 738(c)(3) and table 4B, column three). The performance improvement adjustment amount is \$50,332,880. Per statute, the establishment registration fee is further adjusted to account for the performance improvement adjustment amount. The inflation adjusted establishment registration fee is increased by \$1,663 for an establishment registration fee of \$11,423. The fees in column three in table 4A and column four in table 4B are those we are establishing for FY 2026, which are the standard fees.

TABLE 4A—FEES NEEDED TO ACHIEVE NEW FY 2026 REVENUE TARGET

Application type	FY 2026 Statutory fees (base fees)	FY 2026 Inflation adjusted statutory base fees	Adjusted FY 2026 fees to meet revenue target (uniform proportionate increase)	3-Year average of fee-paying submissions	FY 2026 Revenue from adjusted fees
Full Fee Application	\$455,000	\$531,163	\$579,272	23	\$13,323,256
Small Business	113,750	132,791	144,818	3	434,454
Panel-Track Supplement	364,000	424,930	463,418	23	10,658,614
Small Business	91,000	106,233	115,855	3	347,565
De Novo Classification Request	136,500	159,349	173,782	25	4,344,550
Small Business	34,125	39,837	43,446	56	2,432,976
180-Day Supplement	68,250	79,674	86,891	111	9,644,901
Small Business	17,063	19,919	21,723	19	412,737
Real-Time Supplement	31,850	37,181	40,549	145	5,879,605
Small Business	7,963	9,295	10,137	25	253,425
510(k) Premarket Notification Submission	20,475	23,902	26,067	1,903	49,605,501
Small Business	5,119	5,976	6,517	1,951	12,714,667
30-Day Notice	7,280	8,499	9,268	820	7,599,760
Small Business	3,640	4,249	4,634	61	282,674
513(g) Request for Classification Information	6,143	7,171	7,820	80	625,600
Small Business	3,072	3,585	3,910	62	242,420
Annual Fee for Periodic Reporting	15,925	18,591	20,275	659	13,361,225
Small Business	3,981	4,648	5,069	47	238,243
Total					132,402,173

The standard fee (adjusted base amount) for a premarket application, including a BLA, and for a premarket report and a BLA efficacy supplement, is \$579,272 for FY 2026.

The fees set by reference to the standard fee for a premarket application are:

- For a panel-track supplement, 80 percent of the standard fee
- For a de novo classification request, 30 percent of the standard fee

- For a 180-day supplement, 15 percent of the standard fee
- For a real-time supplement, 7 percent of the standard fee
- For an annual fee for periodic reporting concerning a class III device, 3.5 percent of the standard fee
- For a 510(k) premarket notification, 4.5 percent of the standard fee
- For a 30-day notice, 1.6 percent of the standard fee
- For a 513(g) request for classification information, 1.35 percent of the standard fee

For all submissions other than a 30-day notice and a 513(g) request for classification information, the small business fee is 25 percent of the standard (full) fee for the submission (see 738(d)(2)(C) and (e)(2)(C)). For a 30-day notice and a 513(g) request for classification information, the small business fee is 50 percent of the standard (full) fee for the submission (see 738(d)(2)(C)).

TABLE 4B—FEES NEEDED TO ACHIEVE NEW FY 2026 REVENUE TARGET PLUS/MINUS ADJUSTMENTS

Application type	FY 2026 statutory fees (base fees)	FY 2026 inflation adjusted statutory base fees	Adjusted FY 2026 fees to meet inflation adjusted total revenue amount (Uniform Proportionate In- crease + Further Adjustment to Establishment Registrations)	Adjusted FY 2026 fees to meet inflation adjusted total revenue +/- adjustments	FY 2024 fee-paying submissions	FY 2026 revenue from adjusted fees
Establishment Registrations	\$7,575	\$8,843	\$9,760	\$11,423	30,270	\$295,435,200

The annual fee for establishment registration, after adjustments, is set at \$11,423 for FY 2026. For FY 2026, FDA may, but is not required to, grant a waiver of the fee for annual establishment registration (excluding the initial registration) to applicants that

qualify as a small business if FDA finds that the establishment is a small business and paying the fee for such a year represents a financial hardship to the establishment as determined by FDA. For more information on reduced fees and waivers for small businesses,

please see Section IX. Small Business Fee Reductions and Fee Waivers.

Table 5 summarizes the FY 2026 rates for all medical device fees.

TABLE 5—MEDICAL DEVICE FEES FOR FY 2026

Application fee type	Standard fee (as a percent of the standard fee for a premarket application) (%)	FY 2026 standard fee	FY 2026 small business fee
Premarket application (a PMA submitted under section 515(c)(1) of the FD&C Act (21 U.S.C. 360e(c)(1)), a PDP submitted under section 515(f) of the FD&C Act, or a BLA submitted under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262)).	Base fee specified in statute	\$579,272	\$144,818
Premarket report (submitted under section 515(c)(2) of the FD&C Act).	100	579,272	144,818
Efficacy supplement (to an approved BLA under section 351 of the PHS Act).	100	579,272	144,818
Panel-track supplement	80	463,418	115,855
De novo classification request	30	173,782	43,446
180-day supplement	15	86,891	21,723
Real-time supplement	7	40,549	10,137
510(k) premarket notification submission	4.5	26,067	6,517
30-day notice	1.60	9,268	4,634
513(g) request for classification information	1.35	7,820	3,910
Annual Fee Type:			
Annual fee for periodic reporting on a class III device.	3.50	20,275	5,069
Annual establishment registration fee (to be paid by the establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device, as defined by 21 U.S.C. 379i(14)).	Base fee specified in statute	11,423	11,423

V. How To Qualify as a Small Business for Purposes of Medical Device Fees

If your business, including your affiliates, has gross receipts or sales of no more than \$100 million for the most recent tax year, you may qualify for reduced small business fees. If your business, including your affiliates, has gross sales or receipts of no more than \$30 million, you may also qualify for a waiver of the fee for your first premarket application (*i.e.*, PMA, PDP, or BLA) or premarket report. If you want to pay the small business fee rate for a submission or you want to receive a waiver of the fee for your first premarket application or premarket report, you must submit the materials showing you qualify as a small business at least 60 days before you send your submission to FDA. For more information on fee waivers or reductions, please see Section IX. Small Business Fee Reductions and Fee Waivers.

For FY 2026, FDA may, but is not required to, grant a waiver of the annual establishment registration fee (excluding the initial registration) to applicants that qualify as a small business if FDA finds that the establishment is a small business and paying the fee for such a year represents a financial hardship to the establishment as determined by FDA. For the purpose of the annual registration fee waiver, a small business is defined as one with \$1,000,000 or less in gross receipts or sales in the most recent Federal (U.S.) income tax return

(including the returns of its affiliates). For more information on obtaining such a waiver, see FDA's draft Select Updates for the Medical Device User Fee Small Business Qualification and Certification Guidance, which, when final, will describe FDA's current thinking on the topic.

If your business qualified as a small business for FY 2025, your status as a small business will expire at the close of business on September 30, 2025. You must re-qualify for FY 2026 in order to pay small business fees during FY 2026.

A. Domestic (U.S.) Businesses

If you are a domestic (U.S.) business and wish to qualify as a small business for FY 2026, submit the following to FDA:

1. A completed MDUFA Small Business Request for a Business Headquartered in the United States. The most current FDA Form may be found in the FDA Forms database: <https://www.fda.gov/about-fda/reports-manuals-forms/forms>.

2. A signed copy of your Federal (U.S.) Income Tax Return for the most recent tax year. The most recent tax year will be 2025, except:

- If you submit your MDUFA Small Business Request for FY 2026 before April 15, 2026, and you have not yet filed your return for 2025, you may use tax year 2024.
- If you submit your MDUFA Small Business Request for FY 2026 on or after

April 15, 2026, and have not yet filed your 2025 return because you obtained an extension, you may submit your most recent return filed prior to the extension.

3. For each of your affiliates, either:

- If the affiliate is a domestic (U.S.) business, a signed copy of the affiliate's Federal (U.S.) Income Tax Return for the most recent tax year, or
- If the affiliate is a foreign business and cannot submit a Federal (U.S.) Income Tax Return, a National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority, if extant, of the country in which the firm is headquartered. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates of the gross receipts or sales collected. The business must also submit a statement signed by the head of the business's firm or by its chief financial officer that the business has submitted certifications for all of its affiliates, identifying the name of each affiliate, or that the business has no affiliates.

• If your affiliate is headquartered in a country without a National Taxing Authority, please contact the Division of

Industry and Consumer Education at 800-638-2041 or 301-796-7100 or email at DICE@fda.hhs.gov.

4. Once you have completed and signed the most current FDA Form for a MDUFA Small Business Request, submit your form and your supporting documentation (copies of the Federal (U.S.) income tax returns), using the instructions which are available at the following website: <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm577696.htm>.

If you need assistance, please contact the Division of Industry and Consumer Education at 800-638-2041 or 301-796-7100 or email at DICE@fda.hhs.gov.

B. Foreign Businesses

If you are a foreign business, and wish to qualify as a small business for FY 2026, submit the following:

1. A completed MDUFA Foreign Small Business Request for a Business Headquartered Outside the United States. The most current FDA Form is provided in the FDA Forms database: <https://www.fda.gov/about-fda/reports-manuals-forms/forms>.

2. A National Taxing Authority Certification, completed by, and bearing the official seal of, the National Taxing Authority, if extant, of the country in which the firm is headquartered. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates of the gross receipts or sales collected.

If your firm is headquartered in a country without a National Taxing Authority, please contact the Division of Industry and Consumer Education at 800-638-2041 or 301-796-7100 or email at DICE@fda.hhs.gov.

3. For each of your affiliates, either:

- If the affiliate is a domestic (U.S.) business, a signed copy of the affiliate's Federal (U.S.) Income Tax Return for the most recent tax year (2024 or later), or
- If the affiliate is a foreign business and cannot submit a Federal (U.S.) Income Tax Return, a National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority, if extant, of the country in which the firm is headquartered. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the

local currency to U.S. dollars, and the dates for the gross receipts or sales collected. The business must also submit a statement signed by the head of the business's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, identifying the name of each affiliate, or that the business has no affiliates.

- If your affiliate is headquartered in a country without a National Taxing Authority, please contact the Division of Industry and Consumer Education at 800-638-2041 or 301-796-7100 or email at DICE@fda.hhs.gov.

4. Once you have completed and signed the most current MDUFA Small Business request, submit your form and your supporting documentation, including the following, using the instructions which are available at the following website: <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm577696.htm>.

- A copy of the most recent Federal (U.S.) income tax return for each of your affiliates headquartered in the U.S. and
- A National Taxing Authority Certification for each of your foreign affiliates.

If you need assistance, please contact the Division of Industry and Consumer Education at 800-638-2041 or 301-796-7100 or email at DICE@fda.hhs.gov.

VI. Procedures for Paying Application Fees

If your application or submission is subject to a fee and your payment is received by FDA between October 1, 2025, and September 30, 2026, you must pay the fee in effect for FY 2026. To avoid delay in the review of your application, you should pay the application fee at the time you submit your application to FDA. The later of the date that the application is received in the reviewing center's document room or the date the U.S. Treasury recognizes the payment determines whether the fee rates for FY 2025 or FY 2026 apply. FDA must receive the correct fee at the time that an application is submitted, or the application will not be accepted for filing or review.

FDA requests that you follow the steps below before submitting a medical device application subject to a fee to ensure that FDA links the fee with the correct application.

A. Secure a Payment Identification Number (PIN) and Medical Device User Fee Cover Sheet From FDA Before Submitting Either the Application or the Payment

Log into the User Fee System at: https://userfees.fda.gov/OA_HTML/mdufmaCacdLogin.jsp. Complete the Medical Device User Fee cover sheet. Be sure you choose the correct application submission date range. (Two choices will be offered until October 1, 2025. One choice is for applications and fees that will be received on or before September 30, 2025, which are subject to FY 2025 fee rates. A second choice is for applications and fees received on or after October 1, 2025, which are subject to FY 2026 fee rates.) After completing data entry, print a copy of the Medical Device User Fee cover sheet and note the unique PIN located in the upper right-hand corner of the printed cover sheet.

B. Electronically Transmit a Copy of the Printed Cover Sheet With the PIN

When you are satisfied that the data on the cover sheet is accurate, electronically transmit that data to FDA according to instructions on the screen. Applicants are required to set up a user account and password to assure data security in the creation and electronic submission of cover sheets.

C. Submit Payment for the Completed Medical Device User Fee Cover Sheet

1. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express).¹ FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov*, a web-based payment system, for online electronic payment. You may make a payment via electronic check or credit card after submitting your cover sheet. Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. (Note: Only full payments are accepted. No partial payments can be made online.) Once you search for your invoice, select "Pay Now" to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using

¹ See "Change in Federal Payment and Collection Options" announcement published in the **Federal Register** on June 27, 2025 (90 FR 27639).

U.S. bank accounts as well as U.S. credit cards.

2. If paying with a wire transfer:

- Please include your application's unique PIN (from the upper right-hand corner of your completed Medical Device User Fee cover sheet) in your wire transfer. Without the PIN, your payment may not be applied to your cover sheet and review of your application may be delayed.

- The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee it is required that you add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33.

FDA records the official application receipt date as the later of the following: (1) the date the application was received by the FDA Document Control Center for the reviewing Center or (2) the date the U.S. Treasury recognizes the payment.

D. Submit Your Application to FDA With a Copy of the Completed Medical Device User Fee Cover Sheet

Please submit your application and a copy of the completed Medical Device User Fee cover sheet to the address located at <https://www.fda.gov/cdrh/submitaddress>.

VII. Procedures for Paying the Annual Fee for Periodic Reporting

You will be invoiced at the end of the quarter in which your PMA Periodic Report is due. Invoices will be sent based on the details included on your PMA file. You are responsible for ensuring FDA has your current billing information, and you may update your contact information for the PMA by submitting an amendment to the pending PMA or a supplement to the approved PMA.

1. The preferred payment method is online using electronic check (ACH also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay> (Note: Only full payments are accepted. No partial payments can be made online.) Once you search for your invoice, select "Pay Now" to be redirected to [Pay.gov](https://pay.gov). Note that electronic payment options are based on the balance due. Payment by credit card is available for balances that

are less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

2. When paying by a wire transfer, it is required that the invoice number is included; without the invoice number the payment may not be applied. If the payment amount is not applied, the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required that you add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33.

VIII. Procedures for Paying Annual Establishment Registration Fees

To pay the annual establishment registration fee, firms must access the Device Facility User Fee (DFUF) website at https://userfees.fda.gov/OA_HTML/furls.jsp. (FDA has verified the website address, but FDA is not responsible for any subsequent changes to the website address after this document publishes in the **Federal Register**.) Create a DFUF order and you will be issued a PIN when you place your order. After payment has been processed, you will be issued a payment confirmation number (PCN). You will not be able to register your establishment if you do not have a PIN and a PCN. An establishment required to pay an annual establishment registration fee is not legally registered in FY 2026 until it has completed the steps below to register and pay any applicable fee (see 738(f)(2)).

Companies that do not manufacture any product other than a licensed biologic are required to register in the Blood Establishment Registration (BER) system. FDA's Center for Biologics Evaluation and Research (CBER) will send establishment registration fee invoices annually to these companies.

A. Submit a DFUF Order With a PIN From FDA Before Registering or Submitting Payment

To submit a DFUF Order, you must create or have previously created a user account and password for the user fee website listed previously in this section. After creating a username and password, log into the Establishment Registration User Fee FY 2026 store. Complete the DFUF order by entering the number of establishments you are

registering that require payment. When you are satisfied that the information in the order is accurate, electronically transmit that data to FDA according to instructions on the screen. Print a copy of the final DFUF order and note the unique PIN located in the upper right-hand corner of the printed order.

If you have an approved small business waiver, please reach out to the User Fee Support Staff at UFSS@fda.hhs.gov for further instructions.

B. Pay for Your DFUF Order

Unless paying by U.S. credit card, all payments must be in U.S. currency and drawn on a U.S. bank.

1. *If paying by credit card or electronic check (ACH or eCheck):* The DFUF order will include payment information, including details on how you can pay online using a credit card or electronic check. Follow the instructions provided to make an electronic payment.

2. *If paying with a wire transfer:* Wire transfers may also be used to pay annual establishment registration fees. To send a wire transfer, please read and comply with the following information:

Include your order's unique PIN (in the upper right-hand corner of your completed DFUF order) in your wire transfer. Without the PIN, your payment may not be applied to your facility and your registration may be delayed.

The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required that you add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: U.S. Dept. of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53-0196965.

C. Complete the Information Online To Update Your Establishment's Annual Registration for FY 2026, or To Register a New Establishment for FY 2026

Go to the Center for Devices and Radiological Health's website at <https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing> and click the "Access Electronic Registration" link on the left side of the page. This opens a new page with important information about the FDA Unified Registration and Listing System (FURLS). After reading this information, click on the "Access Electronic Registration" link in the middle of the page. This link takes you to an FDA Industry Systems page with

tutorials that demonstrate how to create a new FURLS user account if your establishment did not create an account in FY 2025. Manufacturers of licensed biologics should register in the electronic Blood Establishment Registration (eBER) system at [https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics-establishment-registration](https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-establishment-registration).

Enter your existing account ID and password to log into FURLS. From the FURLS/FDA Industry Systems menu, click on the Device Registration and Listing Module (DRLM) of FURLS button. New establishments will need to register, and existing establishments will update their annual registration using choices on the DRLM menu. When you choose to register or update your annual registration, the system will prompt you through the entry of information about your establishment and your devices. If you have any problems with this process, email: reglist@cdrh.fda.gov or call 301-796-7400 for assistance. (Note: This email address and this telephone number are for assistance with establishment registration only; they are not to be used for questions related to other aspects of medical device user fees.) Problems with the eBER system should be directed to <https://www.accessdata.fda.gov/scripts/email/cber/bldregcontact.cfm> or call 240-402-8360.

D. Enter Your DFUF Order PIN and PCN

After completing your annual or initial registration and device listing, you will be prompted to enter your DFUF order PIN and PCN, when applicable. This process does not apply to establishments engaged only in the manufacture, preparation, propagation, compounding, or processing of licensed biologic devices. CBER will send invoices for payment of the establishment registration fee to such establishments.

IX. Small Business Fee Reductions and Fee Waivers

To qualify for reduced fees for small businesses or a small business fee waiver, please see the requirements for qualification provided in Section V. How To Qualify as a Small Business for Purposes of Medical Device Fees. The applicant should submit a Small Business Request and the supporting materials showing you qualify as a small business at least 60 days before you send your submission to FDA. FDA will review your information and determine whether you qualify as a small business eligible for the reduced fee and/or fee waiver. If you make a submission before

FDA finds that you qualify as a small business, you must pay the standard (full) fee for that submission.

If you need assistance, please contact the Division of Industry and Consumer Education at 800-638-2041 or 301-796-7100 or email at DICE@fda.hhs.gov.

A. Premarket Approval Fee Reduction or Waiver

A small business applicant may request to pay a reduced rate for premarket approval fees. An applicant may also request a fee waiver for their first premarket application or premarket report (738(d)).

B. Premarket Notification Submission Fee Reduction

A small business applicant may request to pay a reduced rate for a premarket notification submission.

C. Annual Establishment Registration Fee Waiver

For FY 2026, FDA may, but is not required to, grant a waiver of the annual establishment registration fee (excluding the initial registration) to applicants that qualify as a small business if FDA finds that the establishment is a small business and paying the fee for such a year represents a financial hardship to the establishment as determined by FDA.

X. Refunds

To qualify for consideration for a refund, a person shall submit to FDA a written request for a refund not later than 180 days after such fee is due. For more information on qualifying and submitting a refund, see section 738(a)(2)(D) of the FD&C Act (21 U.S.C. 379j(a)(2)(D)).

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-14412 Filed 7-29-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-2247]

Outsourcing Facility Fee Rates for Fiscal Year 2026

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fiscal year (FY) 2026

rates for the establishment and reinspection fees related to entities that compound human drugs and elect to register as outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C Act authorizes FDA to assess and collect an annual establishment fee from outsourcing facilities, as well as a reinspection fee for each reinspection of an outsourcing facility. This document establishes the FY 2026 rates for the small business establishment fee (\$6,829), the non-small business establishment fee (\$20,726), and the reinspection fee (\$20,486) for outsourcing facilities; provides information on how the fees for FY 2026 were determined; and describes the payment procedures outsourcing facilities should follow.

DATES: These fee rates are effective October 1, 2025, and will remain in effect through September 30, 2026.

FOR FURTHER INFORMATION CONTACT: For more information on human drug compounding and outsourcing facility fees, visit FDA's website at: <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding>. For questions relating to this notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240-402-4989; or the User Fees Support Staff at UFSS@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 503B of the FD&C Act (21 U.S.C. 353b), a human drug compounder can register with FDA as an "outsourcing facility." Outsourcing facilities, as defined in section 503B(d)(4), are, in part, facilities that meet all the conditions described in section 503B(a), including registering with FDA as an outsourcing facility and paying an annual establishment fee. If the conditions of section 503B are met, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from three sections of the FD&C Act: (1) section 502(f)(1) (21 U.S.C. 352(f)(1)), concerning the labeling of drugs with adequate directions for use; (2) section 505 (21 U.S.C. 355), concerning the approval of human drug products under new drug applications or abbreviated new drug applications; and (3) section 582 (21 U.S.C. 360eee-1), concerning drug supply chain security requirements. Drugs compounded in outsourcing facilities are not exempt from the requirements of

section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)), concerning current good manufacturing practice requirements for drugs.

Section 744K of the FD&C Act (21 U.S.C. 379j–62) authorizes FDA to assess and collect the following fees associated with outsourcing facilities: (1) an annual establishment fee from each outsourcing facility and (2) a reinspection fee from each outsourcing facility subject to a reinspection (see section 744K(a)(1) of the FD&C Act). Under statutorily defined conditions, a qualified applicant may pay a reduced small business establishment fee (see section 744K(c)(4) of the FD&C Act).

FDA announced in the **Federal Register** of November 24, 2014 (79 FR 69856), the availability of a final guidance for industry entitled “Fees for Human Drug Compounding Outsourcing

Facilities Under Sections 503B and 744K of the FD&C Act.” The guidance provides additional information on the annual fees for outsourcing facilities and adjustments required by law, reinspection fees, how to submit payment, the effect of failure to pay fees, and how to qualify as a small business to obtain a reduction of the annual establishment fee. This guidance can be accessed on FDA’s website at: <https://www.fda.gov/media/136683/download>.

II. Fees for FY 2026

A. Methodology for Calculating FY 2026 Adjustment Factors

1. Inflation Adjustment Factor

Section 744K(c)(2) of the FD&C Act specifies the annual inflation adjustment for outsourcing facility fees. The inflation adjustment has two

components: one based on FDA’s payroll costs and one based on FDA’s non-payroll costs for the first 3 of the 4 previous fiscal years. The payroll component of the annual inflation adjustment is calculated by taking the average change in FDA’s per full-time equivalent (FTE) personnel compensation and benefits (PC&B) in the first 3 of the 4 previous fiscal years (see section 744K(c)(2)(A)(ii) of the FD&C Act). FDA’s total annual spending on PC&B is divided by the total number of FTEs per fiscal year to determine the average PC&B per FTE.

Table 1 summarizes the actual cost and FTE data for the specified fiscal years and provides the percent change from the previous fiscal year and the average percent change over the first 3 of the 4 fiscal years preceding FY 2026. The 3-year average is 5.4494 percent.

TABLE 1—FDA PC&Bs EACH YEAR AND PERCENT CHANGE

	FY 2022	FY 2023	FY 2024	3-Year average
Total PC&B	\$3,165,477,000	\$3,436,513,000	\$3,791,729,000	
Total FTE	18,474	18,729	19,687	
PC&B per FTE	\$171,348	\$183,486	\$192,601	
Percent Change From Previous Year	4.2967%	7.0838%	4.9677%	5.4494%

Section 744K(c)(2)(A)(ii) of the FD&C Act specifies that this 5.4494 percent should be multiplied by the proportion

of PC&B to total costs of an average FDA FTE for the same 3 fiscal years.

TABLE 2—FDA PC&Bs AS A PERCENT OF FDA TOTAL COSTS OF AN AVERAGE FTE

	FY 2022	FY 2023	FY 2024	3-Year average
Total PC&B (proportion of costs)	\$3,165,477,000	\$3,436,513,000	\$3,791,729,000	
Total Costs	6,251,981,000	6,654,058,000	6,976,495,000	
PC&B percent	50.6316%	51.6454%	54.3501%	52.2090%

The payroll adjustment is 5.4494 percent multiplied by 52.2090 percent, or 2.8451 percent.

Section 744K(c)(2)(A)(iii) of the FD&C Act specifies that the portion of the inflation adjustment for non-payroll costs for FY 2026 is equal to the average annual percent change in the Consumer Price Index (CPI) for urban consumers

(U.S. City Average; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data, multiplied by the proportion of all non-PC&B costs to total costs of an average FDA FTE for the same period.

Table 3 provides the summary data for the percent change in the specified

CPI for U.S. cities. These data are published by the Bureau of Labor Statistics and can be found on its website: <https://data.bls.gov/cgi-bin/surveymost?cu>. The data can be viewed by checking the box marked “U.S. city average, All items—CUUR0000SA0” and then selecting “Retrieve Data.”

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN U.S. CITY AVERAGE CPI

	2022	2023	2024	3-Year average
Annual CPI	292.655	304.702	313.689	
Annual Percent Change	8.0027%	4.1165%	2.9494%	5.0229%

Section 744K(c)(2)(A)(iii) of the FD&C Act specifies that this 5.0229 percent should be multiplied by the proportion of all non-PC&B costs to total costs of an average FTE for the same 3 fiscal years.

The proportion of all non-PC&B costs to total costs of an average FDA FTE for FYs 2022 to 2024 is 47.7910 percent (100 percent minus 52.2090 percent equals 47.7910 percent). Therefore, the

non-pay adjustment is 5.0229 percent times 47.7910 percent, or 2.4005 percent.

The PC&B component (2.8451 percent) is added to the non-PC&B

component (2.4005 percent), for a total inflation adjustment of 5.2456 percent (rounded). Section 744K(c)(2)(A)(i) of the FD&C Act specifies that one is added to that figure, making the inflation adjustment 1.052456.

Section 744K(c)(2)(B) of the FD&C Act provides for this inflation adjustment to be compounded after FY 2015. This factor for FY 2026 (5.2456 percent) is compounded by adding one to it, and then multiplying it by one plus the inflation adjustment factor for FY 2025 (29.7679 percent), as published in the **Federal Register** on July 31, 2024 (89 FR 61470). The result of this multiplication of the inflation factors for the 11 years since FY 2015 (1.052456×1.297679) becomes the inflation adjustment for FY 2026. For FY 2026, the inflation adjustment is 36.5750 percent (rounded). We then add one, making the FY 2026 inflation adjustment factor 1.365750.

2. Small Business Adjustment Factor

Section 744K(c)(3) of the FD&C Act specifies that in addition to the inflation adjustment factor, the establishment fee for non-small businesses is to be further adjusted for a small business adjustment factor. Section 744K(c)(3)(B) of the FD&C Act provides that the small business adjustment factor is the adjustment to the establishment fee for non-small businesses that is necessary to achieve total fees equaling the amount that FDA would have collected if no entity qualified for the small business exception in section 744K(c)(4) of the FD&C Act. Additionally, section 744K(c)(5)(A) states that in establishing the small business adjustment factor for a fiscal year, FDA shall provide for the crediting of fees from the previous year to the next year if FDA overestimated the amount of the small business adjustment factor for such previous fiscal year.

Therefore, to calculate the small business adjustment to the establishment fee for non-small businesses for FY 2026, FDA must estimate: (1) the number of outsourcing facilities that will pay the reduced fee for small businesses for FY 2026 and (2) the total fee revenue it would have collected if no entity had qualified for the small business exception (*i.e.*, if each entity that registers as an outsourcing facility for FY 2026 were to pay the inflation-adjusted fee amount of \$20,486).

With respect to (1), FDA estimates that 9 entities will qualify for small business exceptions and will pay the reduced fee for FY 2026. With respect to (2), to estimate the total number of entities that will register as outsourcing

facilities for FY 2026, FDA used data submitted by outsourcing facilities through the voluntary registration process, which began in December 2013. Accordingly, FDA estimates that 84 outsourcing facilities, including 9 small businesses, will be registered with FDA in FY 2026.

If the projected 84 outsourcing facilities paid the full inflation-adjusted fee of \$20,486, this would result in total revenue of \$1,720,824 in FY 2026 ($\$20,486 \times 84$). However, 9 of the entities that are expected to register as outsourcing facilities for FY 2026 are projected to qualify for the small business exception and to pay one-third of the full fee ($\$6,829 \times 9$), totaling \$61,461 instead of paying the full fee ($\$20,486 \times 9$), which would total \$184,374. This would leave a potential shortfall of \$122,913 ($\$184,374$ minus \$61,461).

Additionally, section 744K(c)(5)(A) of the FD&C Act states that in establishing the small business adjustment factor for a fiscal year, FDA shall provide for the crediting of fees from the previous year to the next year if FDA overestimated the amount of the small business adjustment factor for such previous fiscal year. FDA has determined that it is appropriate to credit excess fees collected from the last completed fiscal year, due to the inability to conclusively determine the amount of excess fees from the fiscal year that is in progress at the time this calculation is made. This crediting is done by comparing the small business adjustment factor for the last completed fiscal year, FY 2024 (\$1,796), to what would have been the small business adjustment factor for FY 2024 (\$576) if FDA had estimated perfectly.

The calculation for what the small business adjustment would have been if FDA had estimated perfectly begins by determining the total target collections ($15,000 \times [\text{inflation adjustment factor}] \times [\text{number of registrants}]$). For the most recent complete fiscal year, FY 2024, this was \$1,672,920 ($\$18,588 \times 90$). The actual FY 2024 revenue from the 90 total registrants (*i.e.*, 86 registrants paying FY 2024 non-small business establishment fee and 4 small business registrants) paying establishment fees is \$1,623,352. \$1,623,352 is calculated as follows: (FY 2024 Non-Small Business Establishment Fee adjusted for inflation only) $\times$ (total number of registrants in FY 2024 paying Non-Small Business Establishment Fee) + (FY 2024 Small Business Establishment Fee) $\times$ (total number of small business registrants in FY 2024 paying Small Business Establishment Fee). $\$18,588 \times 86 + \$6,196 \times 4 = \$1,623,352$. This left a

shortfall of \$49,568 from the estimated total target collection amount (\$1,672,920 minus \$1,623,352). This amount (\$49,568) divided by the total number of registrants in FY 2024 paying Standard Establishment Fee (86) equals \$576.

The difference between the small business adjustment factor used in FY 2024 and the small business adjustment factor that would have been used had FDA estimated perfectly is \$1,220 (\$1,796 minus \$576). The \$1,220 (rounded to the nearest dollar) is then multiplied by the number of actual registrants who paid the standard fee for FY 2024 (86), which provides us a total excess collection of \$104,883 in FY 2024.

Therefore, to calculate the small business adjustment factor for FY 2026, FDA subtracts \$104,883 from the projected shortfall of \$122,913 for FY 2026 to arrive at the numerator for the small business adjustment amount, which equals \$18,030. This number divided by 75 (the number of expected non-small businesses for FY 2026), is the small business adjustment amount for FY 2026, which is \$240 (rounded to the nearest dollar).

B. FY 2026 Rates for Small Business Establishment Fee, Non-Small Business Establishment Fee, and Reinspection Fee

1. Establishment Fee for Qualified Small Businesses¹

The amount of the establishment fee for a qualified small business is equal to \$15,000 multiplied by the inflation adjustment factor for that fiscal year, divided by 3 (see section 744K(c)(4)(A) and (c)(1)(A) of the FD&C Act). The inflation adjustment factor for FY 2026 is 1.365750. See section II.A.1 of this document for the methodology used to calculate the FY 2026 inflation adjustment factor. Therefore, the establishment fee for a qualified small business for FY 2026 is one third of \$20,486, which equals \$6,829 (rounded to the nearest dollar).

¹ To qualify for a small business reduction of the FY 2026 establishment fee, entities had to submit their exception requests by April 30, 2025. See section 744K(c)(4)(B) of the FD&C Act. The time for requesting a small business exception for FY 2026 has now passed. An entity that wishes to request a small business exception for FY 2027 should consult section 744K(c)(4) of the FD&C Act and section III.D of FDA's guidance for industry entitled "Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act," which can be accessed on FDA's website at <https://www.fda.gov/media/136683/download>.

2. Establishment Fee for Non-Small Businesses

Under section 744K(c) of the FD&C Act, the amount of the establishment fee for a non-small business is equal to \$15,000 multiplied by the inflation adjustment factor for that fiscal year, plus the small business adjustment factor for that fiscal year, and plus or minus an adjustment factor to account for over or under collections due to the small business adjustment factor in the prior year. The inflation adjustment factor for FY 2026 is 1.365750. The small business adjustment amount for FY 2026 is \$240. See section II.A.2 of this document for the methodology used to calculate the small business adjustment factor for FY 2026. Therefore, the establishment fee for a non-small business for FY 2026 is \$15,000 multiplied by 1.365750 plus \$240, which equals \$20,726 (rounded to the nearest dollar).

3. Reinspection Fee

Section 744K(c)(1)(B) of the FD&C Act provides that the amount of the FY 2026 reinspection fee is equal to \$15,000, multiplied by the inflation adjustment factor for that fiscal year. The inflation adjustment factor for FY 2026 is 1.365750. Therefore, the reinspection fee for FY 2026 is \$15,000 multiplied by 1.365750, which equals \$20,486 (rounded to the nearest dollar). There is no reduction in this fee for small businesses.

C. Summary of FY 2026 Fee Rates

TABLE 4—OUTSOURCING FACILITY FEES	
Fee category	Fee rates for FY 2026
Qualified Small Business Establishment Fee	\$6,829
Non-Small Business Establishment Fee	20,726
Reinspection Fee	20,486

III. Fee Payment Options and Procedures

A. Establishment Fee

Once an entity submits registration information and FDA has determined that the information is complete, the entity will incur the annual establishment fee. FDA will send an invoice to the entity, via email to the email address indicated in the registration file. The invoice will contain information regarding the obligation incurred, the amount owed, and payment procedures. A facility will not be registered as an outsourcing

facility until it has paid the annual establishment fee under section 744K of the FD&C Act. Accordingly, it is important that facilities seeking to operate as outsourcing facilities pay all fees immediately upon receiving an invoice. If an entity does not pay the full invoiced amount within 15 calendar days after FDA issues the invoice, FDA will consider the submission of registration information to have been withdrawn and adjust the invoice to reflect that no fee is due.

Outsourcing facilities that registered in FY 2025 and wish to maintain their status as an outsourcing facility in FY 2026 must register during the annual registration period that lasts from October 1, 2025, to December 31, 2025. Failure to register and complete payment by December 31, 2025, will result in a loss of status as an outsourcing facility on January 1, 2026. Entities should submit their registration information no later than December 10, 2025, to allow enough time for review of the registration information, invoicing, and payment of fees before the end of the registration period.

B. Reinspection Fee

FDA will issue invoices for each reinspection after the conclusion of the reinspection, via email to the email address indicated in the registration file. Payments must be made within 30 days of the invoice date.

C. Fee Payment Procedures

1. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. (Note: only full payments are accepted. No partial payments can be made online.) Once you search for your invoice, click “Pay Now” to be redirected to [Pay.gov](https://pay.gov). Electronic payment options are based on the balance due. Payment by credit card is available for balances less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

2. For payments made by wire transfer, the invoice number must be included. Without the invoice number, the payment may not be applied. Regarding reinspection fees, if the payment amount is not applied, the invoice amount will be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a

wire transfer fee, it is required that the outsourcing facility add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: U.S. Dept of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33. If needed, FDA’s tax identification number is 53–0196965.

Dated: July 25, 2025.
Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
[FR Doc. 2025–14410 Filed 7–29–25; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2337]

Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2026

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fiscal year (FY) 2026 annual fee rate for recognized accreditation bodies and accredited certification bodies, and the initial and renewal fee rate for accreditation bodies applying to be recognized in the third-party certification program authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). We are also announcing the fee rate for certification bodies applying for direct FDA accreditation.
DATES: The fees apply from October 1, 2025, through September 30, 2026.

FOR FURTHER INFORMATION CONTACT: For Questions Related to FSMA Program Fees: FSMAFeeStaff@fda.hhs.gov. For Questions Related to This Notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20993, 240–402–4989; or the User Fees Support Staff at UFSS@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 808(b)(1)(A) of the FD&C Act (21 U.S.C. 384d(b)(1)(A)) directed FDA to establish a recognition system for entities that accredit third-party certification bodies to conduct food

safety audits and issue food and facility certifications to eligible foreign entities. (For the reasons explained in the third-party certification final rule (80 FR 74570 at 74578 to 74579, November 27, 2015), and for consistency with our regulations for the third-party certification program in 21 CFR parts 1, 11, and 16, this notice uses the term “third-party certification body” rather than the term “third-party auditor” used in section 808 of the FD&C Act.) Section 808(b)(1)(A)(ii) of the FD&C Act also allowed us to directly accredit certain third-party certification bodies.

Section 808(c)(8) of the FD&C Act directed FDA to establish a reimbursement (user fee) program by which we assess fees and require reimbursement for our work to administer the third-party certification program. Our regulations pertaining to the user fee program for the third-party certification program can be found at 21 CFR 1.700 through 1.725.

The FY 2026 third-party certification program user fee rates announced in this notice is effective from October 1, 2025, through September 30, 2026.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2026

FDA estimates its costs for each activity to establish fee rates (see 21 CFR 1.705(b)).

A. Estimating the Full Cost per Direct Work Hour in FY 2026

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered “hours worked” for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an FDA-wide total cost per FTE requires three primary cost elements: payroll, non-payroll, and rent.

We used an average of past year cost elements to predict the FY 2026 cost. The FY 2026 FDA-wide average cost for payroll (salaries and benefits) is \$225,917; non-payroll (including equipment, supplies, information technology, general and administrative overhead) is \$116,581; and rent (including cost allocation analysis and adjustments for other rent and rent-related costs) is \$24,627 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent brings the FY 2026 average fully supported cost to \$367,125 (total includes rounding) per FTE, excluding travel costs. FDA will use this base unit fee in determining the hourly fee rate for third-party certification user fees for FY 2026 before including travel costs as applicable for the activity.

To calculate an hourly rate, we divide the FY 2026 average fully supported cost of \$367,125 per FTE by the average number of supported direct FDA work hours in FY 2024 (the last FY for which data are available). See table 1.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2024

Total number of hours in a paid staff year	2,080
Less:	
11 paid holidays	– 88
20 days of annual leave	– 160
10 days of sick leave	– 80
12.5 days of training	– 100
22 days of general administration	– 176
26.5 days of travel	– 212
2 hours of meetings per week	– 104
Net Supported Direct FDA Work Hours Available for Assignments	1,160

Dividing the average fully supported FTE cost in FY 2026 (\$367,125) by the total number of supported direct work hours available for assignment in FY 2024 (1,160) results in an average fully supported cost of \$316 (rounded to the nearest dollar), excluding travel costs, per supported direct work hour in FY 2026.

B. Adjusting FY 2024 Travel Costs for Inflation To Estimate FY 2026 Travel Costs

To adjust the hourly rate for FY 2026, FDA estimates the cost of inflation in each year for FY 2025 and FY 2026. FDA uses the method prescribed for estimating inflationary costs under the Prescription Drug User Fee Act (PDUFA) provisions of the FD&C Act (section 736(c)(1) of the FD&C Act (21 U.S.C. 379h(c)(1))), the statutory method for inflation adjustment in the FD&C

Act. FDA previously determined the FY 2025 inflation rate to be 4.1167 percent; this rate was published in the FY 2025 PDUFA user fee rates notice in the **Federal Register** (July 31, 2024, 89 FR 61474). Using the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 4.1167 percent for FY 2025 and 5.0313 percent for FY 2026, and FDA intends to use this inflation rate to make inflation adjustments for FY 2026.

For the purpose of estimating the fee, we are using the travel cost rate for foreign travel because the majority of onsite assessments made by FDA under this program will require foreign travel. In FY 2024, the Office of Regulatory Affairs spent a total of \$3,209,026 on 487 foreign inspection trips (averaging \$6,589 per foreign inspection trip) related to FDA’s Center for Food Safety and Applied Nutrition and Center for

Veterinary Medicine field activities programs. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing \$6,589 per trip by 120 hours per trip equals \$55 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2024. To adjust \$55 for inflation in FY 2025 and FY 2026, FDA multiplies it by the inflation factor (1.09355 or 9.355 percent), which results in an estimated cost of \$60 per paid hour. That plus \$316 in other costs per average supported direct work hour equals \$376 per paid hour for each direct hour of work requiring foreign inspection travel. FDA will use this rate in charging fees in FY 2026 when travel is required for the third-party certification program.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2026

Fee category	Fee rates for FY 2026
Hourly rate without travel	\$316
Hourly rate if travel is required	376

III. Fees for Accreditation Bodies and Certification Bodies in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

The third-party certification program assesses application fees and annual fees. Specifically, FDA can collect an initial application fee for accreditation bodies seeking recognition, an annual

fee for recognized accreditation bodies, an annual fee for certification bodies accredited by a recognized accreditation body, an initial application fee for a certification body seeking direct accreditation from FDA, and a renewal application fee for recognized accreditation bodies. Table 3 provides an overview of the fees for FY 2026.

TABLE 3—FSMA THIRD-PARTY CERTIFICATION PROGRAM USER FEE SCHEDULE FOR FY 2026

Fee category	Fee rates for FY 2026
Initial Application Fee for Accreditation Body Seeking Recognition	\$53,440
Annual Fee for Recognized Accreditation Body	2,498
Annual Fee for Accredited Certification Body	3,122
Initial Application Fee for a Certification Body Seeking Direct Accreditation from FDA	53,440
Renewal Application Fee for Recognized Accreditation Body	32,724

A. Application Fee for Accreditation Bodies Applying for Recognition in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

Our regulations, at § 1.705(a)(1), require an application fee for accreditation bodies applying for recognition; that fee covers the estimated average cost of the work FDA performs in reviewing and evaluating applications for recognition of accreditation bodies.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. Based on our data since starting the program, we estimate that it would take, on average, 80 person-hours to review an accreditation body's application, 48 person-hours for an onsite performance evaluation of the applicant (including travel and other steps necessary for a fully supported FTE to complete an onsite assessment), and 32 person-hours to prepare a written report documenting the onsite assessment.

FDA employees review applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel (\$316 per hour) to calculate the user fee attributable to those activities: $\$316/\text{hour} \times (80 \text{ hours (application review)} + 32 \text{ hours (written report)}) = \$35,392$. We use the fully supported FTE hourly rate for work requiring travel (\$376 per hour) to calculate the user fee for onsite performance evaluations, since historically most accreditation bodies are in foreign countries: $\$376/\text{hour} \times 48 \text{ hours (i.e., two fully supported FTEs} \times ((2 \text{ travel days} \times 8 \text{ hours}) + (1 \text{ day onsite} \times 8 \text{ hours}))) = \$18,048$. The estimated average cost of our total work for reviewing an application for recognition

for an accreditation body based on these figures would be $\$35,392 + \$18,048 = \$53,440$. Therefore, the application fee for accreditation bodies applying for recognition in FY 2026 will be \$53,440.

B. Annual Fee for Accreditation Bodies Participating in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

To calculate the annual fee for each recognized accreditation body, FDA takes the estimated average cost of our work to monitor performance of a single recognized accreditation body and annualizes that over the average term of recognition. We assume an average term of recognition of 5 years. We also assume that FDA will monitor 10 percent of recognized accreditation bodies onsite. We estimate that one performance evaluation of a recognized accreditation body would take, on average, 22 hours to conduct records review, 8 hours to prepare a report detailing the records review and onsite performance evaluation, and 8 hours of onsite performance evaluation. Using the fully supported FTE hourly rates in table 2, the estimated average cost of our work to monitor performance of a single recognized accreditation body would be $\$9,480 (\$316/\text{hour} \times (22 \text{ hours (records review)} + 8 \text{ hours (written report)}))$ plus $\$3,008 (\$376/\text{hour} \times 8 \text{ hours (onsite evaluation)})$, which is \$12,488. Annualizing this amount over 5 years leads to an annual fee for recognized accreditation bodies of \$2,498 for FY 2026.

C. Annual Fee for Certification Bodies Accredited by a Recognized Accreditation Body in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

To calculate the annual fee for a certification body accredited by a recognized accreditation body, FDA takes the estimated average cost of our work to monitor performance of a single certification body accredited by a recognized accreditation body and annualizes that over the average term of accreditation. We assume an average term of accreditation of 4 years. We estimate that FDA would conduct, on average, the same activities for the same amount of time to monitor certification bodies accredited by a recognized accreditation body as we would to monitor an accreditation body recognized by FDA. Using the fully supported FTE hourly rates in table 2, the estimated average cost of our work to monitor performance of a single accredited certification body would be $\$9,480 (\$316/\text{hour} \times (22 \text{ hours (records review)} + 8 \text{ hours (written report)}))$ plus $\$3,008 (\$376/\text{hour} \times 8 \text{ hours (onsite evaluation)})$, which is \$12,488. Annualizing this amount over 4 years leads to an annual fee for accredited certification bodies of \$3,122 for FY 2026.

D. Initial Application Fee for Certification Bodies Seeking Direct Accreditation From FDA in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

Our regulations, at § 1.705(a)(3), require an application fee for certification bodies applying for direct accreditation from FDA to cover the estimated average cost of our work to review and evaluating initial

applications for direct accreditation of certification bodies.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. We estimate that it would take, on average, 80 person-hours to review a certification body's application, 48 person-hours for an onsite performance evaluation of the applicant, and 32 person-hours to prepare a written report documenting the onsite assessment.

FDA employees are likely to review applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, \$316 per hour, to calculate the portion of the user fee attributable to those activities: $\$316/\text{hour} \times (80 \text{ hours (application review)} + 32 \text{ hours (written report)}) = \$35,392$. For the portion of the fee attributable to onsite performance evaluations, we use the fully supported FTE hourly rate for work requiring travel (\$376 per hour) since historically most certification bodies are in foreign countries: $\$376/\text{hour} \times 48 \text{ hours (i.e., two fully supported FTEs} \times ((2 \text{ travel days} \times 8 \text{ hours}) + (1 \text{ day onsite} \times 8 \text{ hours}))) = \$18,048$. The estimated average cost of our work to review an application for direct accreditation of a certification body is $\$35,392 + \$18,048 = \$53,440$. Therefore, the application fee for certification bodies applying for direct accreditation from FDA in FY 2026 will be \$53,440.

E. Renewal Application Fee for Accreditation Bodies Participating in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

Our regulations, at § 1.705(a)(2), require a renewal application fee for recognized accreditation bodies to cover the estimated average cost of our work to review and evaluate renewal applications for recognition of accreditation bodies.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. We estimate that it would take, on average, 43 person-hours to review an accreditation body's submitted renewal application, 24 person-hours for an onsite performance evaluation of the applicant, and 32 person-hours to prepare a written report documenting the onsite assessment.

FDA employees are likely to review renewal applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel (\$316 per hour) to calculate the portion of the user fee attributable to those activities: $\$316/\text{hour} \times (43 \text{ hours (application review)} + 32 \text{ hours (written report)}) = \$23,700$. For the portion of the fee attributable to onsite performance evaluations, we use the fully supported FTE hourly rate for work requiring travel (\$376 per hour) since historically most accreditation bodies are in foreign countries: $\$376/\text{hour} \times 24 \text{ hours (i.e., fully supported FTE} \times ((2 \text{ travel days} \times 8 \text{ hours}) + (1 \text{ day onsite} \times 8 \text{ hours}))) = \$9,024$. The estimated average cost of our work for reviewing a renewal application for recognition of an accreditation body is $\$23,700 + \$9,024 = \$32,724$. Therefore, the renewal application fee for recognized accreditation bodies in FY 2026 will be \$32,724.

hour $\times 24 \text{ hours (i.e., fully supported FTE} \times ((2 \text{ travel days} \times 8 \text{ hours}) + (1 \text{ day onsite} \times 8 \text{ hours}))) = \$9,024$. The estimated average cost of our work for reviewing a renewal application for recognition of an accreditation body is $\$23,700 + \$9,024 = \$32,724$. Therefore, the renewal application fee for recognized accreditation bodies in FY 2026 will be \$32,724.

IV. Estimated Fees for Accreditation Bodies and Certification Bodies in Other Fee Categories for FY 2026

Our regulations, at § 1.705(a)(4), require application fees for certification bodies applying for renewal of direct accreditation, while § 1.705(b)(2) requires annual fees for certification bodies directly accredited by FDA.

Although to date we have not directly accredited any certification bodies under the Third-Party Certification Program, FDA notifies the public of the program fee schedule annually (21 CFR 1.710). Therefore, we are providing estimates of annual fees and renewal applications for directly accredited certification bodies, based on the fully supported FTE hourly rates for FY 2026 and estimates of the number of hours it would take FDA to perform relevant activities as outlined in the Final Regulatory Impact Analysis for the Third-Party Certification regulation. Table 4 provides an overview of the estimated fees for these other categories.

TABLE 4—ESTIMATED FEE RATES FOR OTHER FEE CATEGORIES UNDER THE FSMA THIRD-PARTY CERTIFICATION PROGRAM

Fee category	Estimated fee rates for FY 2026
Renewal application fee for directly accredited certification body	\$32,724
Annual fee for certification body directly accredited by FDA	25,152

V. How must the fees be paid?

Accreditation bodies seeking recognition must submit the application fee with the application (21 CFR 1.715(a)). For recognized accreditation bodies and accredited certification bodies, an invoice will be sent annually. Payment must be made within 30 days of receipt of billing for the fee (§ 1.715(b)). The payment is to be in U.S. currency drawn on a U.S. bank by electronic check, credit card, or wire transfer. The preferred payment method is online using an electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees

Payment Portal at <https://userfees.fda.gov/pay>. (Note: The system only accepts full payments.) Alternatively, electronic invoices will have a "Pay Now" option that redirects to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available only for balances less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments should be made using U.S. bank accounts or credit cards.

When paying by wire transfer, the invoice number should be included; without the invoice number, the payment may not be applied. The originating financial institution may charge a wire transfer fee. If the

financial institution charges a wire transfer fee, that amount should be added to the payment to ensure that the invoice is paid in full. For international wire transfers, please inquire with the financial institutions before submitting the payment. Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33.

The tax identification number of FDA is 53-0196965.

VI. What are the consequences of not paying this fee?

The consequences of not paying these fees are outlined in 21 CFR 1.725. If FDA does not receive an application fee with an application for recognition, the application will be considered incomplete, and FDA will not review the application. If a recognized accreditation body fails to submit its annual user fee within 30 days of the due date, we will suspend its recognition. If the recognized accreditation body fails to submit its annual user fee within 90 days of the due date, we will revoke its recognition. If an accredited certification body fails to pay its annual fee within 30 days of the due date, we will suspend its accreditation. If the accredited certification body fails to pay its annual fee within 90 days of the due date, we will withdraw its accreditation.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14415 Filed 7–29–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1731]

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Amendment of Notice—Establishment of Public Docket; Request for Comments—Dermal Fillers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee (the Committee). This meeting was announced in the **Federal Register** of July 3, 2025. The amendment is being made to reflect a change in the **ADDRESSES** and **SUPPLEMENTARY INFORMATION** portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Evella Washington, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2404, Silver Spring, MD 20993–0002, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the

Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 3, 2025 (90 FR 29570), FDA announced that a meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee would be held on August 13, 2025. On page 29570, in the first column, “The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 13, 2025,” the date portion of the document is changed to read as follows:

The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 13, 2025.

On page 29571, in the first column, “Background material and the link to the online teleconference and/or video conferencing meeting will be available at the location of the advisory committee meeting and at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.html>. Scroll down to the appropriate advisory committee meeting link,” the link to the website portion of the document is changed to read as follows:

Background material and the link to the online teleconference and/or video conferencing meeting will be available at the location of the advisory committee meeting and at <https://www.fda.gov/advisory-committees/advisory-committee-calendar>. Scroll down to the appropriate advisory committee meeting link.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) and 21 CFR part 14, relating to the advisory committees.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14346 Filed 7–29–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2362]

Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2026

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fiscal year (FY) 2026 fee rates for certain domestic and foreign facility reinspections, failures to comply with a recall order, and importer reinspections that are authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA).

DATES: These fees apply to the period from October 1, 2025, and will remain in effect through September 30, 2026.

FOR FURTHER INFORMATION CONTACT: For questions related to FSMA program fees: FSMAFeeStaff@fda.hhs.gov. For questions related to this notice:

Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20993, 240–402–4989; or the User Fees Support Staff at UFSS@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 743 of the FD&C Act (21 U.S.C. 379j-31) authorizes FDA to assess and collect fees from, in part: (1) the responsible party for each domestic facility and the U.S. agent for each foreign facility subject to a reinspection to cover reinspection-related costs; (2) the responsible party for a domestic facility and an importer who does not comply with a recall order to cover food recall activities associated with such order; and (3) each importer subject to a reinspection to cover reinspection-related costs (sections 743(a)(1)(A), (B), and (D) of the FD&C Act). Section 743 of the FD&C Act directs FDA to establish fees for each of these activities based on an estimate of 100 percent of the costs of each activity for each year (sections 743(b)(2)(A)(i), (ii), and (iv) of the FD&C Act), and these fees must be made available solely to pay for the costs of each activity for which the fee was incurred (section 743(b)(3) of the FD&C Act). These fees are effective on October 1, 2025, and will remain in effect through September 30, 2026.

In section 743(b)(2)(B)(iii) of the FD&C Act, Congress directed FDA to develop a proposed set of guidelines in consideration of the burden of fee amounts on small businesses. FDA issued guidance on this subject in October 2011 (2011 Fee Provision Guidance) (FDA Guidance for Industry, “Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act” (October 2011)). As stated in our 2011 Fee Provision Guidance, FDA recognizes that the full

cost recovery of FDA reinspection or recall oversight could impose severe economic hardship for small businesses (id.). Therefore, as the 2011 Fee Provision Guidance explains, FDA intends to consider reducing certain fees for those firms (id.). Consistent with the 2011 Fee Provision Guidance, FDA does not intend to issue invoices for reinspection or recall order fees until FDA publishes a separate guidance document outlining the process through which firms may request a reduction in fees.

In addition, as stated in the 2011 Fee Provision Guidance, FDA is considering various issues associated with the assessment and collection of importer reinspection fees. The fee rates set forth in this notice will be used to determine any importer reinspection fees assessed in FY 2026.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2026

FDA estimates 100 percent of its costs for each activity to establish fee rates for

FY 2026 (see section 743(b)(2)(A) of the FD&C Act).

A. Estimating the Full Cost per Direct Work Hour in FY 2026

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered “hours worked” for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an FDA-wide total cost per FTE requires three primary cost elements: payroll, nonpayroll, and rent.

We used an average of past year cost elements to predict the FY 2026 cost. The FY 2026 FDA-wide average cost for payroll (salaries and benefits) is \$225,917; non-payroll (including

equipment, supplies, IT, general and administrative overhead) is \$116,581; and rent (including cost allocation analysis and adjustments for other rent and rent-related costs) is \$24,627 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, nonpayroll, and rent, brings the FY 2026 average fully supported cost to \$367,125 (total includes rounding) per FTE, excluding travel costs. FDA will use this base unit fee in determining the hourly fee rate for reinspection and recall order fees for FY 2026 before including domestic or foreign travel costs as applicable for the activity.

To calculate an hourly rate, we divide the FY 2026 average fully supported cost of \$367,125 per FTE by the average number of supported direct FDA work hours in FY 2024 (the last fiscal year for which data are available). See table 1.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2024

Total number of hours in a paid staff year	2,080
Less:	
11 paid holidays	– 88
20 days of annual leave	– 160
10 days of sick leave	– 80
12.5 days of training	– 100
22 days of general administration	– 176
26.5 days of travel	– 212
2 hours of meetings per week	– 104
Net Supported Direct FDA Work Hours Available for Assignments	1,160

Dividing the average fully supported FTE cost in FY 2026 (\$367,125) by the total number of supported direct work hours available for assignment in FY 2024 (1,160) results in an average fully supported cost of \$316 (rounded to the nearest dollar), excluding inspection travel costs, per supported direct work hour in FY 2026.

B. Adjusting FY 2024 Travel Costs for Inflation To Estimate FY 2026 Travel Costs

To adjust the hourly rate for FY 2026, we estimate the cost of inflation in each year for FY 2025 and FY 2026. FDA uses the method prescribed for estimating inflationary costs under the Prescription Drug User Fee Act (PDUFA) provisions of the FD&C Act (section 736(c)(1) of the FD&C Act (21 U.S.C. 379h(c)(1))), the statutory method for inflation adjustment in the FD&C Act that FDA has used consistently. FDA previously determined the FY 2025 inflation rate to be 4.1167 percent; this rate was

published in the FY 2025 PDUFA user fee rates notice in the **Federal Register** (89 FR 61474, July 31, 2024). Using the method set forth in section 736(c)(1) of the FD&C Act, FDA calculated an inflation rate of 4.1167 percent for FY 2025 and 5.0313 percent for FY 2026, and FDA intends to use these inflation rates to make inflation adjustments for FY 2026 for several of its user fee programs.

In FY 2024, FDA’s Office of Regulatory Affairs (ORA) spent a total of \$7,498,059 for domestic regulatory inspection travel costs and General Services Administration Vehicle costs related to FDA’s Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) field activities programs. The total ORA domestic travel costs spent is then divided by the 7,851 CFSAN and CVM domestic inspections, which averages a total of \$955 per inspection. These inspections average 45.09 hours per inspection. Dividing \$955 per

inspection by 45.09 hours per inspection results in a total and an additional cost of \$21 (rounded to the nearest dollar) per hour spent for domestic inspection travel costs in FY 2024. To adjust for the \$21 per hour additional domestic cost inflation increases for FY 2025 and FY 2026, we multiply the FY 2025 PDUFA inflation rate adjustor (1.041167) times the FY 2026 PDUFA inflation rate adjustor (1.050313) times the \$21 additional domestic cost, which results in an estimated cost of \$23 (rounded to the nearest dollar) per paid hour in addition to \$316 for a total of \$339 per paid hour (\$316 plus \$23) for each direct hour of work requiring domestic inspection travel. FDA will use these rates in charging fees in FY 2026 when domestic travel is required.

In FY 2024, ORA spent a total of \$3,209,026 on 487 foreign inspection trips related to FDA’s CFSAN and CVM field activities programs, which averaged a total of \$6,589 per foreign

inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing \$6,589 per trip by 120 hours per trip results in a total and an additional cost of \$55 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2024. To adjust \$55 for inflationary increases in FY 2025, and FY 2026, FDA multiplies it by the same inflation factors mentioned previously in this document (1.041167 and 1.050313), which results in an estimated cost of \$60 (rounded to the nearest dollar) per paid hour in addition to \$316 for a total of \$376 per paid hour (\$316 plus \$60) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2026 when foreign travel is required.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2026

Fee category	Fee rates for FY 2026
Hourly rate if domestic travel is required	\$339
Hourly rate if foreign travel is required	376

III. Fees for Reinspections of Domestic or Foreign Facilities Under Section 743(a)(1)(A) of the FD&C Act

A. What will cause this fee to be assessed?

The fee will be assessed for a reinspection conducted under section 704 of the FD&C Act (21 U.S.C. 374) to determine whether corrective actions have been implemented and are effective and compliance has been achieved to the Secretary of Health and Human Services’ (the Secretary) (and, by delegation, FDA’s) satisfaction at a facility that manufactures, processes, packs, or holds food for consumption necessitated as a result of a previous inspection (also conducted under section 704 of the FD&C Act) of this facility, which had a final classification of Official Action Indicated (OAI) conducted by or on behalf of FDA, when FDA determined the noncompliance was materially related to food safety requirements of the FD&C Act. FDA considers such noncompliance to include noncompliance with a statutory or regulatory requirement under section 402 of the FD&C Act (21 U.S.C. 342) and section 403(w) of the FD&C Act (21 U.S.C. 343(w)). However, FDA does not consider noncompliance that is materially related to a food safety requirement to include circumstances where the noncompliance is of a

technical nature and not food safety related (e.g., failure to comply with a food standard or incorrect font size on a food label). Determining when noncompliance, other than under sections 402 and 403(w) of the FD&C Act, is materially related to a food safety requirement of the FD&C Act may depend on the facts of a particular situation. FDA intends to issue guidance to provide additional information about the circumstances under which FDA would consider noncompliance to be materially related to a food safety requirement of the FD&C Act.

Under section 743(a)(1)(A) of the FD&C Act, FDA is directed to assess and collect fees from the responsible party for each domestic facility (as defined in section 415(b) of the FD&C Act (21 U.S.C. 350d(b))) and the U.S. agent for each foreign facility subject to a reinspection to cover reinspection-related costs.

Section 743(a)(2)(A)(i) of the FD&C Act defines the term “reinspection” with respect to domestic facilities as 1 or more inspections conducted under section 704 of the FD&C Act subsequent to an inspection conducted under such provision which identified noncompliance materially related to a food safety requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary’s satisfaction.

The FD&C Act does not contain a definition of “reinspection” specific to foreign facilities. In order to give meaning to the language in section 743(a)(1)(A) of the FD&C Act to collect fees from the U.S. agent of a foreign facility subject to a reinspection, we are using the following definition of “reinspection” for purposes of assessing and collecting fees under section 743(a)(1)(A) of the FD&C Act, with respect to a foreign facility: “1 or more inspections conducted by officers or employees duly designated by the Secretary subsequent to such an inspection which identified noncompliance materially related to a food safety requirement of the FD&C Act, specifically to determine whether compliance has been achieved to the Secretary’s (and, by delegation, FDA’s) satisfaction.”

This definition allows FDA to fulfill the mandate to assess and collect fees from the U.S. agent of a foreign facility in the event that an inspection reveals noncompliance materially related to a food safety requirement of the FD&C Act, causing one or more subsequent inspections to determine whether compliance has been achieved to the Secretary’s (and, by delegation, FDA’s) satisfaction. By requiring the initial

inspection to be conducted by officers or employees duly designated by the Secretary, the definition ensures that a foreign facility would be subject to fees only in the event that FDA, or an entity designated to act on its behalf, has made the requisite identification at an initial inspection of noncompliance materially related to a food safety requirement of the FD&C Act. The definition of “reinspection-related costs” in section 743(a)(2)(B) of the FD&C Act relates to both a domestic facility reinspection and a foreign facility reinspection, as described in section 743(a)(1)(A) of the FD&C Act.

B. Who will be responsible for paying this fee?

The FD&C Act states that this fee is to be paid by the responsible party for each domestic facility (as defined in section 415(b) of the FD&C Act) and by the U.S. agent for each foreign facility (section 743(a)(1)(A) of the FD&C Act). This is the party to whom FDA will send the invoice for any fees that are assessed under this section.

C. How much will this fee be?

The fee is based on the number of direct hours spent on such reinspections, including time spent conducting the physical surveillance and/or compliance reinspection at the facility, or whatever components of such an inspection are deemed necessary, making preparations and arrangements for the reinspection, traveling to and from the facility, preparing any reports, analyzing any samples or examining any labels if required, and performing other activities as part of the OAI reinspection until the facility is again determined to be in compliance. The direct hours spent on each such reinspection will be billed at the appropriate hourly rate shown in table 2 of this document.

IV. Fees for Noncompliance With a Recall Order Under Section 743(a)(1)(B) of the FD&C Act

A. What will cause this fee to be assessed?

The fee will be assessed for not complying with a recall order under section 423(d) (21 U.S.C. 350l(d)) or section 412(f) of the FD&C Act (21 U.S.C. 350a(f)) to cover food recall activities associated with such order performed by the Secretary (and by delegation, FDA) (section 743(a)(1)(B) of the FD&C Act). Noncompliance may include the following: (1) not initiating a recall as ordered by FDA; (2) not conducting the recall in the manner specified by FDA in the recall order; or

(3) not providing FDA with requested information regarding the recall, as ordered by FDA.

B. Who will be responsible for paying this fee?

Section 743(a)(1)(B) of the FD&C Act states that the fee is to be paid by the responsible party for a domestic facility (as defined in section 415(b) of the FD&C Act) and an importer who does not comply with a recall order under section 423 or under section 412(f) of the FD&C Act. In other words, the party paying the fee would be the party that received the recall order.

C. How much will this fee be?

The fee is based on the number of direct hours spent taking action in response to the firm's failure to comply with a recall order. Types of activities could include conducting recall audit checks, reviewing periodic status reports, analyzing the status reports and the results of the audit checks, conducting inspections, traveling to and from locations, and monitoring product disposition. The direct hours spent on each such recall will be billed at the appropriate hourly rate shown in table 2 of this document.

D. How must the fees be paid?

Section 743(a)(1)(A) and (B) of the FD&C Act require FDA to assess and collect reinspection and recall fees, as appropriate, from responsible parties for domestic and foreign food facilities. Further, section 743(a)(1)(D) requires FDA to assess and collect reinspection fees from importers. An invoice will be sent to the responsible party for paying the fee after FDA completes the work on which the invoice is based. Payment is to be made within 30 days of the invoice date in U.S. currency by electronic check, credit card, or wire transfer. Detailed payment information will be included with the invoice when it is issued.

V. What are the consequences of not paying these fees?

Under section 743(e)(2) of the FD&C Act, any fee that is not paid within 30 days after it is due shall be treated as a claim of the U.S. Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-14414 Filed 7-29-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; The Stem Cell Therapeutic Outcomes Database

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than August 29, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443-3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database OMB No. 0915-0310—Revision.

Abstract: The Stem Cell Therapeutic and Research Act of 2005 (Pub. L. 109-129, December 20, 2005) as amended and codified in Section 379A of the Public Health Service Act (42 U.S.C. 247l), provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. The Public Health Service Act requires the Secretary of HHS to contract for the establishment and maintenance of information related to patients who have received stem cell

therapeutic products and to do so using an electronic format. HRSA has established the Stem Cell Therapeutic Outcomes Database (SCTOD), a component of the C.W. Bill Young Cell Transplantation Program (Program), which necessitates certain electronic record-keeping and reporting requirements to perform functions related to hematopoietic stem cell transplantation (HCT) under contract to HHS. Data are collected from transplant centers by the Center for International Blood and Marrow Transplant Research. They are used for ongoing analysis of transplant outcomes to improve treatment and survival for patients who may benefit from cellular therapies.

The proposed revisions to this ICR reflect the most up-to-date medical evidence while also reducing the burden on hematopoietic stem cell transplantation facilities. Revisions fall into several categories: consolidating questions, implementing interactive requests (such as electronic check boxes, "check all that apply," and pull-down menus) to reduce data entry time, adding necessary information fields, clarifying information requests, and removing items that are no longer clinically significant.

Over time, there is an expected increase in the information reported as the number of transplants performed annually increases and survivorship after transplantation improves. Similarly, because of the ongoing rapid evolution in transplant indications, methods to establish diagnoses, disease prognostic factors, treatments provided before HCT, methods to determine donor matching, and transplantation techniques, the Program anticipates incremental changes in the information collected by the SCTOD after OMB approval to reflect current clinical care, facilitate statistical modeling throughout the approval period to fulfill Program requirements, keep pace with changes in the field, and to enhance the ability to collect information in an automated fashion from respondent source systems, such as electronic health records. Interim updates to the information collected about disease indications, disease definitions, and disease prognostic factors will be triggered by the publication of peer-reviewed scientific articles or public reference materials of updated criteria by organizations such as the World Health Organization, national or international scientific consensus panels (e.g., European LeukemiaNet, International Working Group for Prognosis in MDS), or similar. The updates mentioned above are anticipated to be reflected as changes in

response options to existing information collection and will represent non-substantive changes without additional public notice. Such small incremental changes will not significantly affect the burden.

A 60-day notice published in the **Federal Register** on May 16, 2025, vol. 90, No. 94; pp. 21049–51. There were no public comments.

Need and Proposed Use of the Information: Per statutory responsibilities, the collection of information outlined in the “Total Estimated Annualized Burden Hours”

section below is needed to collect, analyze, and publish stem cell transplantation-related data, including patient outcomes data, and provide the Secretary of HHS with an annual report of transplant center-specific survival data.

Likely Respondents: Transplant centers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to

develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name ¹	Number of respondents ²	Number of responses per respondent ³	Total responses	Average burden per response (in hours)	Total burden hours ⁴
Pre-Transplant Information Collection	182.00	53.80	⁵ 9,788.00	⁶ 2.24	21,902.61
Transplant Procedure and Product Information	182.00	53.80	⁷ 9,788.00	⁸ 0.75	7356.66
Post-Transplant Periodic Information Collection based on Pre-determined Schedule	182.00	418.90	⁹ 76,232.00	¹⁰ 0.57	43,810.53
Total	182.00		95,808.00		73,069.80

¹ This burden estimate table refers to data collections at different time periods consistent with approved practice. The SCTOD contractor is working with respondents to reduce burden by submitting data using interoperability standards. These data collections may include OMB-approved forms.

² The total number of U.S. transplant centers that submit data to the SCTOD is 182 as of April 14, 2025. The number of centers providing data may change intermittently based on opening or closure of centers.

³ The Number of Responses per Respondent was calculated by dividing the Total Responses by the Number of Respondents and rounding to the nearest hundredth.

⁴ The numbers in this column have been rounded to the nearest hundredth and do not sum precisely due to rounding adjustments throughout the table.

⁵ Total responses for Pre-Transplant Information Collection equals the estimated number of new transplant patients in 2024.

⁶ Pre-transplant Data includes baseline recipient data including patient demographics, pertinent medical history, disease characteristics and status, co-morbidities, transplant data procedure characteristics, including preparative regimen, and donor data. This number is rounded to the nearest hundredth. The actual burden estimate for these data is 2.2377.

⁷ Transplant Procedure and Product Information equals estimated number of new transplant patients in 2024.

⁸ Transplant Procedure and Product Information includes Graft-vs-Host Disease prophylaxis, graft source, donor type and degree of HLA matching and graft manipulation; graft characteristic data for cord blood units, including infused cell dose; and product information. This number is rounded to the nearest hundredth. The actual burden estimate for these data is 0.7516.

⁹ The number of responses for Post-Transplant Periodic Information Collection is based on a predetermined schedule: 100 days after transplant, 6 months after transplant, 1 year after transplant, annually for 6 years after transplant and then biennially thereafter. In any given year the number of responses is a function of the number of transplants in that year, the number of transplants in previous years, and expected patient survival between the time of transplant and any follow-up activity.

¹⁰ Post-Transplant Data Collection includes hematopoietic recovery and engraftment, serious complications including Graft-vs-Host Disease and second cancers, disease status, survival status, cause of death, and subsequent procedures. This number is rounded to the nearest hundredth. The actual burden estimate is 0.5747.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2025–14397 Filed 7–29–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: The National Health Service Corps and Nurse Corps Interest Capture Form—OMB No. 0915–0337—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 requirement for opportunity for public comment on proposed data collection projects, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than September 29, 2025.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance

Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: The National Health Service Corps and Nurse Corps Interest Capture Form OMB No. 0915-0337—Revision.

Abstract: HRSA's National Health Service Corps (NHSC) and the Nurse Corps Scholarship and Loan Repayment Programs are committed to improving the health of the nation's underserved by uniting communities in need with caring health professionals and by supporting communities' efforts to build better systems of care. The NHSC and Nurse Corps Interest Capture Form, which can be accessed on the HRSA website at <https://bhwh.hrsa.gov/about-us/ask-question>, is an optional form that

a health profession student, licensed clinician, faculty member, clinical site administrator, or other interested individual can complete and submit to HRSA online. The purpose of the form is to enable individuals and clinical sites to ask questions about the NHSC and/or Nurse Corps Scholarship and Loan Repayment Programs, and to provide their contact information so that HRSA may provide them with periodic program updates and other general information via email. Completed forms will contain information such as the names and roles of the individual(s), their phone number(s) and email address(es), and the HRSA program(s) in which they are interested or about which they have questions. The revisions in this ICR are as follows:

(a) An increase in the annualized information collection burden due to a higher number of respondents.

(b) The addition of an online version of the NHSC and Nurse Corps Interest Capture Form, located on the HRSA website at <https://bhwh.hrsa.gov/about-us/ask-question>.

Need and Proposed Use of the Information: The need and purpose of this information collection is to share resources and information regarding the

NHSC and Nurse Corps Scholarship and Loan Repayment Programs with interested HRSA website (<https://www.hrsa.gov/>) visitors.

Likely Respondents: Health profession students, licensed clinicians, faculty members, clinical site administrators or other individuals who are interested in learning more or have questions about NHSC and Nurse Corps Scholarship and Loan Repayment Programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours *
NHSC and Nurse Corps Interest Capture Form	17,676	1	17,676	0.025	442
Total	17,676		17,676		442

* Total Burden Hours are rounded up to the nearest whole number.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2025-14398 Filed 7-29-25; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[A2407-014-004-065516; #O2412-014-004-047181.1; LLESJ00000]

Right-of-Way Application; Tennessee

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of application.

SUMMARY: The purpose of this notice is to inform the public that the Bureau of Land Management (BLM) has received a right-of-way (ROW) application from East Tennessee Natural Gas, LLC (ETNG) for a natural gas pipeline that is proposed to cross Trousdale, Smith, Jackson, Putnam, Overton, Fentress, Morgan, and Roane counties, Tennessee. The BLM anticipates deciding on the pipeline ROW application after the

publication of this notice, including any associated terms and conditions, if approved.

DATES: On December 30, 2024, the Federal Energy Regulatory Commission (FERC) published a notice of availability in the **Federal Register** (FR 2024-31338) for the Final Environmental Impact Statement (FEIS) regarding the 30-inch natural gas pipeline and appurtenant facilities.

ADDRESSES: The ROW application and maps of the project are available for review at the BLM Southeastern States District Office located at 273 Market Street, Flowood, Mississippi 39232. The FEIS is publicly available to view and download on the FERC eLibrary at the following website https://elibrary.ferc.gov/eLibrary/filelist?accession_num=20241220-3002.

FOR FURTHER INFORMATION CONTACT:

Brian Kennedy, Acting Deputy District Manager, telephone: (601) 919-4697; address: 273 Market Street, Flowood, MS 39232; email: bckennedy@blm.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Mr. Kennedy. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: ETNG has applied for a BLM ROW for a 30-inch diameter pipeline and related facilities that involve approximately 5 miles of Federal lands managed by the U.S. Army Corps of Engineers and Tennessee Valley Authority. The total length of the natural gas pipeline is approximately 122.2 miles, of which approximately 111.4 miles of the pipeline would be co-located within existing utility ROW and transmission corridors. For more detailed information regarding the application, maps, and overall project, refer to the **ADDRESSES** section above.

(Authority: 43 CFR 2884.20)

Shayne Banks,

Acting District Manager, Southeastern States District.

[FR Doc. 2025-14387 Filed 7-29-25; 8:45 am]

BILLING CODE 4331-18-P

DEPARTMENT OF THE INTERIOR**Bureau of Land Management**

[A2407-014-004-065516; #O2412-014-004-047181.1]

Implementing Executive Order 14153 for Special Areas Within the National Petroleum Reserve-Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Based on identified deficiencies, inconsistency with the President's and the Department's national energy strategy, and pursuant to direction in Executive Order 14153, "Unleashing Alaska's Extraordinary Resource Potential," the Bureau of Land Management (BLM), Alaska State Office, is rescinding the BLM notice entitled "Special Areas Within the National Petroleum Reserve in Alaska," published in the **Federal Register** on July 17, 2024, and the report entitled "Maximizing Protection in the National Petroleum Reserve-Alaska," and the

memorandum with subject header "BLM Interim Management of special areas within the National Petroleum Reserve-Alaska" that were issued on January 16, 2025.

FOR FURTHER INFORMATION CONTACT:

Stephanie Kuhns, Arctic District Manager, at 907-474-2310 or skuhns@blm.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point of contact in the United States.

SUPPLEMENTARY INFORMATION: The National Petroleum Reserve-Alaska (NPR-A) is a 23-million-acre tract managed by the BLM under the authority of the Naval Petroleum Reserves Production Act (NPRPA), 42 U.S.C. 6501 *et seq.*, as amended, the Federal Land Policy and Management Act of 1976, as amended, 43 U.S.C. 1701-1787 (FLPMA), and the Alaska National Interest Lands Conservation Act, 16 U.S.C. 3101-3233 (ANILCA). On May 7, 2024, the BLM issued a final rule, entitled "Management and Protection of the National Petroleum Reserve in Alaska" (89 FR 38712), which became effective on June 6, 2024 (2024 Final Rule).

On July 17, 2024, the BLM published a request for information (RFI) in the **Federal Register** requesting public input on any need to: (1) identify additional significant resource values for existing special areas; (2) modify the boundaries or management of existing special areas; and (3) identify public lands that may qualify for designation as new special areas in the NPR-A. That public comment period closed on September 16, 2024, and on January 16, 2025, the BLM issued both a report entitled, "Maximizing Protection in the National Petroleum Reserve-Alaska," (BLM Report) and a memorandum with the subject header, "BLM Interim Management of Special Areas within the National Petroleum Reserve-Alaska" (Interim Measures Guidance) pursuant to the NPR-A regulations at 43 CFR 2361.30. These documents made determinations regarding adding subsistence as a significant resource value for all special areas and proposed both new and expanded special areas.

Executive Order 14153, "Unleashing Alaska's Extraordinary Resource Potential," (90 FR 8347) directs the BLM to rescind the RFI published in the **Federal Register** on July 17, 2024, and to rescind the Bureau's guidance on the

protection of subsistence resource values in the existing special areas and proposed new and modified special areas in the NPR-A that was issued on January 16, 2025.

On June 3, 2025, the BLM published a notice in the **Federal Register** proposing to rescind the 2024 Final Rule because, in summary, the 2024 Final Rule would hamper the exploration, leasing, and development of oil and gas resources within the NPR-A, contrary to the congressional direction in the NPRPA to develop lands within the NPR-A, including special areas, as part of an expeditious program of oil and gas leasing; the rule is unnecessary to effectively manage surface resources in the NPR-A; and it is inconsistent with the priorities of the Trump administration.

This document notifies the public that the BLM is implementing the direction in Executive Order 14153, "Unleashing Alaska's Extraordinary Resource Potential," (90 FR 8347) to rescind a notice published in the **Federal Register** on July 17, 2024, entitled "Special Areas Within the National Petroleum Reserve in Alaska" (89 FR 58181) that solicited public input on special areas for a period of 60 days.

This notice also serves to announce that the BLM is rescinding the report entitled, "Maximizing Protection in the National Petroleum Reserve-Alaska," and the memorandum entitled, "BLM Interim Management of special areas within the National Petroleum Reserve-Alaska" that were issued on January 16, 2025.

These documents are being rescinded for the following reasons: First, the BLM did not comply with the regulations in developing the report or the interim guidance. The regulations at 43 CFR 2361.30(b)(3) direct the BLM authorized officer to provide the public and interested stakeholders with the opportunity to make recommendations about lands, significant resource values, and protection measures for special areas and to "evaluate and respond to recommendations that are made in completing its evaluation." The BLM received more than 80,000 responses to the request, but the vast majority of those were form letters. However, many of the unique letters submitted in response to the RFI (<https://www.blm.gov/alaska/report/npr-special-area-rfi-unique-responses>) opposed the expansion of special areas and the addition of new significant resource values. This includes letters from small businesses, the Alaska Congressional Delegation, the oil and gas industry and trade groups, Alaska Native Corporations, local governments, and

the Alaska Department of Natural Resources. The BLM Report, however, did not evaluate and respond to these public comments. Rather, it dismissed the concerns of these entities with a single line in a section entitled “Other Submissions” stating:

Likewise, the BLM received comments from some entities opposing any change in management or protections in the NPR–A, largely on procedural grounds.

This response does not comply with the requirement in 43 CFR 2361.30(b)(3) to “evaluate and respond to” public input on changes or additions to special areas. Not giving due consideration to opposing viewpoints calls into question the BLM’s determinations in the BLM Report and the Interim Measures Guidance put in place to implement those determinations. This deficiency alone compels the BLM to rescind those documents.

Second, the policies contained in those documents conflict with the President’s and the Department’s national energy strategy that is articulated through E.O. 14153, “Unleashing Alaska’s Extraordinary Resource Potential,” E.O. 14154, “Unleashing American Energy,” E.O. 14156, “Declaring a National Energy Emergency,” Secretary’s Order 3417, “Addressing the National Energy Emergency,” Secretary’s Order 3418, “Unleashing American Energy,” and Secretary’s Order 3422, “Unleashing Alaska’s Extraordinary Resource Potential.” Consistent with the direction from the President and the Secretary, the BLM’s policy is to efficiently and effectively maximize the development and production of the natural resources located on Federal lands within Alaska, consistent with the statutory requirements of the NPRPA to ensure protection of surface resource values, including “the maximum protection of such surface values to the extent consistent with the requirements of this Act for the exploration of the reserve.” 42 U.S.C. 6504(a). The implementation of the BLM Report and Interim Measures Guidance would frustrate those purposes and would likely hinder the expeditious development of an oil and gas program in the Reserve as envisioned by the NPRPA. Additionally, the Interim Measures Guidance identified to protect subsistence as a significant resource value do not provide any substantive protection for subsistence use as a significant resource value and are unnecessary to effectively manage surface resources in the NPR–A.

Third, as noted above, E.O. 14153, “Unleashing Alaska’s Extraordinary Resource Potential,” (90 FR 8347)

directs the BLM to rescind the Bureau’s guidance on the protection of subsistence resource values in the existing special areas and proposed new and modified special areas in the NPR–A that was issued on January 16, 2025.

For the reasons articulated above, the BLM is rescinding the BLM Report as well as the Interim Measures Guidance. This action is a rescission of an internal policy that was not subject to a notice and comment and does not constitute rulemaking under the Administrative Procedure Act. The BLM will continue to engage the public during project-specific National Environmental Policy Act processes and resource management planning to ensure that its decisions implement the dual mandate of the NPRPA including maximum protection of significant resource values in special areas. This change does not affect statutory obligations to conduct ANILCA sec. 810 analyses or to engage with Tribal governments and subsistence users as part of the land use planning and permitting process.

Authority: 43 U.S.C. 1701 *et seq.*; 42 U.S.C. 6501 *et seq.*; 16 U.S.C. 3101 *et seq.*

Kevin J. Pendergast,
State Director, Alaska.

[FR Doc. 2025–14438 Filed 7–29–25; 8:45 am]

BILLING CODE 4331–10–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6381; NPS–WASO–NAGPRA–
NPS0040682; PPWOCRADNO–
PCU00RP14.R50000]

Notice of Inventory Completion: The University of Tennessee, Department of Anthropology, Knoxville, TN

AGENCY: National Park Service, Interior.
ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), The University of Tennessee, Knoxville, Department of Anthropology (UTK), has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains in this notice may occur on or after August 29, 2025.

ADDRESSES: Send written requests for repatriation of the human remains in this notice to Dr. Ellen Lofaro, University of Tennessee, Office of

Repatriation, 5723 Middlebrook Pike, Knoxville, TN 37996, email nagpra@utk.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service’s administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of UTK, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, one individual have been identified. No associated funerary objects are present. This individual was recovered from an unknown site in Osage County, Kansas, by an unknown person on an unknown date. Based on a past pattern of practice, it is likely that William Bass brought these human remains with him from the University of Kansas when he began working at UTK in 1971. To our knowledge, no potentially hazardous substances have been used to treat any of the Ancestral remains.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location of the human remains described in this notice.

Determinations

UTK has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- There is a connection between the human remains and associated funerary objects described in this notice and The Osage Nation.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
 2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.
- Repatriation of the human remains described in this notice to a requestor

may occur on or after August 29, 2025. If competing requests for repatriation are received, UTK must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. UTK are responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: July 15, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025-14381 Filed 7-29-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6365; NPS-WASO-NAGPRA-
NPS0040631; PPWOCRADN0-
PCU00RP14.R50000]

Notice of Intended Repatriation: University of California, Berkeley, Berkeley, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of California, Berkeley intends to repatriate certain cultural items that meet the definition of objects of cultural patrimony and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after August 29, 2025.

ADDRESSES: Send additional, written requests for repatriation of the cultural items in this notice to Alexandra Lucas, University of California, Berkeley, 200 California Hall, Berkeley, CA 94720, email nagpra-ucb@berkeley.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the University of California, Berkeley, and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The

National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Between 1954 and 1955, various individuals with the University of California Archaeological Survey removed 16 lots of objects of cultural patrimony from CA-RIV-56 in Riverside County, CA. The objects of cultural patrimony include pottery, worked stone, worked bone, projectile points, crystals, and faunal remains.

In 1881 S. B. Parrish removed one object of cultural patrimony from "Whitewater Ranch on edge of Colorado Desert, Riverside, Co." The object was donated to the University of California Museum of Anthropology (today the Phoebe A. Hearst Museum of Anthropology) by S. B. Parrish and W. A. Setchall in 1937. The object of cultural patrimony is a steatite bowl.

A.E. Michelbacher, a professor of entomology at the University of California Berkeley, gifted two objects of cultural patrimony from Thousand Palms, Riverside County, CA to the University of California Museum of Anthropology in 1943. The objects of cultural patrimony are pottery.

Collections and collection spaces at the Phoebe A Hearst Museum of Anthropology were treated with substances for preservation and pest control, some potentially hazardous. No records have been found to date at the Museum to indicate whether or not chemicals or natural substances were used prior to 1960.

Determinations

The University of California, Berkeley has determined that:

- The 19 objects of cultural patrimony described in this notice have ongoing historical, traditional, or cultural importance central to the Native American group, including any constituent sub-group (such as a band, clan, lineage, ceremonial society, or other subdivision), according to the Native American traditional knowledge of an Indian Tribe or Native Hawaiian organization.

- There is a connection between the cultural items described in this notice and the Agua Caliente Band of Cahuilla Indians of the Agua Caliente Indian Reservation, California.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or

Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after August 29, 2025. If competing requests for repatriation are received, the University of California, Berkeley must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The University of California, Berkeley is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: July 16, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025-14367 Filed 7-29-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6387; NPS-WASO-NAGPRA-
NPS0040681; PPWOCRADN0-
PCU00RP14.R50000]

Notice of Inventory Completion: Kansas State Historical Society, Topeka, KS

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Kansas State Historical Society (KSHS) has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after August 29, 2025.

ADDRESSES: Send written requests for repatriation of the human remains and associated funerary objects in this notice to Dr. Nicole Klarmann, Kansas State Historical Society, 6425 SW 6th Avenue, Topeka, KS 66615-1099, email kshs.nagpra@ks.gov.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the KSHS, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, one individual have been identified from an unknown county in Kansas (UBS 2015–06). No associated funerary objects are present. The remains are contained in a necklace that was in the possession of an Indian Agent for numerous Tribes in northeast Kansas.

Site 14SH322 from Shawnee County, KS (UBS 1991–16) has five associated funerary objects including a china sherd, chert, and a flake. Remains from this site were repatriated in 1997 and these objects were later determined to be associated with those remains.

An unknown site in Shawnee County, KS (UBS 2005–22) has two associated funerary objects including a silver earring and a “tin visor.” These items were found in a historic burial in a local resident's front yard.

To our knowledge, no known hazardous substances were used to treat any of the human remains or associated funerary objects.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains and associated funerary objects described in this notice.

Determinations

The KSHS has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- The seven objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a connection between the human remains and associated funerary objects described in this notice and the Prairie Band Potawatomi Nation.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary

objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects described in this notice to a requestor may occur on or after August 29, 2025. If competing requests for repatriation are received, the KSHS must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The KSHS is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: July 15, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025–14380 Filed 7–29–25; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6374; NPS–WASO–NAGPRA–NPS0040660; PPWOCRADNO–PCU00RP14.R50000]

Notice of Intended Repatriation: Virginia Museum of Fine Arts, Richmond, VA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Virginia Museum of Fine Arts intends to repatriate certain cultural items that meet the definition of objects of cultural patrimony and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after August 29, 2025.

ADDRESSES: Send additional, written requests for repatriation of the cultural items in this notice to Siera Hyte, Virginia Museum of Fine Arts 200 N Boulevard, Richmond, VA 23220, email siera.hyte@vmfa.museum.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Virginia Museum of Fine Arts and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of three cultural items have been requested for repatriation. The three objects of cultural patrimony are baskets made of willow, sedge root, bulrush, feathers, clamshell disk beads, and ferns. One basket is dated ca. 1897 and was acquired by the museum as a gift from Katherine B. Wallace in 2011. Ms. Wallace acquired the basket as a gift from Helen Hannon, who inherited it from her father, Reverend John Hannon. Museum records indicated that Reverend Hannon acquired the basket while working as a pastor in Ukiah, California around 1897. The other two baskets are dated ca. 1900 and were acquired by the museum as a part of a gift/purchase agreement with Robert and Nancy Nooter of Washington, DC in 2017 and 2018. The basket acquired in 2017 is labelled “Coiled Gift Basket” and was purchase by the Nooters from Gene Quintana in 1986, but beyond that date no further provenance information is known. The other basket, acquired in 2018, has no known provenance. Results of consultation with the Shabaldano Kai/Sherwood Valley Rancheria of Pomo Indians of California's Tribal Historic Preservation Office representatives confirm that these three baskets are objects of cultural patrimony. To our knowledge, no potentially hazardous substances were used to treat the baskets.

Determinations

The Virginia Museum of Fine Arts has determined that:

- The three objects of cultural patrimony described in this notice have ongoing historical, traditional, or cultural importance central to the Native American group, including any constituent sub-group (such as a band, clan, lineage, ceremonial society, or other subdivision), according to the Native American traditional knowledge

of an Indian Tribe or Native Hawaiian organization.

- There is a reasonable connection between the cultural items described in this notice and the Sherwood Valley Rancheria of Pomo Indians of California.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after August 29, 2025. If competing requests for repatriation are received, the Virginia Museum of Fine Arts must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The Virginia Museum of Fine Arts is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: July 15, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025–14372 Filed 7–29–25; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6386; NPS–WASO–NAGPRA–NPS0040680; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Kansas State Historical Society, Topeka, KS

AGENCY: National Park Service, Interior.
ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Kansas State Historical Society (KSHS) has completed an inventory of human remains and has determined that there is a cultural affiliation between the

human remains and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains in this notice may occur on or after August 29, 2025.

ADDRESSES: Send written requests for repatriation of the human remains in this notice to Dr. Nicole Klarmann, Kansas State Historical Society, 6425 SW 6th Avenue, Topeka, KS 66615–1099, email kshs.nagpra@ks.gov.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the KSHS, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, one individual have been identified from the Booth site (14JN349) in Jackson County, KS (UBS 2016–06). No associated funerary objects are present. These remains were found along a terrace of Soldier Creek and sent to the local coroner. No other provenience information is available. To our knowledge, no known hazardous substances were used to treat the human remains.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains described in this notice.

Determinations

The KSHS has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- There is a connection between the human remains described in this notice and the Pawnee Nation of Oklahoma and the Prairie Band Potawatomi Nation.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the authorized representative identified in this notice under

ADDRESSES. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains described in this notice to a requestor may occur on or after August 29, 2025. If competing requests for repatriation are received, the KSHS must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The KSHS is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: July 15, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025–14379 Filed 7–29–25; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6380; NPS–WASO–NAGPRA–NPS0040674; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Kansas State Historical Society, Topeka, KS

AGENCY: National Park Service, Interior.
ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Kansas State Historical Society (KSHS) has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after August 29, 2025.

ADDRESSES: Send written requests for repatriation of the human remains and associated funerary objects in this notice to Dr. Nicole Klarmann, Kansas State Historical Society, 6425 SW 6th Avenue, Topeka, KS 66615–1099, email kshs.nagpra@ks.gov.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the KSHS, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, two individuals have been identified from 14WY402 in Wyandotte County, KS (UBS 1990–01A, UBS 1990–01B). The 184 associated funerary objects include marine shells, a gorget, a medallion, a metal cylinder enclosing leather and hair, buttons, harness buckle, beads, German silver, tacks, and bags of cloth, metal, fiber, leather, nails, sand, bark, wood, and roots. Two historic burials were found south of the Kansas River during dredging operations in 1989. To our knowledge no known hazardous substances were used to treat any of the other human remains and associated funerary objects.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains and associated funerary objects described in this notice.

Determinations

The KSHS has determined that:

- The human remains described in this notice represent the physical remains of two individuals of Native American ancestry.
- The 184 objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a connection between the human remains and associated funerary objects described in this notice and the Shawnee Tribe.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects described in this notice to a requestor may occur on or after August 29, 2025. If competing requests for repatriation are received, the KSHS must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The KSHS is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.110.

Dated: July 15, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025–14377 Filed 7–29–25; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6378; NPS–WASO–NAGPRA–NPS0040665; PPWOCRADNO–PCU00RP14.R50000]

Notice of Inventory Completion: University of Wisconsin Oshkosh, Oshkosh, WI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of Wisconsin Oshkosh (UWO) has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after August 29, 2025.

ADDRESSES: Send written requests for repatriation of the human remains and associated funerary objects in this notice to Adrienne Frie, University of

Wisconsin Oshkosh, 800 Algoma Blvd., Oshkosh, WI 54901, email friea@uwosh.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of UWO, and additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Based on the information available, human remains representing, at least, one individual have been reasonably identified and were removed from the Sandhill Site (47–JU–0428), Juneau County, WI. In 1966, G. Richard Peske, then instructor at Wisconsin State University—Oshkosh (WSU–O), now University of Wisconsin Oshkosh (UWO), was called to a mound site by Chuck Spindler. Peske's incomplete field notes from August 24, 1966, record that someone had dug into the top of the conical mound, "looking for pots" and "uncovering a burial." Peske and Spindler conducted four shovel tests around the mound, while also recovering cultural material and human remains from the mound. The five associated funerary objects are one graver, two lots of undecorated grit tempered body sherds, one lot of mammal bone, and one lot of debitage. UWO has no knowledge or record of any potentially hazardous substances used to treat the human remains or associated funerary objects.

Based on the information available, human remains representing, at least, three individuals have been reasonably identified and were removed from the Grignon #1 (47–WN–0118) and Grignon #2 (47–WN–0119) sites, Winnebago County, WI. This site complex was originally investigated by G. Richard Peske in 1966. Later, in the 1970s when Dr. Alaric Faulkner reported the site to the Wisconsin Historical Society, he separated the location into two components which included a village site (Grignon #1 47–WN–0118/BWN–0193) and burial site (Grignon #2 47–WN–0119/BWN–0153). In 2024, collections held by the University of Wisconsin Milwaukee that were removed from Grignon #1 and #2 were legally transferred to the UWO to be included in the repatriation process, per tribal guidance. The 54 associated funerary objects are one lot of ceramics (missing); one post contact Kaolin pipe

fragment; four lots of faunal remains; two lots of shell; one turtle shell; one lot of charcoal; one lot of glass; five lots of decorated grit tempered body sherds; three lots of undecorated grit tempered body sherds; five lots of decorated grit tempered rim sherds; one lot of undecorated grit tempered rim sherds; six lots of lithics; one lot of lithic debitage; one lot of lithic debitage and pottery sherds; one projectile point; two lots of post-contact ceramics; one post-contact Kaolin pipe; six lots of decorated shell tempered body sherds; eight lots undecorated shell tempered body sherds; one lot of decorated shell tempered rim sherds; and two lots of undecorated shell tempered rim sherds. UWO has no knowledge or record of any potentially hazardous substances used to treat the human remains or associated funerary objects.

Based on the information available, human remains representing, at least, one individual have been reasonably identified and were removed from the Dowling #1 site (47–WN–0141), Winnebago County, WI. The Dowling #1 site was located as part of the 1972 Middle Fox River Valley Survey, administered by Dr. Alaric Faulkner (University of Wisconsin Oshkosh Assistant Professor) and J.D. Volkman. During a survey of the site, Volkman recovered a collection of lithics, as well as the remains of a human femur. The two associated funerary objects are one chipped stone biface and one lot of debitage. UWO has no knowledge or record of any potentially hazardous substances used to treat the human remains or associated funerary objects.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location of the human remains and associated funerary objects described in this notice.

Determinations

UWO has determined that:

- The human remains described in this notice represent the physical remains of five individuals of Native American ancestry.
- The 61 objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a reasonable connection between the human remains and associated funerary objects described in this notice and the Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana; Bad River Band

of the Lake Superior Tribe of Chippewa Indians of the Bad River Reservation, Wisconsin; Bay Mills Indian Community, Michigan; Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota; Chippewa Cree Indians of the Rocky Boy's Reservation, Montana; Citizen Potawatomi Nation, Oklahoma; Crow Creek Sioux Tribe of the Crow Creek Reservation, South Dakota; Flandreau Santee Sioux Tribe of South Dakota; Forest County Potawatomi Community, Wisconsin; Grand Traverse Band of Ottawa and Chippewa Indians, Michigan; Hannahville Indian Community, Michigan; Ho-Chunk Nation of Wisconsin; Iowa Tribe of Kansas and Nebraska; Iowa Tribe of Oklahoma; Keweenaw Bay Indian Community, Michigan; Kickapoo Traditional Tribe of Texas; Kickapoo Tribe of Indians of the Kickapoo Reservation in Kansas; Kickapoo Tribe of Oklahoma; Lac Courte Oreilles Band of Lake Superior Chippewa Indians of Wisconsin; Lac du Flambeau Band of Lake Superior Chippewa Indians of the Lac du Flambeau Reservation of Wisconsin; Lac Vieux Desert Band of Lake Superior Chippewa Indians of Michigan; Little Shell Tribe of Chippewa Indians of Montana; Lower Brule Sioux Tribe of the Lower Brule Reservation, South Dakota; Lower Sioux Indian Community in the State of Minnesota; Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan; Menominee Indian Tribe of Wisconsin; Miami Tribe of Oklahoma; Minnesota Chippewa Tribe, Minnesota (Six component reservations: Bois Forte Band (Nett Lake); Fond du Lac Band; Grand Portage Band; Leech Lake Band; Mille Lacs Band; White Earth Band); Nottawaseppi Huron Band of the Potawatomi, Michigan; Oglala Sioux Tribe; Otoe-Missouria Tribe of Indians, Oklahoma; Pokagon Band of Potawatomi Indians, Michigan and Indiana; Prairie Band Potawatomi Nation; Prairie Island Indian Community in the State of Minnesota; Red Cliff Band of Lake Superior Chippewa Indians of Wisconsin; Red Lake Band of Chippewa Indians, Minnesota; Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota; Sac & Fox Nation of Missouri in Kansas and Nebraska; Sac & Fox Nation, Oklahoma; Sac & Fox Tribe of the Mississippi in Iowa; Saginaw Chippewa Indian Tribe of Michigan; Santee Sioux Nation, Nebraska; Sault Ste. Marie Tribe of Chippewa Indians, Michigan; Shakopee Mdewakanton Sioux Community of Minnesota; Sisseton-Wahpeton Oyate of the Lake Traverse

Reservation, South Dakota; Sokaogon Chippewa Community, Wisconsin; Spirit Lake Tribe, North Dakota; St. Croix Chippewa Indians of Wisconsin; Standing Rock Sioux Tribe of North & South Dakota; Turtle Mountain Band of Chippewa Indians of North Dakota; Upper Sioux Community, Minnesota; Winnebago Tribe of Nebraska; and the Yankton Sioux Tribe of South Dakota.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after August 29, 2025. If competing requests for repatriation are received, UWO must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. UWO is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: July 15, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025–14376 Filed 7–29–25; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6368; NPS–WASO–NAGPRA–NPS0040634; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Heard Museum, Phoenix, AZ

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and

Repatriation Act (NAGPRA), the Heard Museum has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after August 29, 2025.

ADDRESSES: Send written requests for repatriation of the human remains and associated funerary objects in this notice to David Roche, Heard Museum, 2301 N Central Avenue, Phoenix, AZ 85004, email director@heard.org.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Heard Museum, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, three individuals have been identified. The one associated funerary object is a rectangular gray stone. Circumstances and date of acquisition unknown. NA-MIS-PR-T-2: A blue shoe box containing the minimum three individuals and one associated gray stone was located and subsequently accessioned during a full collections inventory in 1991. No information was located in the original Heard catalogue. Prior consultation in 1995 and 2002 did not identify cultural affiliation for the inhumation. Information gathered from the 2002 consultation suggested a geographic location of the Plains in an area with water. Exposure to hazardous substances is unlikely.

Human remains representing, at least, one individual has been identified. No associated funerary objects are present. Circumstances and date of acquisition unknown. NA-MIS-PR-T-4: The inhumation of one individual was located and subsequently accessioned during a full collections inventory in 1991. No information was located in the original Heard catalogue. Prior consultation in 1995, 2002, and 2013 did not identify cultural affiliation. Consultation in 2002 identified red ochre. Exposure to hazardous substances is unlikely.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains and associated funerary objects described in this notice.

Determinations

The Heard Museum has determined that:

- The human remains described in this notice represent the physical remains of four individuals of Native American ancestry.
- The one object described in this notice is reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a connection between the human remains and associated funerary objects described in this notice and the Pawnee Nation of Oklahoma.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects described in this notice to a requestor may occur on or after August 29, 2025. If competing requests for repatriation are received, the Heard Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The Heard Museum is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: July 16, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025–14370 Filed 7–29–25; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6369; NPS–WASO–NAGPRA–NPS0040637; PPWOCRADNO–PCU00RP14.R50000]

Notice of Inventory Completion: Grand Rapids Public Museum, Grand Rapids, MI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Grand Rapids Public Museum has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after August 29, 2025.

ADDRESSES: Send written requests for repatriation of the human remains and associated funerary objects in this notice to Alex Forist, Chief Curator, Grand Rapids Public Museum, 272 Pearl Street NW, Grand Rapids, MI 49504, email aforist@grpm.org.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Grand Rapids Public Museum, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing at least 10 individuals have been identified (two of which are currently missing). During 1962–1964, human remains representing, at minimum, eight individuals were removed from Norton Mounds (20KT1) in Kent County, MI. This site was excavated by staff from the University of Michigan in cooperation with the Grand Rapids Public Museum (GRPM). The human remains consist of

eight fragments of human bone that include: two rib end fragments, three fragments of shaft (these were not accompanied with any context), one fragment of a distal end of the sacrum, and one inferior border fragment. One human manubrium fragment was found in a mix of mammal bones and fill. No known individuals were identified. The two missing human remains include a right tibia fragment and a partial skull which were removed from Norton Mounds in 1894 by Captain Wright L. Coffinberry and/or in 1915 by former museum director Herbert E. Sargent. GRPM continues to look for any missing human remains.

Of the 33 lots of associated funerary objects, 19 are currently present and 14 are currently missing. The 19 present lots of associated funerary objects include ash samples; beads; bird bones (turkey, unknown); drilled tablets; faunal bones; fish bones and scales (catfish, sturgeon, walleye, unknown); historic debris; lithics; mammal bones, claws, and teeth (chipmunk, deer, mole, raccoon, skunk, weasel, woodchuck, unknown); mica; organic materials; rocks; shells (mussel, snail, unknown); sherds; soil samples; textiles; tools (bone, copper, stone); turtle shells and bones; and unknown material. The 14 missing lots of associated funerary objects include beads; bone gorgets; drilled tablets; hematite; limonite; lithics; mammal bones; ochre; organic materials; pipes; rocks; shells (mussel, unknown); tools (copper, stone); and vessels. GRPM continues to look for any missing objects.

The following non-federally recognized Indian groups were invited to consult: the Burt Lake Band of Ottawa and Chippewa and the Grand River Bands of Ottawa Indians.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains and associated funerary objects described in this notice.

Determinations

The Grand Rapids Public Museum has determined that:

- The human remains described in this notice represent the remains of at least 10 individuals of Native American ancestry.
- The 33 lots of objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.

- There is a connection between the human remains and associated funerary objects described in this notice and the Bay Mills Indian Community, Michigan; Citizen Potawatomi Nation, Oklahoma; Forest County Potawatomi Community, Wisconsin; Grand Traverse Band of Ottawa and Chippewa Indians, Michigan; Hannahville Indian Community, Michigan; Keweenaw Bay Indian Community, Michigan; Lac Vieux Desert Band of Lake Superior Chippewa Indians of Michigan; Little River Band of Ottawa Indians, Michigan; Little Traverse Bay Bands of Odawa Indians, Michigan; Match-e-be-nash-she-wish Band of Potawatomi Indians of Michigan; Nottawaseppi Huron Band of the Potawatomi, Michigan; Ottawa Tribe of Oklahoma; Pokagon Band of Potawatomi Indians, Michigan and Indiana; Prairie Band Potawatomi Nation; Red Lake Band of Chippewa Indians, Minnesota; Sac & Fox Nation, Oklahoma; Saginaw Chippewa Indian Tribe of Michigan; and the Sault Ste. Marie Tribe of Chippewa Indians, Michigan.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects described in this notice to a requestor may occur on or after August 29, 2025. If competing requests for repatriation are received, the Grand Rapids Public Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The Grand Rapids Public Museum is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

(Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.)

Dated: July 16, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025–14371 Filed 7–29–25; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6364; NPS–WASO–NAGPRA–NPS0040630; PPWOCRADNO–PCU00RP14.R50000]

Notice of Intended Repatriation: University of California, Berkeley, Berkeley, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of California, Berkeley intends to repatriate certain cultural items that meet the definition of objects of cultural patrimony and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after August 29, 2025.

ADDRESSES: Send additional, written requests for repatriation of the cultural items in this notice to Alexandra Lucas, University of California, Berkeley, 200 California Hall, Berkeley, CA 94720, email nagpra-ucb@berkeley.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the University of California, Berkeley, and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of nine cultural items have been requested for repatriation. The objects of cultural patrimony are from the following accessions: Acc. 1184, Acc. 838, and Acc. 603 in the Phoebe A Hearst Museum of Anthropology at the University of California, Berkeley.

In preparation for an exhibition related to the food economy of California Indians by the University of California Museum of Anthropology (today the Phoebe A. Hearst Museum of Anthropology), Lawrence Dawson, R. K. Eckman, and others removed five lots of

objects of cultural patrimony from Palm Springs, California in 1955. The objects of cultural patrimony are botanical samples.

In 1945, Grace Blair De Pue bequeathed more than 2,000 cultural belongings to the University of California Museum of Anthropology. Correspondence in the accession file indicated that Grace Blair De Pue acquired baskets from many traders, including R.B. Cregar, a prominent trader in the Coachella Valley, California. Two baskets removed from the area of Palm Springs, California by Grace Blair De Pue have been requested for repatriation.

In or before 1924, William Duncan Strong, a student at University of California, Berkeley, took two photographs of sites of importance to the Agua Caliente Band of Cahuilla Indians. The photographs were accessioned by the University of California Museum of Anthropology in 1924.

Collections and collection spaces at the Phoebe A Hearst Museum of Anthropology were treated with substances for preservation and pest control, some potentially hazardous. No records have been found to date at the Museum to indicate whether or not chemicals or natural substances were used prior to 1960.

Determinations

The University of California, Berkeley has determined that:

- The nine lots of objects of cultural patrimony described in this notice have ongoing historical, traditional, or cultural importance central to the Native American group, including any constituent sub-group (such as a band, clan, lineage, ceremonial society, or other subdivision), according to the Native American traditional knowledge of an Indian Tribe or Native Hawaiian organization.

- There is a connection between the cultural items described in this notice and the Agua Caliente Band of Cahuilla Indians of the Agua Caliente Indian Reservation, California.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or

a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after August 29, 2025. If competing requests for repatriation are received, the University of California, Berkeley must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The University of California, Berkeley is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: July 16, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025–14366 Filed 7–29–25; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6367; NPS–WASO–NAGPRA–NPS0040633; PPWOCRADNO–PCU00RP14.R50000]

Notice of Inventory Completion: San Bernardino County Museum, Redlands, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), San Bernardino County Museum has completed an inventory of associated funerary objects and has determined that there is a cultural affiliation between the associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the associated funerary objects in this notice may occur on or after August 29, 2025.

ADDRESSES: Send written requests for repatriation of the associated funerary objects in this notice to Tamara Serrao-Leiva, San Bernardino County Museum, 2024 Orange Tree Lane, Redlands, CA 92374, email tserrao-leiva@sbcm.sbcounty.gov.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the

sole responsibility of the San Bernardino County Museum, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

The two associated funerary objects are one lot of ecofacts and one lot of ceramics. The Lake LeConte collection (SBCM–5922) housed at the museum was originally part of the McCown collection, who was affiliated with Archaeological Survey Association. When ASA disbanded, this collection was donated to the county museum in the early 2000s. At a different collecting event, items were taken from Lake LeConte area, near Davies Valley. These items were given the same number and have lived together with the ancestor since collection. These objects are in addition to human remains and associated funerary objects published in the **Federal Register** in a Notice of Inventory Completion on October 22, 2024 (89 FR 84393).

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the associated funerary objects described in this notice.

Determinations

The San Bernardino County Museum has determined that:

- The two objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.

- There is a connection between the associated funerary objects described in this notice and the Agua Caliente Band of Cahuilla Indians of the Agua Caliente Indian Reservation, California; Augustine Band of Cahuilla Indians, California; Cabazon Band of Cahuilla Indians (*previously* listed as Cabazon Band of Mission Indians, California); Cahuilla Band of Indians; Los Coyotes Band of Cahuilla and Cupeno Indians, California; Morongo Band of Mission Indians, California; Ramona Band of Cahuilla, California; Santa Rosa Band of Cahuilla Indians, California; and the Torres Martinez Desert Cahuilla Indians, California.

Requests for Repatriation

Written requests for repatriation of the associated funerary objects in this notice

must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the associated funerary objects described in this notice to a requestor may occur on or after August 29, 2025. If competing requests for repatriation are received, the San Bernardino County Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the associated funerary objects are considered a single request and not competing requests. The San Bernardino County Museum is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

(Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.)

Dated: July 16, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025-14369 Filed 7-29-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6363; NPS-WASO-NAGPRA-
NPS0040629; PPWOCRADNO-
PCU00RP14.R50000]

Notice of Inventory Completion: Autry Museum of the American West, Los Angeles, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Autry Museum of the American West has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects

in this notice may occur on or after August 29, 2025.

ADDRESSES: Send written requests for repatriation of the human remains and associated funerary objects in this notice to Karimah Richardson, Autry Museum of the American West, 4700 Western Heritage Way, Los Angeles, CA 90027, email krichardson@theautry.org.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Autry Museum of the American West, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing at least 16 individuals have been identified. The 192 associated funerary objects are 28 potsherds, three debitage, three modified faunal bone fragments, eight shell fragments, eight unmodified granite stones, 83 Olivella disk beads (two burned), four glass trade beads, four historic glass fragments, one bag of red ochre fragments, one ground stone fragment, four metal fragments, 26 faunal fragments, 10 burned faunal bone fragments, one lot of charcoal, one lot of organics, one lot of textile fragments, one lot of potsherds, one mortar fragment, two mortar fragments, one possible metate, and one awl fragment. The human remains and associated funerary objects (498.G.3468) were recovered during the Southwest Museum expedition led by museum archaeologists, William and Elizabeth Campbell, in March 1934, and potentially donated in 1959 to the Southwest Museum (now part of the Autry Museum of the American West). The remains were labeled as "Morongo Valley". The Campbells only documented two sites in Morongo Valley from the Lower Morongo Valley District which they labeled as site 519 and site 520. Unfortunately, over the decades materials from the two sites have been combined and the remains from both sites are commingled.

Human remains representing at least one individual have been identified. The 88 associated funerary objects are one quartz Humboldt Cluster Point, one burned bone tool, one burned Olivella disc shell bead, two glass trade beads, eight decorated potsherds, 60 plain body potsherds, and 15 plain rim potsherds. Human remains and

associated funerary objects (546.G.3-7) were recovered during the Southwest Museum expedition led by museum archaeologist Elizabeth Campbell in 1932 and donated in August 1932 to the Southwest Museum (now part of the Autry Museum of the American West). Records state the remains and associated funerary objects were collected from Section 13, in Lower Morongo Valley, CA.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains and associated funerary objects described in this notice.

Determinations

The Autry Museum of the American West has determined that:

- The human remains described in this notice represent the physical remains of 17 individuals of Native American ancestry.

- The 280 objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.

- There is a connection between the human remains and associated funerary objects described in this notice and the Agua Caliente Band of Cahuilla Indians of the Agua Caliente Indian Reservation, California; Cahuilla Band of Indians; Morongo Band of Mission Indians, California; Ramona Band of Cahuilla, California; Soboba Band of Luiseno Indians, California; and the Yuhaaviatam of San Manuel Nation (previously listed as San Manuel Band of Mission Indians, California).

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects described in this notice to a requestor may occur on or after August 29, 2025.

If competing requests for repatriation are received, the Autry Museum of the American West must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The Autry Museum of the American West is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: July 16, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025-14365 Filed 7-29-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6376; NPS-WASO-NAGPRA-
NPS0040663; PPWOCRADNO-
PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Army Corps of Engineers, Omaha District, Omaha, NE, and the University of North Dakota, Grand Forks, ND

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the U.S. Army Corps of Engineers, Omaha District and the University of North Dakota have completed an inventory of human remains and associated funerary objects and have determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after August 29, 2025.

ADDRESSES: Send written requests for repatriation of the human remains and associated funerary objects in this notice to Ms. Livia Taylor, U.S. Army Corps of Engineers, Omaha District, ATTN: CENWO-PMA-D, 1616 Capitol Avenue, Omaha, NE 68102, email Livia.A.Taylor@usace.army.mil and Dr. Crystal Alberts, University of North Dakota, 250 Centennial Drive, Stop 8193, Grand Forks, ND 58202, email und.nagpra@und.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Omaha District and the University of North Dakota, and additional information on the determinations in this notice, including the results of consultation, can be found in their inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Based on information available, human remains of, at least, one individual has been reasonably identified, along with 5,023 associated funerary objects. They were removed from a site in Hughes County, South Dakota.

Based on information available, human remains of, at least, one individual has been reasonably identified, along with 123 associated funerary objects. They were removed from a site in Stanley County, South Dakota.

Based on information available, human remains of, at least, one individual has been reasonably identified, along with 5,963 associated funerary objects. They were removed from a site in Stanley County, South Dakota.

Based on information available, 10 associated funerary objects were removed from a site in Emmons County, North Dakota; four associated funerary objects were removed from a site in Campbell County, South Dakota; 14 associated funerary objects were removed from a site in Hughes County, South Dakota; 60 associated funerary objects were removed from a site in Hughes County, South Dakota; 21 associated funerary objects were removed from a site in Lyman County, South Dakota; 51 associated funerary objects were removed from a site in Lyman County, South Dakota; 81 associated funerary objects were removed from a site in Lyman County, South Dakota; one associated funerary object were removed from a site in Stanley County, South Dakota; 56 associated funerary objects were removed from a site in Stanley County, South Dakota; 131 associated funerary objects were removed from a site in Stanley County, South Dakota; 113 associated funerary objects were removed from a site in Stanley County, South Dakota; 16 associated funerary objects were removed from a site in Stanley County, South Dakota; and 14 associated funerary objects were

removed from a site in Walworth County, South Dakota.

The Omaha District and UND have no record of any potentially hazardous substances being used to treat the Ancestors or associated funerary objects described in this notice.

Based upon a preponderance of the evidence, including Tribal oral history, archeological and geographical information, the Ancestors and associated funerary objects described in this Notice are consistent with cultural affiliation of the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is clearly identified by the information available about the human remains and associated funerary objects described in this notice.

Determinations

The U.S. Army Corps of Engineers, Omaha District and the University of North Dakota have determined that:

- The human remains described in this notice represent the physical remains of a minimum of three individuals of Native American ancestry.
- The 11,681 objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a connection between the human remains and associated funerary objects described in this notice and the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
 2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.
- Repatriation of the human remains and associated funerary objects described in this notice to a requestor may occur on or after August 29, 2025. If competing requests for repatriation are received, the U.S. Army Corps of

Engineers, Omaha District and the University of North Dakota must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The U.S. Army Corps of Engineers, Omaha District and the University of North Dakota are responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: July 15, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025–14374 Filed 7–29–25; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6385; NPS–WASO–NAGPRA–NPS0040677; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Kansas State Historical Society, Topeka, KS

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Kansas State Historical Society (KSHS) has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after August 29, 2025.

ADDRESSES: Send written requests for repatriation of the human remains and associated funerary objects in this notice to Dr. Nicole Klarmann, Kansas State Historical Society, 6425 SW 6th Avenue, Topeka, KS 66615–1099, email kshs.nagpra@ks.gov.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the KSHS, and additional information on the

determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, one individual have been identified from site 14LC307 in Lincoln County, KS (UBS 1991–08). The 14,520 associated funerary objects are beads, a possible shield, and wooden, metal, stone, shell, and cloth artifacts. A hilltop burial was exposed during earthmoving associated with a gravel pit operation. To our knowledge, no known hazardous substances were used to treat any of the human remains or associated funerary objects.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains and associated funerary objects described in this notice.

Determinations

The KSHS has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- The 14,520 objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a connection between the human remains and associated funerary objects described in this notice and the Prairie Band Potawatomi Nation and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco, & Tawakonie), Oklahoma.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects

described in this notice to a requestor may occur on or after August 29, 2025. If competing requests for repatriation are received, the KSHS must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The KSHS is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: July 15, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025–14378 Filed 7–29–25; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6366; NPS–WASO–NAGPRA–NPS0040632; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intended Repatriation: University of California, Berkeley, Berkeley, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of California, Berkeley intends to repatriate certain cultural items that meet the definition of unassociated funerary objects or objects of cultural patrimony and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after August 29, 2025.

ADDRESSES: Send additional, written requests for repatriation of the cultural items in this notice to Alexandra Lucas, University of California, Berkeley, 200 California Hall, Berkeley, CA 94720, email nagpra-ucb@berkeley.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the University of California, Berkeley, and additional information on the determinations in

this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of 52 cultural items in the Phoebe A Hearst Museum of Anthropology at the University of California, Berkeley have been requested for repatriation.

In 1929, Theodore D. McCown, a student at University of California, Berkeley, removed one object of cultural patrimony from Turner Ranch in San Bernardino County, California. The object of cultural patrimony is one lot of pottery.

In 1949, Albert Mohr via the University of California Archaeological Survey removed 16 lots of unassociated funerary belongings from CA-SBR-66 and 35 lots of objects of cultural patrimony from the following sites in San Bernardino County, California: CA-SBR-58, CA-SBR-59, CA-SBR-60, CA-SBR-61, CA-SBR-62, CA-SBR-63, CA-SBR-65, CA-SBR-69, CA-SBR-71, and CA-SBR-72. The unassociated funerary belongings include beads, worked stone, and ground stone. The objects of cultural patrimony include ground stone, and worked stone,

Collections and collection spaces at the Phoebe A Hearst Museum of Anthropology were treated with substances for preservation and pest control, some potentially hazardous. No records have been found to date at the Museum to indicate whether or not chemicals or natural substances were used prior to 1960.

Determinations

The University of California, Berkeley has determined that:

- The 16 lots of unassociated funerary objects described in this notice are reasonably believed to have been placed intentionally with or near human remains, and are connected, either at the time of death or later as part of the death rite or ceremony of a Native American culture according to the Native American traditional knowledge of a lineal descendant, Indian Tribe, or Native Hawaiian organization. The unassociated funerary objects have been identified by a preponderance of the evidence as related to human remains, specific individuals, or families, or removed from a specific burial site or burial area of an individual or individuals with cultural affiliation to an Indian Tribe or Native Hawaiian organization.

- The 36 lots of objects of cultural patrimony described in this notice have

ongoing historical, traditional, or cultural importance central to the Native American group, including any constituent sub-group (such as a band, clan, lineage, ceremonial society, or other subdivision), according to the Native American traditional knowledge of an Indian Tribe or Native Hawaiian organization.

- There is a reasonable connection between the cultural items described in this notice and the Yuhaaviatam of San Manuel Nation (*previously* listed as San Manuel Band of Mission Indians, California.).

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after August 29, 2025. If competing requests for repatriation are received, the University of California, Berkeley must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The University of California, Berkeley is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: July 16, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025-14368 Filed 7-29-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6375; NPS-WASO-NAGPRA-NPS0040662; PPWOCRADN0-PCU00RP14.R50000]

Notice of Inventory Completion: Sam Noble Oklahoma Museum of Natural History, University of Oklahoma, Norman, OK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Sam Noble Oklahoma Museum of Natural History (SNOMNH), has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after August 29, 2025.

ADDRESSES: Send written requests for repatriation of the human remains and associated funerary objects in this notice to Zachary Garrett, Sam Noble Oklahoma Museum of Natural History, University of Oklahoma, 2401 Chautauqua Avenue, Norman, OK 73072-7029, email zacgarrett@ou.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of SNOMNH, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing at least, 80 individuals have been identified. The 93 associated funerary objects are 14 lots of stone projectile points, 25 lots of ceramic pottery sherds, one lot of ceramic beads, one lot of manos, 13 lots of faunal remains, four lots of stone bifaces, two lots of faunal pins, two lots of stone flakes, five lots of hematite, three lots of worked faunal remains, one lot of worked stone, one lot of boatstone, one lot of worked shell, one lot of stone celts, three lots of stone hoes, 10 lots of shell, one lot of stone drills, four lots of unmodified stone, and one lot of hammerstones. These individuals and

associated funerary objects were removed from the Phillips Site, (34LF43). This mound site is located on the north side of Redwine Lake, in LeFlore County, Oklahoma, and was excavated by the Works Progress Administration in 1941–42, after which the individuals and objects removed from the site were deposited at SNOMNH. This site was occupied during the Fourche Maline phase (300–800 CE), and possibly through the Spiro Phase. To our knowledge, no potentially hazardous substances were used to treat any of the human remains or associated funerary objects.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is clearly identified by the information available about the human remains and associated funerary objects described in this notice.

Determinations

SNOMNH has determined that:

- The human remains described in this notice represent the physical remains of 80 individuals of Native American ancestry.
- The 93 objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a connection between the human remains and associated funerary objects described in this notice and the Caddo Nation of Oklahoma and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco, & Tawakonie), Oklahoma.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects described in this notice to a requestor may occur on or after August 29, 2025. If competing requests for repatriation are received, SNOMNH must determine the most appropriate requestor prior to

repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. SNOMNH is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: July 15, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025–14373 Filed 7–29–25; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6362; NPS–WASO–NAGPRA–NPS0040628; PPWOCRADNO–PCU00RP14.R50000]

Notice of Intended Repatriation: Autry Museum of the American West, Los Angeles, CA

AGENCY: National Park Service, Interior.
ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Autry Museum of the American West intends to repatriate certain cultural items that meet the definition of unassociated funerary objects, sacred objects, and/or objects of cultural patrimony and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after August 29, 2025.

ADDRESSES: Send additional, written requests for repatriation of the cultural items in this notice to Karimah Richardson, Autry Museum of the American West, 4700 Western Heritage Way, Los Angeles, CA 90027, email krichardson@theautry.org.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Autry Museum of the American West, and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The

National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of one cultural item has been requested for repatriation. The object of cultural patrimony is one smoothing stone. Sometime between 1911–1933, Mr. Clifford Park Baldwin, collected the cultural item from an unknown site in Morongo Valley, San Bernardino County, CA. In 1993, Mr. Baldwin sold it to the Southwest Museum (now part of the Autry Museum of the American West). The object is considered cultural patrimony, as the tribes have stated it is significant to both the Cahuilla and Serrano people.

A total of one cultural item has been requested for repatriation. The object of cultural patrimony is one olla. In 1933, Miss Marjorie Dougan collected the olla from an unknown site in Morongo Valley, San Bernardino County, CA. Miss Dougan donated the olla to the Southwest Museum in 1964. The object is considered cultural patrimony, as the tribes have stated it is significant to both the Cahuilla and Serrano people.

A total of one cultural item has been requested for repatriation. The object of cultural patrimony is one ceramic bowl. Dr. Oscar S. Brown collected the pottery bowl circa 1904 from possibly Morongo Valley in San Bernardino County, CA. His daughter, Miss Brown, donated the cultural item to the Southwest Museum in 1944. The object is considered cultural patrimony, as the tribes have stated it is significant to both the Cahuilla and Serrano people.

A total of 14 cultural items have been requested for repatriation. The 14 sacred objects are five pottery ollas, two pottery bowls, six pottery spindle whorls, and one pottery miniature bowl. Sometime between 1932–1934, Mrs. Pearly Alice Othelia Compton collected the cultural items from a cave in an unknown site in Morongo Valley, San Bernardino County, CA. Mr. John F. Compton. In 1970, her husband, Mr. John F. Compton, donated the cultural items to the Southwest Museum. The objects are considered sacred as they were found in a cave.

Determinations

The Autry Museum of the American West has determined that:

- The 14 sacred objects described in this notice are specific ceremonial objects needed by a traditional Native American religious leader for present-day adherents to practice traditional Native American religion, according to the Native American traditional knowledge of a lineal descendant,

Indian Tribe, or Native Hawaiian organization.

- The three objects of cultural patrimony described in this notice have ongoing historical, traditional, or cultural importance central to the Native American group, including any constituent sub-group (such as a band, clan, lineage, ceremonial society, or other subdivision), according to the Native American traditional knowledge of an Indian Tribe or Native Hawaiian organization.

- There is a reasonable connection between the cultural items described in this notice and the Agua Caliente Band of Cahuilla Indians of the Agua Caliente Indian Reservation, California; Cahuilla Band of Indians; Morongo Band of Mission Indians, California; Ramona Band of Cahuilla, California; Soboba Band of Luiseno Indians, California; and the Yuhaaviatam of San Manuel Nation (*previously* listed as San Manuel Band of Mission Indians, California).

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after July 30, 2025. If competing requests for repatriation are received, the Autry Museum of the American West must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The Autry Museum of the American West is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: July 16, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025-14364 Filed 7-29-25; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[N6377; NPS-WASO-NAGPRA-NPS0040664; PPWOCRADNO-PCU00RP14.R50000]

Notice of Inventory Completion: University of Wisconsin Oshkosh, Oshkosh, WI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of Wisconsin Oshkosh (UWO) has completed an inventory of associated funerary objects and has determined that there is a cultural affiliation between the associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the associated funerary objects in this notice may occur on or after August 29, 2025.

ADDRESSES: Send written requests for repatriation of the associated funerary objects in this notice to Adrienne Frie, University of Wisconsin Oshkosh, 800 Algoma Boulevard, Oshkosh, WI 54901, email friea@uwosh.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of UWO, and additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Based on the information available, associated funerary objects have been identified from the St. Cloud Mound Group (47-FD-0036), Fond du Lac County, WI. In 1976, an archaeology student at Wisconsin State University—Oshkosh (WSU—O), now the University of Wisconsin Oshkosh (UWO), was called to a farm where mounds were known to exist. This student, Daniel Seurer, worked with Dr. Alaric Faulkner, Assistant Professor at WSU—O, to salvage the land before the mounds were destroyed from plowing. There were no field notes from the salvage work. The human remains and items recovered from this farm were not looked at until 2012, when University of Wisconsin—Milwaukee affiliated researcher, Mark Bruhy, analyzed the

collection. He noticed that there was an original small bag labeled, “Lithics and Human Bone,” however, no bone was found in this bag. All efforts to identify the human remains from 47-FD-0036 from the UWO collection and elsewhere have failed. UWO is working under the assumption that Seurer and Dr. Faulkner removed Ancestral human remains in 1976 but they have since been disassociated from their items. The 14 associated funerary objects are six lots of lithic debitage, five lots of undecorated grit tempered body sherds, two lots of lithics, and one metal bullet casing. UWO has no knowledge or record of any potentially hazardous substances used to treat the associated funerary objects.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location of the associated funerary objects described in this notice.

Determinations

UWO has determined that:

- The 14 objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.

- There is a reasonable connection between the associated funerary objects described in this notice and the Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana; Bad River Band of the Lake Superior Tribe of Chippewa Indians of the Bad River Reservation, Wisconsin; Bay Mills Indian Community, Michigan; Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota; Chippewa Cree Indians of the Rocky Boy's Reservation, Montana; Citizen Potawatomi Nation, Oklahoma; Crow Creek Sioux Tribe of the Crow Creek Reservation, South Dakota; Flandreau Santee Sioux Tribe of South Dakota; Forest County Potawatomi Community, Wisconsin; Grand Traverse Band of Ottawa and Chippewa Indians, Michigan; Hannahville Indian Community, Michigan; Ho-Chunk Nation of Wisconsin; Iowa Tribe of Kansas and Nebraska; Iowa Tribe of Oklahoma; Keweenaw Bay Indian Community, Michigan; Kickapoo Traditional Tribe of Texas; Kickapoo Tribe of Indians of the Kickapoo Reservation in Kansas; Kickapoo Tribe of Oklahoma; Lac Courte Oreilles Band of Lake Superior Chippewa Indians of Wisconsin; Lac du Flambeau Band of Lake Superior Chippewa Indians of the Lac du Flambeau Reservation of

Wisconsin; Lac Vieux Desert Band of Lake Superior Chippewa Indians of Michigan; Little River Band of Ottawa Indians, Michigan; Little Shell Tribe of Chippewa Indians of Montana; Little Traverse Bay Bands of Odawa Indians, Michigan; Lower Brule Sioux Tribe of the Lower Brule Reservation, South Dakota; Lower Sioux Indian Community in the State of Minnesota; Match-e-be-nash-she-wish Band of Pottawatomie Indians of Michigan; Menominee Indian Tribe of Wisconsin; Miami Tribe of Oklahoma; Minnesota Chippewa Tribe, Minnesota (Six component reservations: Bois Forte Band (Nett Lake); Fond du Lac Band; Grand Portage Band; Leech Lake Band; Mille Lacs Band; White Earth Band); Nottawaseppi Huron Band of the Potawatomi, Michigan; Oglala Sioux Tribe; Ojibwe-Missouri Tribe of Indians, Oklahoma; Pokagon Band of Potawatomi Indians, Michigan and Indiana; Prairie Band Potawatomi Nation; Prairie Island Indian Community in the State of Minnesota; Red Cliff Band of Lake Superior Chippewa Indians of Wisconsin; Red Lake Band of Chippewa Indians, Minnesota; Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota; Sac & Fox Nation of Missouri in Kansas and Nebraska; Sac & Fox Nation, Oklahoma; Sac & Fox Tribe of the Mississippi in Iowa; Saginaw Chippewa Indian Tribe of Michigan; Santee Sioux Nation, Nebraska; Sault Ste. Marie Tribe of Chippewa Indians, Michigan; Shakopee Mdewakanton Sioux Community of Minnesota; Sisseton-Wahpeton Oyate of the Lake Traverse Reservation, South Dakota; Sokaogon Chippewa Community, Wisconsin; Spirit Lake Tribe, North Dakota; St. Croix Chippewa Indians of Wisconsin; Standing Rock Sioux Tribe of North & South Dakota; Turtle Mountain Band of Chippewa Indians of North Dakota; Upper Sioux Community, Minnesota; Winnebago Tribe of Nebraska; and the Yankton Sioux Tribe of South Dakota.

Requests for Repatriation

Written requests for repatriation of the associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the associated funerary objects in this notice to a requestor may occur on or after August 29, 2025. If competing requests for repatriation are received, UWO must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the associated funerary objects are considered a single request and not competing requests. UWO is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: July 15, 2025.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2025–14375 Filed 7–29–25; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[OMB Control Number 1029–0115; S1D1S SS08011000 SX064A000 256S180110; S2D2S SS08011000 SX064A000 25XS501520]

Submission to the Office of Management and Budget for Review and Approval; Requirements for Permits and Permit Processing

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments. To be considered, your comments must be received on or before August 28, 2025.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to William Frankel, Office of Surface Mining Reclamation and Enforcement, 4547 Stewart Udall Building, Washington, DC 20240, by email to wfrankel@osmre.gov, or by phone at (202) 208–0121. Please reference OMB Control Number 1029–0115 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT:

William Frankel by email wfrankel@osmre.gov. Individuals in the United

States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at <http://www.reginfo.gov/public/do/PRAMain>.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on May 16, 2025 (90 FR 21076). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) is the collection necessary to the proper functions of the agency; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the agency enhance the quality, utility, and clarity of the information to be collected; and (5) how might the agency minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: This collection of information is authorized by 30 CFR

part 773, which implements various provisions of the Surface Mining Control and Reclamation Act of 1977 (Act), including sections 506, 507, 510, 513, and 514 (30 U.S.C. 1256, 1257, 1260, 1263, and 1264) by identifying general and specific information requirements for applicants to provide in the permitting process, and for regulatory authorities to review permit applications, determine permit eligibility, and ascribe permit conditions. Part 773 also contains provisions governing provisionally issued permits, improvidently issued permits, and challenges of ownership or control listings and findings. This information collection also authorizes the collection of permit processing fees approved under OSMRE regulations.

Title of Collection: Requirements for Permits and Permit Processing.

OMB Control Number: 1029–0115.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Businesses, State and Tribal governments.

Total Estimated Number of Annual Respondents: 950.

Total Estimated Number of Annual Responses: 4,198.

Estimated Completion Time per Response: Varies 1 hour to 32 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 46,982.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: \$83,400.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

William L. Frankel,

*Information Collection Clearance Officer,
Office of Surface Mining Reclamation and
Enforcement.*

[FR Doc. 2025–14421 Filed 7–29–25; 8:45 am]

BILLING CODE 4310–05–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–747 (Fifth Review)]

Fresh Tomatoes From Mexico; Termination of Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission instituted the subject five-year review on August 1, 2024 to determine whether termination of the suspended antidumping duty investigation on fresh tomatoes from Mexico would be likely to lead to continuation or recurrence of material injury to a domestic industry. Effective July 14, 2025, the Department of Commerce (“Commerce”) withdrew from and terminated the 2019 Agreement Suspending the Antidumping Duty Investigation on Fresh Tomatoes from Mexico (“2019 Agreement”) and issued the antidumping duty order. On July 17, 2025, Commerce published notice in the **Federal Register** that it was withdrawing from and terminating the 2019 Agreement (90 FR 33363). Accordingly, since there is no longer a suspension agreement of which to conduct a five-year review, the Commission gives notice of the termination of its review involving fresh tomatoes from Mexico.

DATES: July 14, 2025 (effective date of revocation of the 2019 Agreement and issuance of the antidumping duty order).

FOR FURTHER INFORMATION CONTACT:

Lawrence Jones (202–205–3358), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>.

Authority: This review is being terminated under authority of title VII of the Tariff Act of 1930 and pursuant to section 207.40(a) of the Commission’s Rules of Practice and Procedure (19 CFR 207.40(a)). This notice is published pursuant to section 201.10 of the Commission’s rules (19 CFR 201.10).

By order of the Commission.

Issued: July 25, 2025.

Susan Orndoff,

Secretary to the Commission.

[FR Doc. 2025–14386 Filed 7–29–25; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–0052]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Reinstatement of a Currently Approved Collection; Emergency Clearance for an Existing Collection; Claims Under the Radiation Exposure Compensation Act

AGENCY: Civil Division, Department of Justice.

ACTION: Emergency clearance notice and request for comments.

SUMMARY: The Department of Justice (DOJ), Civil Division, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments on this proposal for emergency review should be received within August 11, 2025. We are requesting OMB to take action within 10 calendar days from the close of this **Federal Register** Notice on the request for emergency review. This process is conducted in accordance with 5 CFR 1320.1

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Jason C. Bougere, U.S. Department of Justice, P.O. Box 146, Ben Franklin Station, Washington, DC 20044–014, at (202) 307–2737 or Jason.c.bougere@usdoj.gov.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Civil Division, including whether the information will have practical utility;
- Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Abstract: Information collection form for individuals applying for compensation under the Radiation Exposure Compensation Act.

Overview of this information collection:

1. Type of Information Collection: Extension of a previously approved collection.
 2. Title of the Form/Collection: Claims Under the Radiation Exposure Compensation Act.
 3. Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form Number: OMB #1105–0052. DOJ Component: Civil Division.
 4. Affected public who will be asked or required to respond, as well as a brief abstract: Affected Public: Primary: Individuals or households.
- Abstract:** Information is collected to determine whether an individual is entitled to compensation under the Radiation Exposure Compensation Act.
5. Obligation to Respond: Voluntary but required to obtain a benefit.
 6. Total Estimated Number of Respondents: Approximately 70,000.
 7. Estimated Time per Respondent: 2.5 hours.
 8. Frequency: Once.
 9. Total Estimated Annual Time Burden: 175,000 hours.
 10. Total Estimated Annual Other Costs Burden: \$0 [This is captured in #7 of the 60day notice as well as item 13 of the Supporting Statement A].

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Service Engineering and Investment Oversight, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: July 25, 2025.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2025–14344 Filed 7–29–25; 8:45 am]

BILLING CODE 4410–12–P

DEPARTMENT OF JUSTICE

Meeting of the Religious Liberty Commission

AGENCY: Office of the Associate Attorney General, United States Department of Justice (DOJ).

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The DOJ is publishing this notice to announce the second Federal advisory committee meeting of the Religious Liberty Commission (Commission).

DATES: Open to the public September 8, 2025, from 9:00 a.m. to 4:00 p.m.

ADDRESSES: The meeting will be held in the World Stage Theater, Museum of the Bible, 400 4th St. SW, Washington, DC 20024. The meeting will be recorded and broadcast at justice.gov/live.

FOR FURTHER INFORMATION CONTACT:

Mary Margaret Bush, Religious Liberty Commission Designated Federal Officer, RLC@usdoj.gov, 202–297–3196. Mrs. Bush can also be contacted to request a reasonable accommodation to attend the meeting.

Registration Information: Registration is required for in-person attendance. In-person attendance is limited to the first 300 people who register. Members of the public may register on the Religious Liberty Commission website, <https://www.justice.gov/religious-liberty-commission>. Members of the public who attend in-person will be required to present identification and go through security screening.

We ask guests from the media to register through the Office of Public Affairs by September 5, 2025 at 5 p.m. Media should be prepared to go through security checks and present government-issued photo I.D. and valid media credentials.

SUPPLEMENTARY INFORMATION: The Religious Liberty Commission is a federal advisory committee established by the President through Executive Order 14291. The Commission is composed of a chair, a vice chair, 11 members appointed by the President, including representatives from the private sector, employers, educational institutions, religious communities and States, and three ex-officio members. The Commission advises the Domestic Policy Council and the White House Faith Office on religious liberty policies of the United States, and will produce a comprehensive report to the President on the foundations of religious liberty in America, the impact of religious liberty on American society, current threats to domestic religious liberty, strategies to

preserve and enhance religious liberty protections for future generations, and programs to increase awareness of and celebrate America's peaceful religious pluralism.

Agenda: During its second meeting on September 8, 2025, the Commission will discuss religious liberty issues in public education from the perspectives of parents and students. The hearing will include panels with testimonies from parents as well as elementary, secondary, undergraduate, and graduate students. The hearing will also include testimonies from individuals with expertise in the areas of religious liberty and public education. The hearing's objective will be to understand the historic landscape of religious liberty in the public education setting, recognize present threats to religious liberty in public education, and identify opportunities to secure religious liberty in this context for the future.

Public Comment: Written comments may be sent by email to RLC@usdoj.gov or by mail to U.S. Department of Justice, Office of the Associate Attorney General, ATTN: Religious Liberty Commission, 950 Pennsylvania Avenue NW, Room 5706, Washington, DC 20530. The deadline for comments is September 1, 2025.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*).

Dated: July 28, 2025.

Mary Margaret Bush,

Designated Federal Officer, Religious Liberty Commission.

[FR Doc. 2025–14436 Filed 7–29–25; 8:45 am]

BILLING CODE 4410–21–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Benefit Rights and Experience Report

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employment and Training Administration (ETA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before August 29, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Michael Howell by telephone at 202–693–6782, or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: The data in the ETA 218, Benefit Rights and Experience Report, includes numbers of individuals who were and were not monetarily eligible, those eligible for the maximum benefits, those eligible based on classification by potential duration categories, and those exhausting their full entitlement as classified by actual duration categories. This data is collected as part of the initial claim process. It is transmitted electronically to the National Office on a quarterly basis. This data is used by the National Office in solvency studies, cost estimating and modeling, and to assess State benefit formulas. If this data were not available, cost estimating and modeling would be less accurate. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 11, 2025 (90 FR 11752).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency’s estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–ETA.

Title of Collection: Benefit Rights and Experience Report.

OMB Control Number: 1205–0177.

Affected Public: State, Local and Tribal Government.

Total Estimated Number of Respondents: 55.

Total Estimated Number of Responses: 216.

Total Estimated Annual Time Burden: 108 hours.

Total Estimated Annual Other Costs Burden: \$0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Michael Howell,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2025–14388 Filed 7–29–25; 8:45 am]

BILLING CODE 4510–FN–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–259, 50–260, and 50–296; NRC–2024–0030]

Tennessee Valley Authority; Browns Ferry Nuclear Plant, Units 1, 2, and 3; Exemption

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption from the regulation that would otherwise require the application for subsequent renewal of Facility Operating License Nos. DPR–33, DPR–52, and DPR–68 for Browns Ferry Nuclear Plant (BFN), Units 1, 2, and 3, respectively, to be referred to the Advisory Committee on Reactor Safeguards (ACRS) for a review and report, with any report being made part of the record of the application and made available to the public, except to the extent that security classification prevents disclosure. The NRC finds that the required criteria are met due to the special circumstance presented by Executive Order (E.O.) 14300, “Ordering the Reform of the Nuclear Regulatory Commission,” section 4(b) (stating that “[r]eview by ACRS of permitting and licensing issues shall focus on issues that are truly novel or noteworthy”).

DATES: The exemption was issued on July 25, 2025.

ADDRESSES: Please refer to Docket ID NRC–2024–0030 when contacting the NRC staff about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2024–0030. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301–415–1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov.

- *NRC’s PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jessica Hammock, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0740; email: Jessica.Hammock@nrc.gov.

SUPPLEMENTARY INFORMATION: The text of the exemption is attached.

Dated: July 28, 2025.

For the Nuclear Regulatory Commission.

Jessica Hammock,

Project Manager, Division of New and Renewed Licenses, Office of Nuclear Reactor Regulation.

Attachment—Exemption

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–259, 50–260, and 50–296; NRC–2024–0030]

Tennessee Valley Authority; Browns Ferry Nuclear Plant, Units 1, 2, and 3; Exemption

I. Background

The Tennessee Valley Authority (TVA) is the holder of Facility Operating License Nos. DPR–33, DPR–52, and DPR–68 for Browns

Ferry Nuclear Plant (BFN), Units 1, 2, and 3, respectively. The licenses provide, among other things, that the licensee is subject to all rules, regulations, and orders of the Commission now or hereafter in effect. The U.S. Nuclear Regulatory Commission (NRC) issued the initial operating licenses for BFN, Units 1, 2, and 3 on December 20, 1973, June 28, 1974, and July 2, 1976, respectively. BFN Units 1, 2, and 3 are General Electric boiling-water reactors designated BWR/4 with Mark I containments and each have a licensed thermal power of 3,952 megawatts thermal (MWt). BFN Units 1, 2, and 3 are located in Athens, Alabama along the Tennessee River.

On January 19, 2024, TVA submitted to the NRC an application for subsequent renewal of Facility Operating License Nos. DPR–33, DPR–52, and DPR–68 for BFN, pursuant to title 10 of the *Code of Federal Regulations* (10 CFR) Part 54, “Requirements for Renewal of Operating Licenses for Nuclear Power Plants” requesting renewal for a period of 20 years beyond the current facility operating license expirations of December 20, 2033, June 28, 2034, and July 2, 2036, for BFN Units 1, 2, and 3, respectively. A final decision on the application is expected on October 15, 2025.

Under 10 CFR 54.25, “[e]ach renewal application will be referred to the Advisory Committee on Reactor Safeguards for a review and report. Any report will be made part of the record of the application and made available to the public, except to the extent that security classification prevents disclosure.” The December 31, 1991 rulemaking that promulgated 10 CFR 54.25 (Nuclear Power Plant License Renewal, (56 FR 64943, 64966)) noted that review by the ACRS was desirable but such review was not required by statute.

On May 23, 2025, the President issued Executive Order (E.O.) 14300 (90 FR 22587), “Ordering the Reform of the Nuclear Regulatory Commission,” and section 4(b) of E.O. 14300 states that “[r]eview by ACRS of permitting and licensing issues shall focus on issues that are truly novel or noteworthy.”

On July 18, 2025, the NRC staff issued a Safety Evaluation (SE) (ML25195A021) documenting the NRC staff’s review of TVA’s subsequent license renewal application for BFN. Section 5 of the SE described the plan to meet 10 CFR 54.25 by referring the application to the ACRS, and the plan for the NRC staff and the applicant to attend a meeting of the full committee of the ACRS to discuss the renewal application. Because the NRC staff identified no issues in this license renewal application review that are “truly novel or noteworthy,” and the NRC is now granting an exemption to the requirement in 10 CFR 54.25 to send the application to the ACRS for review, the planned actions in Section 5 of the SE will not occur.

II. Action

In light of E.O. 14300, the status of the review of the subsequent license renewal application for BFN, Units 1, 2 and 3, and the fact that the NRC staff found no “truly novel or noteworthy” issues in the application that would benefit from an ACRS review, the NRC staff determined that a staff-initiated exemption to 10 CFR 54.25 was warranted

and should be granted. Pursuant to 10 CFR 54.15, “Specific exemptions,” exemptions from the requirements of 10 CFR part 54 may be granted by the Commission in accordance with 10 CFR 50.12. Per 10 CFR 50.12(a), “[t]he Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of the regulations of this part,” when certain conditions are met. Further, per 10 CFR 50.12(a)(2), the Commission will not consider granting an exemption unless special circumstances are present. Under 10 CFR 50.12(b)(vi), special circumstances are present whenever there is present any other material circumstance not considered when the regulation was adopted for which it would be in the public interest to grant an exemption, but if such condition is relied on exclusively for satisfying paragraph (a)(2), then the exemption may not be granted until the Executive Director for Operations (EDO) has consulted with the Commission. The NRC staff has determined that those criteria are met and an exemption from 10 CFR 54.25 may be granted for the reasons explained below.

III. Discussion

As described in 10 CFR 1.13, the ACRS was established by the Atomic Energy Act of 1954 (AEA), as amended. Among other things, the ACRS reviews and reports on safety studies and applications for construction permits as well as facility operating licenses. The ACRS also reviews any generic issues or other matters referred to it by the Commission for advice.

In addition, 10 CFR 54.25, as originally promulgated in 1991, requires that “[e]ach renewal application will be referred to the Advisory Committee on Reactor Safeguards for a review and report. Any report will be made part of the record of the application and made available to the public, except to the extent that security classification prevents disclosure.” The December 31, 1991 rulemaking notice explained (56 FR 64966) the background of the requirement thusly:

Section 182.b of the AEA states:

The ACRS shall review each application under section 103 or section 104b. for a construction permit or an operating license for a facility, any application under section 104c. for a construction permit or an operating license for a testing facility, any application under section 104a. or c. specifically referred to it by the Commission, and any application for an amendment to a construction permit or an amendment to an operating license under section 103 or 104a., b., or c. specifically referred to it by the Commission * * *

Section 182.b does not explicitly refer to applications for renewal of an operating license as requiring ACRS review. However, The Commission believes that review by the ACRS is desirable. Accordingly, § 54.25 of the final rule requires ACRS review of a license renewal application.

The Commission has not changed 10 CFR 54.25 since its initial issuance in 1991. Further, no subsequent amendments of the AEA have set forth a requirement for the ACRS to review an application for a renewed license.

10 CFR 54.15, “Specific exemptions,” states that “[e]xemptions from the requirements of this part may be granted by the Commission in accordance with 10 CFR 50.12.” Pursuant to 10 CFR 50.12(a)(1), “Specific exemptions,” the Commission may, “upon application by any interested person or upon its own initiative, grant exemptions from the requirements of the regulations of this part, which are authorized by law, will not present an undue risk to the public health and safety, and are consistent with the common defense and security.”

Exemptions Are Authorized by Law

For an exemption to be authorized by law the item to be exempted cannot be required by statute. The requirement in 10 CFR 54.25 is not required by the AEA, nor required by any other law. As noted by the Commission in 1991 (56 FR 64966), the AEA does not explicitly refer to applications for renewal of an operating license as requiring ACRS review. This remains true today. Accordingly, the NRC finds that the exemption is authorized by law.

Exemption Will Not Present an Undue Risk to the Public Health and Safety

The standards and criteria that must be met before the Commission issues a renewed or subsequent renewed license are not affected by an exemption to 10 CFR 54.25. After an exemption to 54.25, the regulation at 10 CFR 54.29 will continue to set forth the safety criteria that must be met before a renewed or subsequent renewed license may be issued by the Commission. The NRC staff, which has a robust process for reviewing applications for renewed licenses, has completed its detailed review of how the BFN, Units 1, 2 and 3 subsequent license renewal application addressed the standards of 10 CFR 54.29 (and other relevant regulations). The result of the safety review is documented in a safety evaluation report. The already-completed reviews by the NRC staff confirmed that the application did not contain anything “truly novel or noteworthy,” thereby assuring that an exemption from 10 CFR 54.25’s requirement to refer the application to the ACRS will not present an undue risk to public health and safety.

Exemption Is Consistent With the Common Defense and Security

The NRC staff has determined that the exemption from an ACRS review of the subsequent license renewal application does not impact common defense and security in large part because the common defense and security are not within the scope of subsequent license renewal review that is concerned with aging effects. When promulgating revisions to the license renewal rules (60 FR 22461, 22463–64) in 1995, the Commission re-affirmed its philosophy that the existing regulatory process is adequate to ensure that the licensing bases of all currently operating plants provides and maintains an acceptable level of safety so that operation will not be inimical to public health and safety or common defense and security. The exemption from an ACRS review, otherwise required by 10 CFR 54.25, does not alter any common defense or

security matter or regulation. Thus, the exemption is consistent with common defense and security.

Special Circumstances Are Present

Pursuant to 10 CFR 50.12(a)(2), the Commission will not consider granting an exemption unless special circumstances are present. 10 CFR 50.12(a)(2)(vi) states that special circumstances are present when, “[t]here is present any other material circumstance not considered when the regulation was adopted for which it would be in the public interest to grant an exemption. If such condition is relied on exclusively for satisfying paragraph (a)(2) of this section, the exemption may not be granted until the Executive Director for Operations has consulted with the Commission.”

The 2025 E.O. 14300 did not, of course, exist when 10 CFR 54.25 was promulgated in 1991. Thus E.O. 14300 was not, and could not, be considered when 10 CFR 54.25 was issued with a blanket requirement that all renewal applications be referred to ACRS. Section 4(b) of E.O. 14300 states that “[r]eview by ACRS of permitting and licensing issues shall focus on issues that are truly novel or noteworthy.” The NRC staff determined that there were no “truly novel or noteworthy” issues in the BFN, Units 1, 2, and 3 subsequent license renewal application. To make a determination that the subsequent license renewal application for BFN, Units 1, 2, and 3 contained no novel or noteworthy issues, the NRC staff drew upon its demonstrated past experience with a total of 90 approved license renewal applications and 13 approved subsequent license renewal applications. When those past reviews identified a novel or noteworthy issues (e.g., issues related to buried gray cast iron piping), the NRC staff took appropriate action. However, no such issues are present in the subsequent license renewal application for BFN, Units 1, 2, and 3. Accordingly, because the Commission did not specifically refer this application for an ACRS review, there are no “truly novel or noteworthy” issues in the subsequent license renewal application for BFN, Units 1, 2, and 3. Furthermore, since E.O. 14300 was recently issued, the NRC staff finds that special circumstances are present under 10 CFR 50.12(a)(2). Thus, given that following E.O. 14300 is in the public interest, the E.O. represents the special circumstance under 10 CFR 50.12(a)(2)(vi) and an exemption from 10 CFR 54.25 is warranted. In fulfillment of 10 CFR 50.12(a)(2)(vi), the EDO consulted with the Commission.

Environmental Consideration

This exemption removes the requirement in 10 CFR 54.25 to refer the subsequent license renewal application to the ACRS for a review and report, with any report being made part of the record of the application and made available to the public, except to the extent that security classification prevents disclosure. The NRC staff has determined that this exemption does not have an effect on the human environment and, therefore, a categorical exclusion under 10 CFR 51.22 is appropriate.

Under 10 CFR 51.22(c), licensing, regulatory, and administrative actions

eligible for categorical exclusion shall meet the following criterion, namely that “[t]he action belongs to a category of actions which the Commission, by rule or regulation, has declared to be a categorical exclusion, after first finding that the category of actions does not individually or cumulatively have a significant effect on the human environment.” Under 10 CFR 51.22(c)(25), categories of actions that are categorical exclusions include granting of an exemption from the requirements of any regulation of 10 CFR Chapter I, provided that: (i) there is no significant hazards consideration; (ii) there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; (iii) there is no significant increase in individual or cumulative public or occupational radiation exposure; (iv) there is no significant construction impact; (v) there is no significant increase in the potential for or consequences from radiological accidents; and (vi) the requirements from which an exemption is sought involving an item listed in 10 CFR 51.22(c)(25)(vi)(A)–(I); 10 CFR 51.22(c)(25)(vi)(A), (B), and (I) are “recordkeeping requirements,” “reporting requirements,” or “other requirements of an administrative, managerial, or organizational nature,” respectively. As explained below, these criteria are satisfied.

An exemption involves no significant hazards consideration if, as provided in 10 CFR 50.92(c), operation of the facility in accordance with the proposed exemption would not: “(1) [i]nvolve a significant increase in the probability or consequences of an accident previously evaluated; or (2) [c]reate the possibility of a new or different kind of accident from any accident previously evaluated; or (3) [i]nvolve a significant reduction in a margin of safety.” This exemption has no bearing on the operation of BFN and the NRC staff identified no “truly novel or noteworthy” issues for an ACRS review. Referring (or declining to refer) the application to the ACRS does not change any manner in which the facility would operate and, accordingly, the factors above are met. The requirement in 10 CFR 54.25 for the application to be referred to the ACRS for review and report, with any report being made part of the record of the application fits within 10 CFR 51.22(c)(25)(vi)(A), (B), and (I) in that they involve “recordkeeping requirements,” “reporting requirements,” or “other requirements of an administrative, managerial, or organizational nature.” Accordingly, an exemption from 10 CFR 54.25 meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(25). Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the issuance of the exemption.

IV. Conclusions

Accordingly, the Commission has determined that, pursuant to 10 CFR 54.15, “Specific exemptions,” (stating that exemptions from the requirements of 10 CFR part 54 may be granted by the Commission in accordance with 10 CFR 50.12), an exemption from the 10 CFR 54.25

requirement to send the BFN, Units 1, 2, and 3 subsequent license renewal application to the ACRS for review is granted. The standards of 10 CFR 50.12(a) are met in that the exemption from 10 CFR 54.25 is authorized by law, will not present an undue risk to the public health and safety, is consistent with the common defense and security, special circumstances are present, and the EDO has consulted with the Commission. Therefore, the subsequent license renewal application is no longer required to be referred to the ACRS for a review and report. The planned steps to meet 10 CFR 54.25 described in Section 5 of the July 18, 2025 SE (ML25195A021) are no longer needed and will not be taken.

The exemption is effective upon issuance.

Dated at Rockville, Maryland, this 25th day of July 2025.

For the Nuclear Regulatory Commission.

/RA/

Michele Sampson,
Director, Division of New and Renewed
Licenses, Office of Nuclear Reactor
Regulation.

[FR Doc. 2025–14425 Filed 7–29–25; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2025–1587 and K2025–1579; MC2025–1591 and K2025–1583]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission’s consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 4, 2025.

ADDRESSES: Submit comments electronically via the Commission’s Filing Online system at <https://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Introduction
- II. Public Proceeding(s)
- III. Summary Proceeding(s)

I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal

Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (<http://www.prc.gov>). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.¹

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). The Public Representative does not represent any individual person, entity or particular point of view, and, when Commission attorneys are appointed, no attorney-client relationship is established. Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041.

Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. *See* 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

1. *Docket No(s):* MC2025–1587 and K2025–1579; *Filing Title:* USPS Request to Add Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 84 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 25, 2025; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Katalin Clendenin; *Comments Due:* August 4, 2025.

2. *Docket No(s):* MC2025–1591 and K2025–1583; *Filing Title:* USPS Request to Add Priority Mail Contract 912 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing*

Acceptance Date: July 25, 2025; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Kenneth Moeller; *Comments Due:* August 4, 2025.

III. Summary Proceeding(s)

None. *See* Section II for public proceedings.
This Notice will be published in the **Federal Register**.

Jennie L. Jbara,
Primary Certifying Official.
[FR Doc. 2025–14402 Filed 7–29–25; 8:45 am]
BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage Negotiated Service Agreements; Priority Mail Negotiated Service Agreements

AGENCY: Postal Service.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* July 30, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), it filed with the Postal Regulatory Commission the following requests:

Date filed with Postal Regulatory Commission	Negotiated service agreement product category and No.	MC Docket No.	K Docket No.
07/22/25	PME–PM–GA 1393	MC2025–1582	K2025–1575
07/23/25	PM 910	MC2025–1583	K2025–1576
07/23/25	PME–PM–GA 1394	MC2025–1584	K2025–1577
07/23/25	PM 911	MC2025–1586	K2025–1578
07/25/25	PM 912	MC2025–1591	K2025–1583

Documents are available at www.prc.gov.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2025–14385 Filed 7–29–25; 8:45 am]
BILLING CODE 7710–12–P

¹ *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information,

June 27, 2018, Attachment A at 19–22 (Order No. 4679).

**SECURITIES AND EXCHANGE
COMMISSION**

[Investment Company Act Release No. 35694]

**Deregistration Under Section 8(f) of the
Investment Company Act of 1940**

July 25, 2025.

AGENCY: Securities and Exchange Commission (“Commission” or “SEC”).

ACTION: Notice of Applications for Deregistration under Section 8(f) of the Investment Company Act of 1940.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of July 2025. A copy of each application may be obtained via the Commission’s website by searching for the applicable file number listed below, or for an applicant using the Company name search field, on the SEC’s EDGAR system. The SEC’s EDGAR system may be searched at <https://www.sec.gov/edgar/searchedgar/companysearch.html>. You may also call the SEC’s Office of Investor Education and Advocacy at (202) 551–8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by emailing the SEC’s Secretary at Secretaries-Office@sec.gov and serving the relevant applicant with a copy of the request by email, if an email address is listed for the relevant applicant below, or personally or by mail, if a physical address is listed for the relevant applicant below. Hearing requests should be received by the SEC by 5:30 p.m. on August 19, 2025, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer’s interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission’s Secretary at Secretaries-Office@sec.gov.

ADDRESSES: The Commission: Secretaries-Office@sec.gov.

FOR FURTHER INFORMATION CONTACT: Shawn Davis, Assistant Director, at (202) 551–6413 or Chief Counsel’s Office at (202) 551–6821; SEC, Division of Investment Management, Chief Counsel’s Office, 100 F Street NE, Washington, DC 20549–8010.

Centre Funds [File No. 811–22545]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Horizon Funds, and on April 17, 2025, made a final distribution to its shareholders based on net asset value. Expenses of \$585,676 incurred in connection with the reorganization were paid by the applicant’s investment adviser and the acquiring fund’s investment adviser.

Filing Dates: The application was filed on June 5, 2025, and amended on July 21, 2025.

Applicant’s Address: 48 Wall Street, Suite 1100, New York, New York 10005.

**Mandatorily Exchangeable Securities
Trust [File No. 811–09433]**

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Dates: The application was filed on June 28, 2024 and amendments on June 3, 2025 and July 23, 2025.

Applicant’s Address: 200 West Street, New York, New York 10282.

**Neuberger Berman California
Municipal Fund Inc. [File No. 811–
21167]**

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Neuberger Berman Municipal Fund Inc., and on October 20, 2023 made a final distribution to its shareholders based on net asset value. Expenses of \$179,295 incurred in connection with the reorganization were paid by the applicant.

Filing Date: The application was filed on June 27, 2025.

Applicant’s Address: 1290 Avenue of the Americas, New York, New York 10104–0002.

**Neuberger Berman New York
Municipal Fund Inc. [File No. 811–
21169]**

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Neuberger Berman Municipal Fund Inc., and on October 20, 2023 made a final distribution to its shareholders based on net asset value. Expenses of \$177,865 incurred in connection with the

reorganization were paid by the applicant.

Filing Date: The application was filed on June 27, 2025.

Applicant’s Address: 1290 Avenue of the Americas, New York, New York 10104–0002.

**Security Equity Separate Account 27
[File No. 811–08892]**

Summary: Applicant, a unit investment trust, seeks an order declaring that it has ceased to be an investment company. On April 9, 2025, applicant made a liquidating distribution to its shareholders based on net asset value. Expenses of \$500 incurred in connection with the liquidation were paid by the depositor of the applicant.

Filing Date: The application was filed on June 23, 2025.

Applicant’s Address: 200 Park Avenue, New York, New York 10166.

**Stone Ridge Longevity Risk Premium
Fixed Income Trust 80M [File No. 811–
23538]**

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On April 26, 2024, applicant made a liquidating distribution to its shareholders based on net asset value. Expenses of \$500 incurred in connection with the liquidation were paid by the applicant’s investment adviser.

Filing Date: The application was filed on April 29, 2024.

Applicant’s Address: One Vanderbilt Avenue, 65th Floor, New York, New York 10017.

Templeton China World Fund [File No. 811–07876]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Templeton Developing Markets Trust, and on October 25, 2024 made a final distribution to its shareholders based on net asset value. Expenses of \$159,103.61 incurred in connection with the reorganization were paid by the applicant, the applicant’s investment adviser and the acquiring fund.

Filing Dates: The application was filed on June 18, 2025, and amended on July 22, 2025.

Applicant’s Address: 300 South East 2nd Street, Fort Lauderdale, Florida 33301–1923.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025–14361 Filed 7–29–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–103551; File No. SR–IEX–2025–17]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish IEX Options LLC as a facility of Investors Exchange LLC

July 25, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)¹ and Rule 19b–4 thereunder,² notice is hereby given that on July 17, 2025, the Investors Exchange LLC (“IEX” or the “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Act³ and Rule 19b–4 thereunder,⁴ the Exchange is filing with the Commission a proposed rule change to establish IEX Options LLC (“IEX Options” or the “Company”) as a facility of the Exchange, as that term is defined in Section 3(a)(2) of the Act,⁵ that will operate the Exchange’s market for the listing and trading of options issued by the Options Clearing Corporation (“OCC”).⁶ The Exchange

also proposes to adopt the Operating Agreement of IEX Options LLC (“IEX Options LLC Agreement”), in the form attached as Exhibit 5 hereto, prior to the commencement of operations by IEX Options LLC as a Facility of the Exchange that operates a market for the trading of options. Pursuant to the Operating Agreement, the Exchange will be the sole member of IEX Options. IEX Group, Inc. (“IEXG”), in turn, is the sole member of the Exchange and thus the sole indirect owner of IEX Options. The Exchange has designated this proposal as non-controversial and provided the Commission with the notice required by Rule 19b–4(f)(6)(iii) under the Act.⁷

The text of the proposed rule change is available at the Exchange’s website at <https://www.iexexchange.io/resources/regulation/rule-filings>, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

As described in the IEX Options Trading Rules Proposal, the Exchange is proposing to adopt rules to govern the listing and trading of options issued by OCC on IEX Options, which rules will, upon Commission approval, be incorporated into the Exchange’s rulebook. In connection with that

Proposal, the Exchange proposes to establish IEX Options, LLC, a Delaware limited liability company wholly owned by the Exchange, as a Facility of the Exchange as that term is defined in Section 3(a)(2) of the Act.⁸ The proposed IEX Options LLC Agreement, together with the Third Amended and Restated Operating Agreement of Investors’ Exchange LLC, dated as of August 11, 2020 (“Exchange LLC Agreement”),⁹ to the extent it is incorporated by reference into the IEX Options LLC Agreement, are the source of governance and operating authority for IEX Options, and therefore function in a similar manner as articles of incorporation and bylaws function for a corporation. As detailed below, the proposed IEX Options LLC Agreement provisions are based upon, and are generally the same as, the provisions of the Exchange LLC Agreement unless specified otherwise in this rule filing. IEX notes that it is not novel for an affiliated entity registered as a limited liability company under the laws of Delaware to be operated as a facility of a national securities exchange.¹⁰

As an exchange, IEX is required to provide “fair access,” meaning fair and equal access to all qualified broker-dealers seeking to become IEX Members that meet financial responsibility and other applicable requirements, which also enables access to all investors who wish to trade through those broker-dealers.¹¹ As a Facility of the Exchange, IEX Options would be subject to these “fair access” provisions, and any proposed IEX Options Rules applicable to the Facility would also be subject to review for compliance with such provisions. The proposed ownership and governance structure of IEX Options, which mirror requirements that have been applied consistently to all national securities exchanges and is subject to review of the Commission,¹²

⁸ 15 U.S.C. 78c(a)(2).

⁹ The Exchange LLC Agreement is available at: Governance | Resources | IEX Exchange | IEX.

¹⁰ See, e.g., Securities Exchange Act Release No. 88806 (February 17, 2022), 87 FR 10401 (SR–BOX–2021–14) (February 24, 2022) (“BSTX Facility Approval Order”) (approving Boston Security Token Exchange, LLC, a Delaware limited liability company affiliated with BOX Exchange LLC, to operate as a facility of the BOX Exchange LLC).

¹¹ 15 U.S.C. 78f(b)(2).

¹² See, e.g., Securities Exchange Act Release No. 34–78101, pp. 20–21 (June 17, 2016), 81 FR 41142, 41146–47 (June 23, 2016) (File No. 10–222) (“IEX Approval Order”) (approving IEX application); Securities Exchange Act Release No. 102853 (April 11, 2025) (File No. 10–244), 90 FR 16207 (“GIX Exchange Approval Order”); Securities Exchange Act Release No. 101777 (November 27, 2024), 89 FR 97092 (File No. 10–242) (“24X Exchange Approval Order”); Securities Exchange Act Release No. 88808 (May 4, 2020), 85 FR 27451 (May 8, 2020) (File No. 10–237) (“MEMX Exchange Approval Order”);

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ 15 U.S.C. 78s(b)(1).

⁴ 17 CFR 240.19b–4.

⁵ Under the Act, the term “‘facility’ when used with respect to an exchange includes its premises, tangible or intangible property whether on the premises or not, any right to the use of such premises or property or any service thereof for the purpose of effecting or reporting a transaction on an exchange (including, among other things, any system of communication to or from the exchange, by ticker or otherwise, maintained by or with the consent of the exchange), and any right of the exchange to the use of any property or service.” See 15 U.S.C. 78(c)(a)(2).

⁶ See Securities Exchange Act Release No. 102190 (January 14, 2025), 90 FR 7205 (January 21, 2025), SR–IEX–2025–02 (“Initial Filing”); Securities

Exchange Act Release No. 34–102663, 90 FR 12890 (March 13, 2025), Amendment No. 1 (“IEX Options Trading Rules Proposal”), available at <https://www.iexexchange.io/resources/regulation/rule-filings>. Amendment No. 1 superseded and replaced the Initial Filing. On April 21, 2025, the Commission instituted proceedings to determine whether to disapprove the proposed rule change. Securities Exchange Act Release No. 34–102895 (April 21, 2025), 90 FR 17474 (April 25, 2025). On June 13, 2025, the Exchange filed Amendment No. 2, which superseded and replaced Amendment No. 1. On June 17, 2025, the Exchange withdrew Amendment No. 2 and filed Amendment No. 3, which superseded and replaced Amendment No. 2.

⁷ 17 CFR 240.19b–4(f)(6)(iii).

is designed to promote fair access and non-discriminatory standards for trading across investors, broker members, and other market participants. Nothing in this filing would impact the manner in which the Exchange's current market for continuous matching and execution of orders in equities operates.

Structure of the Company¹³

IEX Options would be a wholly-owned subsidiary of the Exchange, and the Exchange Board (as well as each committee thereof) would have the same authority, functions, and responsibilities with respect to IEX Options as the Board (and its committees) have with respect to the Exchange.¹⁴ Section 1(a) of proposed Art. III of the IEX Options LLC Agreement makes clear that the Board would have the authority "to do any and all acts necessary, convenient or incidental to or for the furtherance of" managing the business and affairs of the Company. In addition, the Board would have the authority to appoint, remove and replace the Company's officers, employees or agents, and the authority to delegate any of its powers to any officer, employee or agent, or any committee appointed pursuant to Article V of the Exchange LLC Operating Agreement.¹⁵ As a result, the Board's authority over and ability to manage the business and affairs of IEX Options would be equivalent to, and coextensive with, its authority with regard to managing the business and affairs of the Exchange. Accordingly, the proposed IEX Options LLC Agreement's governance provisions would be generally the same in all material respects as those provided in the Exchange LLC Agreement with the exception of certain conforming changes applicable only to IEX Options, for example, providing that the effective and operational dates in IEX Options LLC Agreement would refer to the effective and operational dates of IEX Options, not the Exchange.¹⁶

BSTX Facility Approval Order, *supra* note 10; Securities Exchange Act Release No. 68341 (December 3, 2012), 77 FR 73089 (December 7, 2012) (File No. 10-207) ("MIAX Exchange Approval Order"); Securities Exchange Act Release No. 53382 (February 27, 2006), 71 FR 11271, 11256 (SR-NYSE-2005-77) ("Order Approving NYSE's Merger with Archipelago Holdings").

¹³ References to "the Company" in the IEX Options LLC Agreement refer to IEX Options.

¹⁴ See proposed Art. III, Section 1(f) of the IEX Options LLC Agreement. The Board and each committee would continue to be selected and operate in accordance with the Exchange LLC Agreement.

¹⁵ See proposed Art. III, Section 1(a) of the IEX Options LLC Agreement.

¹⁶ See *id.*, proposed Art. VIII, Section 1.

As proposed, IEX Options' ownership structure would be substantially similar to that of its direct owner, the Exchange, but for minor variances and corporate formalities designed to maintain the separation of the organizational structure of IEX Options. For example, by virtue of being wholly owned by the Exchange which is in turn wholly owned by IEXG, IEX Options would have the same Commission-approved restrictions on ownership and voting interests as the Exchange and IEXG. These include ownership and voting limits that apply to the direct or indirect ownership and voting control of IEXG, as the Exchange's sole shareholder and IEX Options' sole indirect shareholder.¹⁷ They also include limits on the amount of IEXG stock that can be owned by any single Member.¹⁸ As a Facility of the Exchange, IEX Options would be subject to the provision of the IEX Rulebook with respect to ownership limitations applicable to Options Members.¹⁹

The day-to-day management of IEX Options would be conducted by the officers of IEX Options. In addition, the Chief Regulatory Officer ("CRO") of the Exchange, who reports to the Regulatory Oversight Committee ("ROC") of the Exchange's Board of Directors, would serve as the CRO of IEX Options. IEX Options' regulatory functions (such as disciplinary proceedings, membership matters, proposed rule changes, and other regulatory matters) performed by Exchange staff reporting to the CRO for the Exchange would be handled in the same manner for IEX Options. And with respect to the funding and capitalization of IEX Options, proposed Article IV, Section 4 of IEX Options LLC Agreement would specify that IEX

¹⁷ See Exchange LLC Agreement, *supra*, note 9, Section III.B.1, pp. 16-17. See Third Amended and Restated Certificate of Incorporation of IEX Group, Inc. ("IEXG Cert. of Incorp."), TENTH Section B(1), available at Governance | Resources | IEX Exchange | IEX. No person, either alone or together with related persons, may beneficially own more than 40% of any class of capital stock of IEXG.

¹⁸ See IEXG Cert. of Incorp., *supra* note 17. No Member, either alone or together with related persons, may own more than 20% of any class of capital stock of IEXG.

¹⁹ See IEX Rule 2.210 ("No Affiliation between Exchange and any Member"). Specifically, no person alone or together with related persons may own more than 40% of any class of stock in IEXG, unless the Board and the Commission approve a waiver. In addition, no Member of the Exchange alone or together with related persons may own more than 20% of any class of stock in IEXG unless the Commission approves otherwise. Further, no person, alone or together with related persons, may directly or indirectly vote or cause the voting of more than 20% of the voting power of the IEXG, unless the Board and the Commission approve a waiver. See IEXG Cert. of Incorp., TENTH Section B(2.2), *supra* note 17; IEX Approval Order, Section III.B.1, *supra* note 13.

Options and the Exchange have entered into an expense sharing agreement.

IEX has separately filed a proposed rule change to establish the trading rules for the IEX Options.²⁰ Upon effectiveness of all applicable rule filings filed with the Commission, IEX Options would begin operating as a Facility of the Exchange that IEX Members²¹ can qualify to use for the continuous matching and execution of orders in options. These proposals, as discussed herein, are based on established parameters that the Commission has historically applied to all national securities exchanges to ensure compliance with the requirements of the Act, particularly Section 6(b)(1),²² and are designed to ensure that IEX Options is able to carry out its regulatory obligations to enforce compliance by its members and persons associated with its members with, and to operate in a manner consistent with, the provisions of the Act, the rules and regulations thereunder, and the IEX Options Rules. Furthermore, all IEX rules are subject to review and approval by the Commission to ensure that they do not unfairly discriminate among member firms.²³

The Governance of the Company

The proposed governance rules are designed to help ensure the role of IEX Options, as a Facility of the Exchange, as a neutral platform to facilitate trading for others, as well as the independence of its regulatory function to discharge the oversight responsibilities under the Act. The IEX Options LLC Agreement provides that the Exchange's Board of Directors would oversee the business and affairs of IEX Options based on the applicable requirements for establishing and operating IEX Options as a Facility of the Exchange under Section 6 of the Act, including, that the IEX Options Rules shall be designed to protect investors and the public interest; and the Exchange shall be so organized and have the capacity to carry out the purposes of the Act and to enforce compliance by its members and persons associated with its members.

As proposed and discussed below, IEX Options would be subject to regulatory oversight by the Exchange's

²⁰ See IEX Options Trading Rules Proposal, *supra* note 6.

²¹ See IEX Rule 1.160(s). IEX intends to allow any Member of the Exchange to transact on IEX Options if they meet certain qualifications. See IEX Options Trading Rules Proposal, *supra* note 6, Rule 2.160 and Chapter 18.

²² 15 U.S.C. 78f(b)(1).

²³ 15 U.S.C. 78f(b)(5). See also Exchange LLC Agreement, *supra* note 9, Art. X, Section 1(a); and proposed Art. VII, Section 1(a) of the IEX Options LLC Agreement.

regulatory function. These provisions, including an independent regulatory program, “are designed to minimize the potential that a person or entity can improperly interfere with or restrict the ability of IEX to effectively carry out its regulatory oversight responsibilities under the Act.”²⁴ In addition, the IEX Options’ Rules “provide it with the ability to comply, and with the ability to enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the rules of IEX.”²⁵ Further, the ownership and voting restrictions discussed above applicable to Options Members support these objectives by limiting the ability of one or more Options Members to interfere with or attempt to influence the ability of the Exchange to effectively carry out its regulatory oversight responsibilities under the Act.²⁶

As proposed, IEX Options would be a separate legal entity from the Exchange. In respect of the corporate form, IEX Options would be separately and adequately capitalized, with distinct assets, books and records, and other appropriate corporate formalities as compared to the Exchange. The discussion below describes the variances between the IEX Options and Exchange LLC Agreements, which the Exchange believes reflect minor changes and corporate governance formalities. Throughout the IEX Options LLC Agreement, references to the “LLC Member” would refer to the Exchange, instead of IEXG, as in the Exchange LLC Agreement. Additionally, references to the Board (or Board of Directors) would refer to the Exchange Board, just as they do in the Exchange LLC Agreement because IEX Options would not have its own Board of Directors.²⁷

References to meetings of the LLC Member in the Exchange LLC

Agreement²⁸ would, in the corresponding provisions of the IEX Options LLC Agreement, instead refer to meetings of the Board of Directors of the Exchange, rather than meetings of the Board of Directors of IEXG.²⁹ Article X of the Exchange LLC Agreement (“Exchange Authorities”) would, in the IEX Options LLC Agreement, be renumbered as Article VII and renamed as “Authorities of the Board over the Company as a Facility of the Exchange” to reflect that the IEX Options LLC Agreement describes the Board’s oversight of IEX Options as a Facility of the Exchange. Similarly, references to the Exchange in Article X of the Exchange LLC Agreement would, in the corresponding provisions of the IEX Options LLC Agreement, be changed to refer to the Company or the Company as a Facility of the Exchange, as applicable.³⁰

Most of Articles III (Board of Directors), IV (LLC Member), and V (Committees of the Board) of the Exchange LLC Agreement have not been replicated in the IEX Options LLC Agreement because, as proposed, IEX Options would not have its own separate board of directors and, as previously noted, the Board and each Board committee would have the same functions and responsibilities with respect to IEX Options as the Board and such committees have with respect to the Exchange.³¹ For the same reason, the Exchange proposes to not include in the IEX Options LLC Agreement other similar provisions that pertain specifically to the Board, such as the composition of the Board, terms of Directors, nomination and election of Directors, and vacancies of Directors.³²

²⁸ See Exchange LLC Agreement, *supra* note 9, Art. IV.

²⁹ See *id.*, proposed Art. III, Sections 2 and 3 of the IEX Options LLC Agreement.

³⁰ See *id.*, proposed Art. IV.

³¹ See *id.*, proposed Art. III, Section 1(f). The Exchange does propose to replicate Art. IV, Section 4 (Assignment) from the Exchange LLC Agreement, which provides that the LLC Member (*i.e.*, the Exchange) may not transfer or assign its ownership interest in IEX Options unless such transfer or assignment is approved by the Commission pursuant to Section 19 of the Exchange Act. See *id.*, proposed Art. III, Section 6 and proposed Art. VIII, Section 12.

³² Specifically, the Exchange is not proposing to adopt provisions in the IEX Options LLC Agreement that correspond to Art. III, Sections 2 through 13, and 16 of the Exchange LLC Agreement (Composition of the Board; Terms of Office; Nomination and Election; Chairman of the Board; Vacancies; Removal and Resignation; Place and Mode of [Board] Meetings; Exchange Member Meetings; Voting, Quorum and Action by the Board; Presumption of Assent; Action in Lieu of Meeting; Waiver of Notice; Compensation of Board and Committee Members) because there is no separate board for IEX Options. Pursuant to Art. III, Section 1(a), however, the Board shall have the power to do

However, Exchange LLC Agreement Article III, Sections 1(a)–(e), which pertain to governance, have been replicated in the IEX Options LLC Agreement, with edits to reflect that IEX Options is governed by the Exchange Board. For example, references to the Board have been changed to “LLC Member” to reflect that IEX Options does not have its own board and is fully owned and controlled by the Exchange and uses the Exchange Board.

The proposed IEX Options LLC Agreement would further provide that, in discharging his or her responsibilities as a member of the Board of Directors or as an officer or employee of IEX Options, each such director, officer or employee shall comply with the federal securities laws and the rules and regulations thereunder and shall cooperate with the Commission, the Exchange, and IEX Options pursuant to its regulatory authority.³³ The IEX Options LLC Agreement, where relevant and as set forth in more detail below, further describes the governance and oversight roles the Exchange and its Board would provide for IEX Options.³⁴

Proposed Article VIII, Section 1 of the IEX Options LLC Agreement establishes that IEX Options will not operate as a Facility of the Exchange until this rule filing is effective. In addition, the proposed IEX Options LLC Agreement would authorize the Board to adopt rules and amendments thereto that it “deem[s] necessary or appropriate pertaining to the Company as a Facility” and further provides that any such rules or amendments would become effective upon approval by the Commission or otherwise as provided in the Exchange Act, and the rules or amendments would become operative as of the date of Commission approval or effectiveness unless the Exchange declared a later operative date.³⁵

any and all acts necessary, convenient or incidental to or for the furtherance of managing the business and affairs of the Company. In addition, to the fullest extent permitted by applicable law, the IEX Options LLC Agreement, the Exchange LLC Agreement, and the IEX Options Rules, the Board would have the authority to appoint, remove and replace any officers, employees or agents of the Company, and may delegate any of its powers to a committee appointed pursuant to Art. V of the Exchange LLC Operating Agreement, or to any officer, employee, or agent of the Company.

³³ See proposed Art. III, Section 1(d) of the IEX Options LLC Agreement.

³⁴ See proposed Arts. III (Management), IV (Officers, Agents and Employees), and VII (Authorities of the Board over the Company as a Facility of the Exchange) of the IEX Options LLC Agreement.

³⁵ See proposed Art. VII, Section 1(a) of the IEX Options LLC Agreement.

²⁴ See IEX Approval Order, *supra* note 12, pp. 20–21 (stating that “[t]he Commission believes that IEX’s and IEXG’s proposed governance provisions are consistent with the Act, including Section 6(b)(1), which requires, in part, an exchange to be so organized and have the capacity to carry out the purposes of the Act.”).

²⁵ See IEX Approval Order, *supra* note 12, p. 81.

²⁶ See IEXG Cert. of Incorpor., *supra* note 17.

²⁷ As set forth above, IEX Options, as proposed, would not have its own Board of Directors, but rather will be governed by the Exchange’s Board of Directors. Therefore, the Articles of the Exchange LLC Agreement relating to the constitution, selection, and functions of the Board of Directors are not replicated in the IEX Options LLC Agreement. Instead, the proposed IEX Options LLC Agreement, where relevant, describes the manner in which the Exchange and its Board would provide governance and oversight of IEX Options. See, e.g., proposed Arts. III, IV and VII of the IEX Options LLC Agreement.

Regulatory Oversight

The Exchange believes that by leveraging the existing regulatory structure set forth in the Exchange LLC Agreement and proposed IEX Options LLC Agreement, the Exchange would be able to carry out its regulatory responsibilities for IEX Options in a manner consistent with the Exchange Act. The proposed IEX Options LLC Agreement creates a regulatory structure that is designed to ensure the independence of the Exchange's regulatory oversight over IEX Options as a Facility of the Exchange. Specifically, the IEX Options LLC Agreement would require that, in light of the unique nature of the Company as a Facility of the Exchange, the Board evaluate any proposal that comes before it by taking into account factors such as (i) the potential impact on the integrity of the national securities exchange; and (ii) whether the proposal promotes just and equitable principles of trade with respect to facilitating transactions in securities.³⁶

Article III, Section 1(d) of the IEX Options LLC Agreement would require the Board, in managing the business and affairs of the Company, to consider the applicable requirements for establishing and operating the Company as a Facility of the Exchange under Section 6 of the Exchange Act, including that the IEX Options Rules shall be designed to protect investors and the public interest, and that the Exchange shall be so organized and have the capacity to carry out the purposes of the Exchange Act and to enforce compliance by its "members" as that term is defined in Section 3 of the Exchange Act.

Article V, Section 6(c) of the Exchange LLC Agreement mandates that the Board's ROC, as part of its role in overseeing the adequacy and effectiveness of the Exchange's regulatory and SRO responsibilities, assess the Exchange's regulatory performance, and assist the Board and Board committees in reviewing the regulatory plan and the overall effectiveness of the Exchange's regulatory functions. The Exchange LLC Agreement also requires the Board take all steps reasonably necessary to ensure that the CRO and senior regulatory personnel are able to act independently of the commercial interests of the Exchange.³⁷ In addition, the Exchange

LLC Agreement establishes procedures for maintaining confidentiality of information and records relating to the SRO function, and prohibitions on the use of confidential regulatory information for any commercial or other non-regulatory purposes.³⁸ For example, proposed Article VIII, Section 4 of the IEX Options LLC Agreement, which is substantially similar to Article XI, Section 4, of the Exchange LLC Agreement, specifies that the Exchange shall have "complete and full access" to the books and records of the Company pertaining to the SRO function. These provisions would apply with equal force to the Exchange's regulatory oversight of the Company. The proposed IEX Options LLC Agreement provides that the Board and Board committees will have the same authority, functions, and responsibilities with respect to IEX Options as they do with respect to the Exchange.³⁹

In addition, the Exchange proposes certain differences between the IEX Options LLC and Exchange LLC Agreements to make clear that the Exchange would carry out regulatory functions and oversight of IEX Options as a Facility of the Exchange. For example, proposed Art. III, Section 1(d) of the IEX Options LLC Agreement specifies that, in connection with managing the business and affairs of the Company, the Board shall consider applicable requirements for establishing the Company as a Facility of the Exchange, whereas the corresponding provision in the Exchange LLC Agreement provides that the Board shall consider applicable requirements for registration as a national securities exchange (rather than as a facility). In addition, consistent with the Company operating as a Facility of the Exchange, the Exchange proposes to specify in proposed Article VIII, Section 4 of IEX Options LLC Agreement that the Exchange shall have complete and full access to the books and records of the Company, including those that relate to the Exchange's regulatory oversight of the Company.

As part of the Exchange's regulatory oversight of the Company, the Exchange CRO would also serve as the CRO of the Company as a Facility of the Exchange.⁴⁰ As specified in proposed Article IV, Section 9 of IEX Options LLC Agreement, the Exchange CRO "shall have general supervision of the

regulatory operations of the Company in the same manner as with respect to the Exchange, including responsibility for overseeing the surveillance, examination, and enforcement functions of the Exchange with respect to the Company and for administering any regulatory services agreements with another self-regulatory organization to which the Exchange is a party that pertain to the Company." As the senior executive and manager of the Exchange's regulation staff, the CRO is knowledgeable of the Exchange's rules, IEX Options' proposed rules, and the regulations applicable to them. Accordingly, the CRO is well positioned to help ensure that the Exchange, including the operation of IEX Options as a Facility of the Exchange, continues to be so organized and has the capacity to carry out the purposes of the Act, including to prevent inequitable and unfair practices.

Regulatory Jurisdiction Over Members

As a national securities exchange, IEX's operations are subject to ongoing SEC oversight, including reviews to determine that the Exchange is fulfilling its self-regulatory obligations. This comprehensive SEC oversight will extend to IEX Options as a Facility of the Exchange. The CRO would have responsibility for overseeing the surveillance, examination, and enforcement functions of the Exchange with respect to the Company.⁴¹ To assist it in complying with its regulatory obligations, the Exchange intends to update its existing regulatory services agreement ("RSA") with the Financial Industry Regulatory Authority ("FINRA")⁴² to engage FINRA to conduct IEX Options-related market surveillance, examination, investigation, and enforcement functions on IEX's behalf. The amended RSA would enable the Exchange to leverage FINRA's substantial regulatory resources and experience in fulfilling its regulatory obligations with respect to IEX Options. The Exchange would oversee FINRA's activities and would remain directly responsible for the discharge of its SRO duties with respect to IEX Options, as is the case today with respect to the Exchange.⁴³

In addition, prior to IEX Options' commencement of operations, the

³⁶ See proposed Art. III, Section 1(e) of the IEX Options LLC Agreement. The Exchange LLC Agreement has a similar provision regarding the Board's consideration of any proposal concerning the Exchange. See Exchange LLC Agreement, *supra* note 9, Art. III, Section 1(e).

³⁷ See Exchange LLC Agreement, *supra* note 9, Art. V, Section 6(c).

³⁸ See *id.*, Art. XI, Section 4.

³⁹ See proposed Art. III, Section 1(f) of the IEX Options LLC Agreement.

⁴⁰ See proposed Art. IV, Section 9 of the IEX Options LLC Agreement. IEX expects some, but potentially not all, of the officers of IEX Options would also be officers of the Exchange.

⁴¹ See proposed Art. IV, Section 9 of the IEX Options LLC Agreement.

⁴² See IEX Approval Order, *supra* note 12, Section III.B.4(b), pp. 29–30.

⁴³ See proposed Art. IV, Section 9 of the IEX Options LLC Agreement, which provides that the CRO would be responsible "for administering any regulatory services agreements . . . to which the Exchange is a party that pertain to the Company."

Exchange will join the existing options industry agreements pursuant to Section 17(d) of the Act.⁴⁴ Section 17(d) of the Exchange Act and the related Exchange Act rules permit SROs to allocate certain regulatory responsibilities to avoid duplicative oversight and regulation. Exchange Act Rule 17d-2⁴⁵ permits SROs to allocate among each other the responsibility to receive regulatory reports from, and examine and enforce compliance with the Exchange Act, the rules and regulations thereunder, and SRO rules by, firms that are members of more than one SRO. These agreements include the Options Sales Practices Agreement and the Options-Related Market Surveillance Agreement.⁴⁶ The Exchange and FINRA are also party to a bilateral Rule 17d-2 agreement that requires minor modifications due to the proposed launch of IEX Options. The Exchange intends to modify and seek Commission approval of the modified bilateral Rule 17d-2 agreement prior to commencing operations for IEX Options.

Regulatory Funds

“Regulatory Funds” would remain a defined term in proposed Article I of IEX Options LLC Agreement, but the definition would be modified to reflect that IEX Options would not have its own regulatory operations. Specifically, proposed Article II(t) defines “Regulatory Funds” as “fees, fines, or penalties derived from the regulatory operations of the Exchange in enforcing IEX Options Rules related to trading on or through the Company as a Facility of the Exchange. ‘Regulatory Funds’ shall not be construed to include revenues derived from listing fees, market data revenues, transaction revenues, or any other aspect of the commercial operations of the Exchange or the Company, even if a portion of such revenues are used to pay costs associated with the regulatory operations of the Company.”

Similarly, proposed Article VII, Section 4 of IEX Options LLC Agreement (“Fees, Dues, Assessments, and Other Charges”) is almost identical to Article X, Section 4 of the Exchange LLC Agreement, with the exception that the IEX Options LLC Agreement would provide that any regulatory funds resulting from enforcement of IEX Options Rules would be applied to fund the Exchange’s regulatory operations, including those pertaining to the Company as a Facility of the Exchange.

By contrast, the Exchange LLC Agreement does not permit the Exchange to distribute regulatory funds to its member, IEXG, because IEXG performs no regulatory services for the Exchange or any of its facilities. Because the Exchange would perform regulatory services, including enforcement of the options rules, on behalf of the Company as a Facility of the Exchange, the Exchange believes that it is appropriate that any regulatory funds resulting therefrom be applied to fund the Exchange’s regulatory operations.

2. Statutory Basis

The Exchange believes that this proposed rule change is consistent with Section 6(b) of the Act,⁴⁷ in general, and furthers the objectives of Section 6(b)(1),⁴⁸ in particular, in that it enables the Exchange, and the Company as a Facility of the Exchange, to be so organized so as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its Members—whether they trade on the Exchange, IEX Options, or both—with the provisions of the Act, the rules and regulations thereunder, and the rules of the Exchange.⁴⁹ The Exchange also believes that this filing furthers the objectives of Section 6(b)(5) of the Act⁵⁰ in that it is designed to facilitate transactions in securities, to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, to protect investors and the public interest.

Specifically, the Exchange believes that the existing ownership and governance provisions, which have historically been applied to all national securities exchanges, and are designed to mitigate inherent conflicts of interest, support the Commission’s ability to find that the Company, as a Facility of the

Exchange, is so organized as to be able to meet the requirements of the Act.⁵¹ The Exchange believes the provisions discussed above in the Purpose section, limiting an Options Member to a maximum of 20% economic ownership and 20% voting ownership of IEXG, and by extension, the Exchange or IEX Options, unless the Commission approves otherwise, are consistent with the requirements of the Act.⁵² Further, consistent with ownership provisions that have been consistently approved by the Commission for IEX and other exchanges, provisions that limit any person, either alone or together with its related persons, from beneficially owning shares constituting more than 40% of any class of capital stock of the exchange or exchange owner, unless the Commission approves otherwise, are consistent with the Exchange Act, particularly Section 6(b)(1) thereof, which requires, in part, that an exchange be so organized and have the capacity to carry out the purposes of the Act. These ownership and voting limits provisions, which largely mirror those of other national securities exchanges, are designed to provide the Exchange and IEX Options as its Facility the ability to fairly and objectively carry out their regulatory responsibilities under the Act, particularly with Section 6(b)(1) of the Exchange Act,⁵³ by minimizing the potential that a person or entity could improperly interfere with the Exchange’s ability to carry out its regulatory oversight responsibilities under the Act.⁵⁴ Accordingly, the Exchange does not believe that this proposed structure, where an affiliated entity operates as a facility of a national securities exchange, raises any new or novel issues not already considered by the Commission.

The Exchange is the entity that will have and will exercise regulatory oversight of IEX Options. As discussed above, the Exchange believes that the requirement for Commission approval for certain changes in ownership will help to ensure the independence of the Exchange’s regulatory oversight of IEX Options and facilitate the ability of the

⁵¹ See *supra* note 12.

⁵² 15 U.S.C. 78f(b)(1); see IEX Approval Order, *supra* note 12, Section III.B.1; *c.f.* Securities Exchange Act Release No. 59281 (January 22, 2009), 74 FR 5014, 5018–19 (January 28, 2009) (SR–NYSE–2008–120) (“NYBX Order”) (Commission-approved exception to exchange membership ownership restrictions to allow a member firm to hold a 50% interest in a new facility of NYSE provided a number of restrictions, procedures, and internal controls were adhered to for the preservation of regulatory independence).

⁵³ 15 U.S.C. 78f(b)(1).

⁵⁴ See, e.g., GIX Approval Order, *supra* note 12, pp. 16–18.

⁴⁷ 15 U.S.C. 78f(b).

⁴⁸ 15 U.S.C. 78f(b)(1).

⁴⁹ See, e.g., GIX Exchange Approval Order, *supra* note 12, 90 FR at 16208 (“[T]he Commission shall by order grant an application for registration as a national securities exchange if the Commission finds, among other things, that the proposed exchange is so organized and has the capacity to carry out the purposes of the Act and can comply, and can enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the rules of the exchange.”).

⁵⁰ 15 U.S.C. 78f(b)(5).

⁴⁴ 15 U.S.C. 78q(d).

⁴⁵ 17 CFR 240.17d-2.

⁴⁶ See IEX Options Trading Rules Proposal, *supra* note 6, 90 FR at 12906.

Exchange to carry out its regulatory responsibilities and operate in a manner consistent with the Act. The Exchange further believes these limits, which already apply to IEXG and the Exchange, continue to be appropriate in connection with IEX Options as a Facility of the Exchange, and are consistent with the requirements of the Act and Section 6(b)(1) thereof, which requires, in part, that an exchange be so organized and have the capacity to carry out the purposes of the Act.⁵⁵

Subject to the Exchange's independent regulatory oversight, the proposed Facility's directors, officers, and employees would have full independent authority to manage the development, operations, business and affairs of IEX Options.⁵⁶ As discussed in the Purpose section, the directors, officers, and employees of the Exchange and IEX Options must give due regard to the preservation of the independence of the self-regulatory functions of the Exchange and IEX Options, respectively, and must not take any action that would interfere with the effectuation of such regulatory functions (including disciplinary matters) or interfere with their ability to carry out their regulatory responsibilities under the Act.⁵⁷ In addition, the Exchange has an independent CRO who would oversee IEX Options' regulatory operations and who reports to the ROC. The Exchange believes these provisions, which are designed to maintain the independence of IEX Options' regulatory function, are appropriate and consistent with the requirements of the Act, particularly with Section 6(b)(1), which requires, in part, an exchange to be so organized and have the capacity to carry out the purposes of the Act.⁵⁸

Finally, the Exchange believes that the few variances between the IEX Options LLC Agreement and the Exchange LLC Agreement described in the Purpose section are consistent with the Exchange Act because they reflect minor changes and corporate formalities designed to maintain the separation of the organizational structure of IEX Options. The Exchange believes that IEX Options' organizational structure will allow it to promote just and equitable principles of trade while retaining the regulatory independence required to prevent fraudulent and manipulative acts and practices, all of which should perfect the mechanism of a free and

open market and a national market system that protects investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Given the substantial growth of investors trading in standardized options,⁵⁹ the Exchange believes that providing a facility of a national securities exchange that can list and trade options issued by OCC, subject to transparent rules reviewed or approved by the Commission, allows for a well-regulated, competitive market for the trading of options. Moreover, as noted above, the provisions proposed herein are of the type that the Commission has required consistently of every national securities exchange that trades options.⁶⁰ Consequently, the Exchange does not believe that these provisions raise any new or novel issues not already considered by the Commission.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the proposal is designed to enhance IEX's competitiveness with other markets by creating a trading platform subject to SRO oversight on which options issued by OCC can be listed and traded. Moreover, other exchanges are free to adopt similar provisions subject to the Commission's rule filing process.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

⁵⁹ See, e.g., Staff Report on Equity and Options Market Structure Conditions in Early 2021, (Oct. 14, 2021) at 16 n. 52 (discussing the substantial increase of investors trading in options and noting that "[b]y the end of the first quarter of 2020, standardized listed options trading had grown to over 30 million contracts a day on average, more than 50% higher than the 19.6 million contracts per day traded in December 2019"), available at <https://www.sec.gov/files/staff-report-equity-options-market-structure-conditions-early-2021.pdf>.

⁶⁰ See, e.g., BSTX Exchange Approval Order, *supra* note 10; MIA Exchange Approval Order, *supra* note 12.

A. significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act⁶¹ and Rule 19b-4(f)(6)⁶² thereunder.⁶³ At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-IEX-2025-17 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-IEX-2025-17. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange.

⁶¹ 15 U.S.C. 78s(b)(3)(A).

⁶² 17 CFR 240.19b-4(f)(6).

⁶³ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

⁵⁵ 15 U.S.C. 78f(b)(1).

⁵⁶ See proposed Art. IV, Sections 1, 5-13 of the IEX Options LLC Agreement.

⁵⁷ See, e.g., IEX Approval Order, *supra* note 12, pp. 21-25.

⁵⁸ 15 U.S.C. 78f(b)(1).

Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–IEX–2025–17 and should be submitted on or before August 20, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶⁴

Sherry R. Haywood,
Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–103549; File No. SR–NYSE–2025–20]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change Amending Section 302.00 of the NYSE Listed Company Manual

July 25, 2025.

On June 6, 2025, New York Stock Exchange LLC (the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),¹ and Rule 19b–4 thereunder,² a proposed rule change to exempt closed-end management investment companies registered under the Investment Company Act of 1940 from the requirement to hold annual shareholder meetings. The proposed rule change was published for comment in the **Federal Register** on June 17, 2025.³

Section 19(b)(2) of the Act⁴ provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reason for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute

proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is August 1, 2025. The Commission is extending this 45-day time period.

The Commission finds it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change, the issues raised therein, and the comments received. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,⁵ designates September 15, 2025, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSE–2025–20).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025–14359 Filed 7–29–25; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–103547; File No. SR–PEARL–2025–36]

Self-Regulatory Organizations: MIAx PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 519C, Mass Cancellation of Trading Interest, To Adopt a New Selective Liquidity Auto Purge (“SLAP”)

July 25, 2025.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder,² notice is hereby given that on July 15, 2025, MIAx PEARL, LLC (“MIAx Pearl” or the “Exchange”) filed with the Securities and Exchange Commission (“Commission”) a proposed rule change as described in Item II below, which Item has been prepared by MIAx Pearl. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

⁵ 15 U.S.C. 78s(b)(2).

⁶ 17 CFR 200.30–3(a)(31).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange Rule 519C, Mass Cancellation of Trading Interest, to adopt new mass order cancellation functionality that will be available via the MEO Interface.³

The text of the proposed rule change is available on the Exchange’s website at <https://www.miaxglobal.com/markets/us-equities/pearl-equities/rule-filings> and at MIAx Pearl’s principal office.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, MIAx Pearl included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. MIAx Pearl has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 519C, Mass Cancellation of Trading Interest, to adopt a new Selective Liquidity Auto Purge (“SLAP”) feature, which provides more granular mass cancellation functionality. Currently, Members ⁴ may submit a mass cancellation request via the MEO interface using the Liquidity Mass Cancel Request message. The Liquidity Mass Cancel Request message contains a Mass Cancel Scope field which allows the Member to determine the behavior following the mass cancellation of orders. For example, populating the Mass Cancel Scope field with an “A” will instruct the System ⁵ to cancel all open binary orders and block all subsequent binary orders

³ The term “MEO Interface” means a binary order interface used for submitting certain order types (as set forth in Rule 516) to the MIAx Pearl System. See Exchange Rule 100.

⁴ The term “Member” means an individual or organization that is registered with the Exchange pursuant to Chapter II of the MIAx PEARL Rules for purposes of trading on the Exchange as an “Electronic Exchange Member” or “Market Maker.” Members are deemed “members” under the Exchange Act. See Exchange Rule 100.

⁵ The term “System” means the automated trading system used by the Exchange for the trading of securities. See Exchange Rule 100.

⁶⁴ 17 CFR 200.30–3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 103244 (June 12, 2025), 90 FR 25659. Comments on the proposed rule change are available at: <https://www.sec.gov/comments/sr-nyse-2025-20/srnyse202520.htm>.

⁴ 15 U.S.C. 78s(b)(2).

(including immediate orders); populating the field with a “D” will instruct the System to cancel all open binary orders and block all subsequent binary orders (excluding immediate orders).⁶

The Exchange now proposes to adopt new paragraph (e) to Exchange Rule 519C, to adopt the SLAP feature. The SLAP feature, the use of which is optional, will provide more granular mass cancellation functionality by allowing users to mass cancel specific groups of orders as determined by the Member on an order by order basis. Orders submitted via the MEO interface may optionally contain one or more SLAP codes from 1 through 8.⁷ Each individual order can be part of eight (8) unique SLAP groups identified by their SLAP code (numbered 1 through 8).⁸

To remove orders with a SLAP code, a SLAP request is sent to the System containing the MPID,⁹ underlying, and SLAP code of the orders to be removed from the System. Following completion of processing the SLAP request all new inbound orders with matching criteria submitted to the System will be blocked. The System will provide a notification to the requestor upon receipt of the SLAP request and another upon completion of the SLAP request. A SLAP reset request must be submitted to the System to resume entry of orders for the same MPID, underlying, and SLAP code. Orders received for the same MPID, underlying, and SLAP code prior to a SLAP reset will be rejected. Intermarket Sweep Orders¹⁰ and orders

with a time in force of immediate-or-cancel (“IOC”)¹¹ will not be eligible to receive a SLAP code.

To facilitate SLAP processing the Exchange has amended and enhanced existing MEO messages. Specifically, Members will use the Standard Order—New message in MEO to send an order to the System. A new field, “SLAP Codes,” has been added to the message, which will allow the Member to identify the order with a SLAP Code of 1 through 8, as desired. A Member will use the Liquidity Mass Cancel Request message in MEO to remove orders with the designated SLAP Code. The Mass Cancel Scope field of the Liquidity Mass Cancel Request message has been enhanced to include new value “S” to indicate that the Liquidity Mass Cancel Request is a Selective Liquidity Auto Purge (“SLAP request”). The Liquidity Mass Cancel Request message also includes the corresponding field, “SLAP Codes,” for Members to identify the SLAP Codes of the orders that are being cancelled.

The System will notify the Member that the SLAP request has been received by providing the Member with a new SLAP Protection Trigger Notification message. The System will then notify the Member that the SLAP request has been processed using the existing Liquidity Mass Cancel Response message. Additionally, the Liquidity Mass Cancel Response message has been modified to include new responses specifically related to SLAP requests to provide Members with more specific information regarding the status of their SLAP request should it not be successfully executed.

The Member will submit the existing Liquidity Protection Reset Request message to re-enable the System to process orders with a SLAP code. The Liquidity Protection Reset Request message has been enhanced to include a “Scope” field where a value of “S” indicates the reset is for SLAP. Additionally, the Liquidity Protect Reset Request message includes a SLAP Codes field to allow a reset for specific SLAP code groups.

The SLAP code is an additional, optional, field in the Standard Order—New message and as such Members may (i) include a SLAP code on an order; (ii) modify an order that does not contain a SLAP code to assign a SLAP code; (iii) modify an order that has a SLAP code to change it to a different SLAP code; or

(iv) modify an order that contains a SLAP code to remove it.

To implement the SLAP feature the Exchange proposes to adopt new paragraph (e) to Rule 519C, Mass Cancellation of Trading Interest, to provide that a Member may use the Selective Liquidity Auto Purge (“SLAP”) feature for orders delivered via the MEO Interface. Orders submitted to the System may optionally contain one or more SLAP codes numbered 1 through 8. When a Member submits a SLAP request, orders with the corresponding MPID, underlying, and SLAP code will be removed from the System and new inbound orders with matching criteria will be blocked. The System will provide notification messages to the Member regarding the status of the SLAP request. A Member must submit a SLAP reset request to the System to enable new incoming orders for the same MPID, underlying, and SLAP code. Intermarket Sweep Orders and orders with a time in force of IOC are not eligible to receive a SLAP code.

The Exchange has analyzed its capacity and represents that it has the necessary systems capacity to handle the potential additional message traffic that may arise from the cancellation of open orders as a result of a SLAP request being received.

Implementation

The Exchange will announce the implementation date of the proposed rule change by Regulatory Circular to be published no later than 60 days following the operative date of the proposed rule. The implementation date will be no later than 60 days following the issuance of the Regulatory Circular.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.¹² Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹³ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market

⁶ See Section 4.1.3, Liquidity Mass Cancel Request, in the MIA Express Orders, Binary Orders for Trading Options, MEO Interface Specification, version 2.1a, 4/8/2024 available online at https://www.miaxglobal.com/miax_express_orders_meo.pdf.

⁷ Orders may contain multiple SLAP codes.

⁸ The Exchange notes that there is no limit on the number of orders that may be included in a SLAP group.

⁹ The term “MPID” means unique market participant identifier. See Exchange Rule 100.

¹⁰ An Intermarket Sweep Order or “ISO”, as defined in Rule 1400(i), is a limit order that is designated by a Member as an ISO in the manner prescribed by the Exchange, and is executed within the System by Members without respect to Protected Quotations of other Eligible Exchanges as defined in Rule 1400(q) and (g). ISOs are immediately executable within the System and shall not be eligible for routing. ISOs that are not designated as immediate or cancel will be cancelled by the System if not executed upon receipt. Simultaneously with the routing of an ISO to the System, one or more additional limit orders, as necessary, are routed by the entering Member to execute against the full displayed size of any Protected Bid or Protected Offer, as defined in Rule 1400(p), in the case of a limit order to sell or buy with a price that is superior to the limit price of the limit order identified as an ISO. These additional routed orders must be identified as ISOs. An ISO is not valid during the Opening Process described in Rule 503. See Exchange Rule 516(f).

¹¹ An immediate-or-cancel order is an order that is to be executed in whole or in part upon receipt. Any portion not so executed is cancelled. An immediate-or-cancel order is not valid during the Opening Process described in Rule 503. See Exchange Rule 516(e).

¹² 15 U.S.C. 78f(b).

¹³ 15 U.S.C. 78f(b)(5).

system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁴ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed changes remove impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by providing Members with a customizable mass cancellation mechanism.

The ability of a Member to engage the SLAP feature is a valuable tool in assisting Members in risk management. Without adequate risk management tools Members could reduce the size of their quotations and orders which could undermine the quality of the markets available to customers and other market participants. The proposed rule change removes impediments to and is designed to perfect the mechanisms of a free and open market by giving Members the ability to further refine their risk protections from an option class level to a specific subset of Member defined groups. Accordingly, the SLAP feature is designed to provide Members with greater control over their orders in the market, thereby removing impediments to and helping to perfect the mechanisms of a free and open market and a national market system and, in general, protecting investors and the public interest. In addition, providing Members with more tools for managing risk will facilitate transactions in securities because, as noted above, Members will have more confidence that protections are in place that reduce the risks from market events. As a result, the new functionality has the potential to promote just and equitable principles of trade.

The proposed rule change removes impediments to and is designed to perfect the mechanisms of a free and open market by giving Members more granular control over their orders by allowing Members to create custom groupings of orders by MPID and underlying, and additional criteria, such as option or side of the market (buy or sell), by assigning up to eight different SLAP codes to each order. This flexibility allows Members to group specific subsets of their orders based on their own risk requirements. The ability to group orders allows for the flexibility to submit cancel requests for a subset of open orders tailored to varying levels of risk tolerance.

The Exchange believes the proposed changes remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest, and promote a fair and orderly market by excluding Intermarket Sweep Orders and orders with a time in force of IOC from SLAP functionality. Intermarket Sweep Orders are used to prevent locked and crossed markets from occurring¹⁵ and it is in the public interest for markets to remain uncrossed to promote competition and price discovery. Orders with a time in force of IOC are executed immediately with any remaining balance cancelled, therefore these orders do not rest on the Book¹⁶ and as such do not require risk protection that is provided to resting orders.

The Exchange believes the proposed changes remove impediments to and perfects the mechanism of a free and open market and a national market system and, in general, protects investors and the public interest by providing Members with an additional risk management tool. Members who are Market Makers¹⁷ have a heightened obligation on the Exchange and are obligated to submit continuous two-sided quotations in a certain number of series in their appointed classes for a certain percentage of time in each trading session,¹⁸ rendering them vulnerable to risk from market conditions. Additionally, EEMs¹⁹ may also submit a large volume of orders that rest on the Book also rendering them vulnerable and at risk to market conditions.

The Exchange notes that the proposed rule change will not relieve Exchange Market Makers of their continuous quoting obligations under Exchange Rule 605²⁰ or any other obligation under the Rules of the Exchange, or any obligations arising under Reg NMS Rule 602.²¹ Nor will the proposed rule

change prohibit the Exchange from taking disciplinary action against a Market Maker for failing to meet their continuous quoting obligation each trading day.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rule change will foster competition by providing Members with the ability to specifically customize their use of the Exchange's risk management tools in order to compete for executions and order flow.

Additionally, the Exchange believes that the proposed rule change should promote competition as it is designed to allow Members greater flexibility and control of their risk exposure to protect them from market conditions that may increase their risk exposure in the market. The Exchange does not believe the proposed rule change will impose a burden on intra-market competition as the optional risk protection feature is equally available to all Members of the Exchange.

The Exchange believes that the proposed rule change should promote inter-market competition as the proposal is designed to allow Members greater flexibility and control over their risk exposure in order to protect them from market risk or events that may increase their exposure in the market. Additionally, the proposed rule change should instill additional confidence in market participants that submit orders to the Exchange that there are adequate risk protections in place, and thus should encourage market participants to submit additional order flow to the Exchange, thereby promoting inter-market competition.

For all the reasons stated, the Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, and believes the proposed change will enhance competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

¹⁵ See *supra* note 10.

¹⁶ The term "Book" means the electronic book of buy and sell orders and quotes maintained by the System. See Exchange Rule 100.

¹⁷ The term "Market Maker" or "MM" means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of MIAAX Pearl Rules. See Exchange Rule 100.

¹⁸ See Exchange Rule 605(d).

¹⁹ The term "Electronic Exchange Member" or "EEM" means the holder of a Trading Permit who is a Member representing as agent Public Customer Orders or Non-Customer Orders on the Exchange and those non-Market Maker Members conducting proprietary trading. Electronic Exchange Members are deemed "members" under the Exchange Act. See Exchange Rule 100.

²⁰ See Exchange Rule 605(d).

²¹ 17 CFR 242.602.

¹⁴ *Id.*

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act²² and Rule 19b-4(f)(6)²³ thereunder. Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act²⁴ and Rule 19b-4(f)(6)²⁵ thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-PEARL-2025-36 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-PEARL-2025-36. This file

number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-PEARL-2025-36 and should be submitted on or before August 20, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁶

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-14357 Filed 7-29-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0033]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension: Rule 17a-3

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("SEC" or "Commission") is soliciting comments on the proposed collection of information.

Rule 17a-3, 17 CFR 240.17-3, under the Securities Exchange Act of 1934 establishes minimum standards with respect to business records that broker-dealers registered with the Commission must make and keep current. These records are maintained by the broker-dealer (in accordance with a separate rule), so they can be used by the broker-dealer and reviewed by Commission examiners, as well as other regulatory authority examiners, during inspections of the broker-dealer.

The collections of information included in Rule 17a-3 are necessary to

enable the Commission, self-regulatory organization ("SRO"), and state examiners to conduct effective and efficient examinations to determine whether broker-dealers are complying with relevant laws, rules, and regulations. If broker-dealers were not required to create these baseline, standardized records, Commission, SRO, and state examiners could be unable to determine whether broker-dealers are in compliance with the Commission's antifraud and anti-manipulation rules, financial responsibility program, and other Commission, SRO, and State laws, rules, and regulations.

The collection of information is mandatory and is confidential subject to the provisions of the Freedom of Information Act (5 U.S.C. 552.)

As of December 31, 2024 there were 3,342 broker-dealers registered with the Commission. The Commission estimates that these broker-dealer respondents incur a total hour burden of approximately 9,818,416 hours per year to comply with Rule 17a-3.

In addition, Rule 17a-3 contains ongoing operation and maintenance costs for broker-dealers, including the cost of postage to provide customers with account information, and costs for equipment and systems development. The Commission estimates that the total cost burden associated with Rule 17a-3 would be approximately \$138,852,510 per year.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the SEC, including whether the information will have practical utility; (b) the accuracy of the SEC's estimate of the burden imposed by the proposed collection of information, including the validity of the methodology and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated, electronic collection techniques or other forms of information technology.

Please direct your written comments on this 60-Day Collection Notice to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg via email to PaperworkReductionAct@sec.gov by September 29, 2025. There will be a second opportunity to

²² 15 U.S.C. 78(b)(3)(A).

²³ 17 CFR 240.19b-4(f)(6).

²⁴ 15 U.S.C. 78s(b)(3)(A).

²⁵ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

²⁶ 17 CFR 200.30-3(a)(12).

comment on this SEC request following the **Federal Register** publishing a 30-Day Submission Notice.

Dated: July 25, 2025.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-14351 Filed 7-29-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-103548; File Nos. SR-NYSE-2025-12, SR-NYSEAMER-2025-21, SR-NYSEARCA-2025-29, SR-NYSETEX-2025-03, SR-NYSEENAT-2025-07]

Self-Regulatory Organizations; New York Stock Exchange LLC; NYSE American LLC; NYSE Arca, Inc.; NYSE Texas, Inc.; NYSE National, Inc.; Notice of Filing of Amendments and Order Granting Accelerated Approval of Proposed Rule Changes, Each as Modified by the Amendment, To Expand the Virtual Control Circuit Service in the Connectivity Fee Schedule

July 25, 2025.

I. Introduction

On April 7, 2025, New York Stock Exchange LLC (“NYSE”), NYSE American LLC (“NYSE American”), NYSE Arca, Inc. (“NYSE Arca”), NYSE Texas, Inc. (“NYSE Texas”), and NYSE National, Inc. (“NYSE National”) (each an “Exchange,” collectively, “Exchanges”) each filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b-4 thereunder, ² a proposal to amend its connectivity fee schedule to add and establish fees for connectivity from the Mahwah Data Center to one or more trading floors. On April 16, 2025, NYSE American filed Amendment No. 1 to its proposed rule change. ³ The proposed rule changes were published for comment in the **Federal Register** on April 28, 2025. ⁴ On June 11, 2025, pursuant to Section 19(b)(2) of the Act, ⁵

the Commission designated a longer period within which to approve the proposed rule changes, disapprove the proposed rule changes, or institute proceedings to determine whether to disapprove the proposed rule changes. ⁶ The Commission has not received any comments on the proposed rule changes. On June 26, 2025, NYSE, NYSE Arca, NYSE Texas and NYSE National each filed Amendment No. 1 to its proposed rule change, and NYSE American filed Amendment No. 2 to its proposed rule change (each an “Amendment” and collectively, “Amendments”). ⁷ The Amendments superseded each Exchange’s prior filing in its entirety. ⁸ This order provides notice of the filings of Amendment No. 1 to NYSE, NYSE Arca, NYSE Texas and NYSE National’s proposed rule changes, and notice of the filing of Amendment No. 2 to NYSE American’s proposed rule change, and grants approval of the proposed rule changes, each as modified by Amendment No. 1 or Amendment No. 2, as applicable, on an accelerated basis.

⁶ See Securities Exchange Act Release No. 103224, 90 FR 25698 (June 17, 2025) (designating July 27, 2025, as the date by which the Commission shall either approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change).

⁷ Amendment No. 1 to the proposed rule changes for NYSE, NYSE Arca, NYSE Texas and NYSE National, and Amendment No. 2 to NYSE American’s proposed rule change are identical in substance. For ease of reference, this order provides page citations to SR-NYSE-2025-12 Amendment No. 1, which is available on the Commission’s website at: <https://www.sec.gov/comments/sr-nyse-2025-12/srnyse202512-617407-1811334.pdf> (“Amendment No. 1”).

⁸ The Amendments revise the proposals to provide additional explanation for why the Exchanges believe the proposed service is reasonable. Specifically, the Exchanges, in the Amendments, provide additional support for the assertion that telecommunication service providers (“Telecoms”) provide a substantially similar substitute for the Exchanges’ proposed service, including a description of the path the Telecoms and Exchanges take to the Exchanges’ trading floors. The Exchanges also clarify that the pathways offered by the proposed connections and the Telecom circuits are not normalized within the Exchange buildings. The Amendment for each filing is available on the Commission’s website at: <https://www.sec.gov/comments/sr-nyse-2025-12/srnyse202512-617407-1811334.pdf> (SR-NYSE-2025-12); <https://www.sec.gov/comments/sr-nyseamer-2025-21/srnyseamer202521-617427-1811354.pdf> (SR-NYSEAMER-2025-21); <https://www.sec.gov/comments/sr-nysearca-2025-29/srnysearca202529-617428-1811374.pdf> (SR-NYSEARCA-2025-29); <https://www.sec.gov/comments/sr-nysetex-2025-03/srnysetex202503-617467-1811414.pdf> (SR-NYSETEX-2025-03); <https://www.sec.gov/comments/sr-nysestat-2025-07/srnysestat202507-617447-1811394.pdf> (SR-NYSEENAT-2025-07).

II. Description of the Proposed Rule Changes, as Modified by the Amendments

A. Background

The Exchanges currently offer a virtual control circuit (“VCC”) service ⁹ that is a unicast connection through which two Users can establish a connection between two points over dedicated bandwidth. ¹⁰ The Exchanges offer VCC connections between two Users in the Mahwah Data Center (“MDC”). ¹¹ The Exchanges, in 2024, amended this service to also offer VCCs between the MDC and the U.S. FIDS remote access centers; specifically, the Exchanges offer a connection between a User in the MDC and either the same User outside the MDC at a remote access center or a third party outside the MDC at a remote access center. ¹² Fees for VCC services are based on the bandwidth requirements chosen by the User per VCC connections. ¹³ Connectivity to VCCs requires permission from both parties before the Exchanges will establish the connection. ¹⁴

The Exchanges propose to further expand this service to offer connectivity from the MDC to the NYSE, NYSE American, and NYSE Arca trading floors (each a “Trading Floor,” collectively, “Trading Floors”). ¹⁵ These connections may be between a User at the MDC and itself on a Trading Floor, or between a User at the MDC and a third party on

⁹ See Securities Exchange Act Release No. 80311 (March 24, 2017), 82 FR 15741 (March 30, 2017) (SR-NYSE-2016-45); 80309 (March 24, 2017), 82 FR 15725 (March 30, 2017) (SR-NYSEAMKT-2016-63); 80310 (March 24, 2017), 82 FR 15763 (March 30, 2017) (SR-NYSEARCA-2016-89); 83351 (May 31, 2018), 83 FR 26314 (June 6, 2018) (SR-NYSEENAT-2018-07); 87408 (October 28, 2019), 84 FR 58778 (November 1, 2019) (SR-NYSECHX-2019-12) (adding the VCC service and related fees).

¹⁰ See Amendment No. 1, *supra* note 7, at 4.

¹¹ *Id.* The Exchanges state that through its Fixed Income and Data Services (“FIDS”) business, Intercontinental Exchange, Inc. (“ICE”) operates the MDC and that the Exchanges are indirect subsidiaries of ICE. See *id.*, at 4 n.5.

¹² *Id.* See also Securities Exchange Act Release Nos. 101582 (November 12, 2024), 89 FR 90812 (November 18, 2024) (SR-NYSE-2024-69); 101575 (November 12, 2024), 89 FR 90770 (November 18, 2024) (SR-NYSEAMER-2024-64); 101576 (November 12, 2024), 89 FR 90775 (November 18, 2024) (SR-NYSEARCA-2024-91); 102902 (November 12, 2024), 89 FR 90893 (November 18, 2024) (SR-NYSECHX-2024-31); 101578 (November 12, 2024), 89 FR 90794 (November 18, 2024) (SR-NYSEENAT-2024-28) (adding VCC services between the MDC and the U.S. remote access centers to the connectivity fee schedule).

¹³ *Id.* at 5.

¹⁴ *Id.*

¹⁵ As noted by the Exchanges, “Trading Floor” is used as defined in, as applicable, NYSE Rule 6A (Trading Floor), NYSE American Scope of Terms (17), and NYSE Arca Rule 1 (Definitions), Floor, Trading Floor and Options Trading Floor. NYSE National and NYSE Texas do not have trading floors. *Id.* at 4 n.3.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ Amendment No. 1 to NYSE American’s proposed rule change more closely conformed the text of Exhibit 1 of the proposed rule change to the filed Form 19b-4.

⁴ See Securities Exchange Act Release Nos. 102898 (April 22, 2025), 90 FR 17635 (SR-NYSE-2025-12); 102897 (April 22, 2025), 90 FR 17658 (SR-NYSEAMER-2025-21); 102899 (April 22, 2025), 90 FR 17640 (SR-NYSEARCA-2025-29); 102902 (April 22, 2025), 90 FR 17665 (SR-NYSETEX-2025-03); 102900 (April 22, 2025), 90 FR 17675 (SR-NYSEENAT-2025-07).

⁵ 15 U.S.C. 78s(b)(2).

a Trading Floor (“Trading Floor Connections”).¹⁶ As with the existing VCCs, the Trading Floor Connections would be unicast connections over dedicated bandwidth over the IGN network.¹⁷ The Trading Floor Connections can be in the form of a VCC between the MDC and a single Trading Floor (“Trading Floor VCC”) or a virtual routing and forwarding service between the MDC and one or more Trading Floors (“Trading Floor VRF”).¹⁸

As with the current VCC service, the monthly charge for a Trading Floor VCC or VRF connection would be based on the size of the bandwidth connection the User requests.¹⁹ The Exchanges propose to charge the same fee for the Trading Floor Connections as the Exchanges currently charge for VCCs.²⁰ The per connection fees for one Trading Floor VCC and one Trading Floor VRF connection would be identical to each other and to the current fees for a VCC connection.²¹

The Exchanges state that Users would determine how the Trading Floor Connections are used and that neither the Exchanges nor FIDS have visibility into Users’ Trading Floor Connections.²² The Exchanges state that the Trading Floor Connections are not used for latency-sensitive trading data, but for trading-related data or communications like email or chat with a User’s back office.²³ Specifically, potential uses could include receiving and transmitting trading-related information, including trading data and

clearing information (e.g., an options market maker²⁴ on a Trading Floor using a computer with a firm’s options market data to provide verbal bids/offers in response to floor broker requests for quotes) and providing access to back office services to individuals physically located on a Trading Floor.²⁵ Each Exchange represents that a User’s Trading Floor Connection will not be through the Exchange’s execution systems and that a Trading Floor Connection will not provide direct access or order entry to the Exchange’s execution systems.²⁶ The Exchanges also state that establishing a Trading Floor Connection would not give FIDS or an Exchange the right to use the relevant Exchange’s systems.²⁷

The Exchanges further represent that all NYSE, NYSE American, and NYSE Arca equities and options members and member organizations, including NYSE floor brokers and Designated Market Makers, and floor brokers, options market makers, and specialists on the NYSE American and NYSE Arca Trading Floors remain subject to NYSE, NYSE American, and NYSE Arca rules regarding activities on the Trading Floors.²⁸ The Exchanges state that all NYSE, NYSE American or NYSE Arca rules would continue to apply, including any rules regarding limitations on the use of electronic communications from or to the Trading Floor.²⁹ The Exchanges represent that the proposed connections from the MDC to the Trading Floors do not contravene or limit the rules or the ability of the NYSE, NYSE American, or NYSE Arca to surveil for compliance with such rules.³⁰ These rules include NYSE Rules 36 (Communications Between Exchange and Member Offices), 98 (Operation of a DMM Unit), and 104 (Dealings and Responsibilities of DMMs).³¹

III. Discussion and Commission Findings

The Commission has historically applied a “market-based” test in its assessment of market data fees, which has also been applied in the context of connectivity fees, such as those proposed here.³² Under that test, the

Commission considers “whether the exchange was subject to significant competitive forces in setting the terms of its proposal . . . , including the level of any fees.”³³ If an exchange meets this burden, the Commission will find that its proposal is consistent with the Act unless “there is a substantial countervailing basis to find that the terms” of the proposal violate the Act or the rules thereunder.³⁴ If an exchange cannot demonstrate that it was subject to significant competitive forces, it must “provide a substantial basis, other than competitive forces, . . . demonstrating that the terms of the proposal are equitable, fair, reasonable, and not unreasonably discriminatory.”³⁵

The Commission finds that the proposed rule changes, each as modified by Amendment No. 1 or Amendment No. 2, as applicable, are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.³⁶ In particular, the Commission finds that each of the proposed rule changes is consistent

NYSE–2020–11, SR–NYSEAMER–2020–10, SR–NYSEARCA–2020–15, SR–NYSECHX–2020–05, SR–NYSENAT–2020–08) (Notice of Filings of Partial Amendment No. 3 and Order Granting Accelerated Approval to Proposed Rule Changes, Each as Modified by Partial Amendment No. 3, To Establish a Wireless Fee Schedule Setting Forth Available Wireless Bandwidth Connections and Wireless Market Data Connections) (“Wireless Order”).

See also Securities Exchange Act Release Nos. 85459 (March 29, 2019), 84 FR 13363, 13367 (April 4, 2019) (File Nos. SR–BOX–2018–24; SR–BOX–2018–37; and SR–BOX–2019–04) (Order Disapproving Proposed Rule Changes To Amend the Fee Schedule on the BOX Market LLC Options Facility To Establish BOX Connectivity Fees for Participants and Non-Participants Who Connect to the BOX Network); and 88493 (March 27, 2020) 85 FR 18617 (April 2, 2020) (File Nos. SR–BOX–2018–24; SR–BOX–2018–37; and SR–BOX–2019–04) (Order Affirming Action by Delegated Authority and Disapproving Proposed Rule Changes Related to Connectivity and Port Fee) (“BOX Order”).

³³ Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74781 (December 9, 2008) (“2008 ArcaBook Approval Order”).

³⁴ *Id.* See also In the Matter of the Application of SIFMA, Securities Exchange Act Release No. 84432, 22 (October 16, 2018), available at <https://www.sec.gov/litigation/opinions/2018/34-84432.pdf> (“SIFMA Decision”), vacated on other grounds, *NASDAQ Stock Mkt., LLC v. SEC*, 961 F.3d 421 (D.C. Cir. 2020).

³⁵ 2008 ArcaBook Approval Order, *supra* note 33, at 74781. See also SIFMA Decision, *supra* note 34, at 22. See also BOX Order, *supra* note 32, at 18622–24 (noting that the exchange had failed to demonstrate significant competitive forces, and therefore did not establish a basis on which to conclude that the proposed fees were equitable and reasonable.)

³⁶ In approving the proposed rule changes, each as modified by Amendment No. 1 or Amendment No. 2, as applicable, the Commission notes that it has considered the proposed rules’ impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹⁶ *Id.* at 4. The connection would run between the MDC and the User’s or third party’s equipment physically located on one or more of the Trading Floors.

¹⁷ See *id.*

¹⁸ The Exchanges state that because both Trading Floor VCCs and Trading Floor VRFs use the IGN network, both sets of connections are substantially the same in latency and reliability. A User would choose between them based on factors including technical preference and consistency. As an example, the Exchanges state that a User might prefer a Trading Floor VRF if it was setting up a link between the MDC and two Trading Floors but might prefer to use a Trading Floor VCC if it was already using VCCs. *Id.* at 4.

¹⁹ *Id.* at 5.

²⁰ *Id.* The Exchanges state that all Trading Floor Connections must be authorized by both parties before FIDS will establish the connection.

²¹ *Id.* The Exchanges note that although the proposed fees for the Trading Floor VCC and the Trading Floor VRF are identical, a User’s monthly fee could vary based which form of connection the User chooses. For example, if a User chooses to purchase VCCs or a combination of VCCs and a VRF, it would be charged separately for each connection. If the User chose one VRF to connect to multiple Trading Floors, it would be charged for one connection. The Exchanges propose to amend the connectivity fee schedule to clarify the potential impact of the choice of the connection on the fees. *Id.*

²² *Id.*

²³ *Id.* at 8.

²⁴ *Id.* at 5 n.8 and accompanying text.

²⁵ *Id.* at 5.

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.* at 5.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² See Securities Exchange Act Release No. 90209 (October 15, 2020), 85 FR 67044 (October 21, 2020) (File Nos. SR–NYSE–2020–05, SR–NYSEAMER–2020–05, SR–NYSEARCA–2020–08, SR–NYSECHX–2020–02, SR–NYSENAT–2020–03, SR–

with Section 6(b)(4) of the Act³⁷ which requires that a national securities exchange provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities; Section 6(b)(5) of the Act,³⁸ which requires that the rules of a national securities exchange be designed, among other things, to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers or dealers; and Section 6(b)(8) of the Act,³⁹ which requires that the rules of a national securities exchange do not impose any burden on competition that is not necessary or appropriate in furtherance of the Act.

The Exchanges state that the Trading Floor Connections are offered on terms that are reasonable and do not impose a burden on competition that is not necessary or appropriate because they are offered in a competitive environment where substantially similar substitutes are available.⁴⁰ The Exchanges state that the Trading Floor Connections compete with circuits offered by Telecoms.⁴¹ These Telecom circuits, like the Trading Floor Connections, can also provide connectivity between the MDC and the Trading Floors.⁴² The Exchanges state that sixteen Telecoms currently have installed their equipment in the Exchanges' two meet-me-rooms at the MDC.⁴³ The Exchanges state that there

are also Telecoms currently located in the same buildings as the Trading Floors.⁴⁴ The Telecoms would connect to a Trading Floor entity's equipment in the same building as the Trading Floor, in an area that the Exchanges state is "essentially a meet-me-room."⁴⁵ The Exchanges state that once the Trading Floor Connections and the Telecom circuits reach the Trading Floor buildings, the connections would extend to the Trading Floor itself through the Exchanges' network and infrastructure.⁴⁶

The Exchanges state that the Telecoms are not at a competitive disadvantage created by the Exchanges with respect to the Telecoms' connectivity inside the MDC and the Trading Floor buildings. Specifically, the Exchanges state that Trading Floor Connections do not have a competitive advantage over the Telecom circuits in terms of the pathways that the connections would take to reach the Trading Floors.⁴⁷ With respect to the MDC, the Exchanges state that the Trading Floor Connections do not have a distance or latency advantage over the Telecoms' circuits.⁴⁸ FIDS has normalized (a) the distance between the meet-me-rooms and the colocation halls and (b) the distance between the rooms where the FIDS circuits and the Trading Floor Connections exit the MDC and the colocation halls.⁴⁹ As a result, according to the Exchanges, a User choosing whether to use the Trading Floor Connections or Telecom circuits does not face any difference in the distances or latency within the MDC.⁵⁰

With respect to the Trading Floor buildings, the Exchanges state that the Trading Floor Connections do not have any bandwidth or substantial distance advantage over the Telecoms' circuits within the buildings of the Trading Floors.⁵¹ The Exchanges state that once the Trading Floor Connections and the Telecom circuits connections reach the Trading Floor buildings, the pathways that both types of connections would

take to reach the Trading Floor are the same (*i.e.*, extending to the Trading Floor itself through the Exchanges' network and infrastructure).⁵² The Exchanges also state that Telecoms can offer circuits with a variety of latency and bandwidth specifications, some of which may exceed the specifications of the Trading Floor Connections.⁵³

The Exchanges also state that they have no competitive advantage over Telecom circuits with respect to fees they charge the Telecoms for access to the meet-me-rooms at the MDC.⁵⁴ The Exchanges believe that the amount of the meet-me-room fees they can charge Telecoms are constrained, and they do not have a competitive advantage over any third-party competitor by virtue of owning and operating the MDC meet-me-rooms.⁵⁵ The Exchanges state that they are incentivized to set fees to operate in the meet-me-room at a reasonable rate because reasonable fees will incentivize Telecoms to participate in the meet-me-rooms.⁵⁶ The Exchanges state that these Telecoms would compete with each other by pricing circuits at competitive rates, which will draw Users to the MDC and that the Exchanges benefit from the Telecoms selling circuits to Users because these Users increase the customer base to which the Exchanges can sell their colocations services, including cabinets, power, ports, and connectivity to third-party data feeds.⁵⁷ The Exchanges also state that more Users would lead, in many cases, to greater participation on the Exchanges.⁵⁸ The Exchanges state that the incentive to attract Telecoms to the MDC meet-me-rooms constrains the Exchanges' meet-me-room fees such that the Exchanges do not have an advantage in terms of costs when compared to

³⁷ 15 U.S.C. 78f(b)(4).

³⁸ 15 U.S.C. 78f(b)(5).

³⁹ 15 U.S.C. 78f(b)(8).

⁴⁰ See Amendment No. 1, *supra* note 7, at 7–10. The Exchanges further state that the Trading Floor Connections are offered on terms that are equitable and not unfairly discriminatory because they are voluntary and available to all market participants on an equal basis. They also believe that the proposal to offer two forms of Trading Floor Connections (VCCs and VRFs) is equitable, not unfairly discriminatory and would not impose a burden on competition that is not necessary or appropriate because both forms of connectivity are over the IGN network and therefore are substantially the same in latency and reliability. See *id.*, at 11–12.

⁴¹ *Id.* at 7.

⁴² See *id.* at 8.

⁴³ *Id.* at 7–8. The Exchanges filed to add meet-me-room services and associated fees in 2023. See Securities Exchange Act Release Nos. 97998 (July 26, 2023), 88 FR 50238 (August 1, 2023) (SR–NYSE–2023–27); 97999 (July 26, 2023), 88 FR 50190 (August 1, 2023) (SR–NYSEAMER–2023–36); 98000 (July 26, 2023), 88 FR 50244 (August 1, 2023) (SR–NYSEARCA–2023–47); 98001 (July 26, 2023),

88 FR 50196 (August 1, 2023) (SR–NYSECHX–2023–14); 98002 (July 26, 2023), 88 FR 50232 (August 1, 2023) (SR–NYSEAT–2023–12).

⁴⁴ *Id.* at 8.

⁴⁵ *Id.*

⁴⁶ *Id.* The Exchanges represent that "[t]he path the traffic takes from when it enters the building of the Trading Floor to the Trading Floor—its pathway—is the same irrespective of whether the service is a Telecom circuit or a TF Connection." *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.* at 9. The Exchanges state with respect to the MDC that they are not aware of any differences under their control that give the Exchanges a latency advantage. *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.* at 8. The Exchanges acknowledge that the pathways of the Trading Floor Connections and the Telecom circuits are not normalized within Exchanges' buildings (*i.e.*, the length of the connections may "slightly" differ) but state that the connections do not need to be normalized because Users would not use them for latency-sensitive purposes (*e.g.*, transmitting data to the matching engine). *Id.* Instead, the Exchanges state that they would be used for purposes such as communicating with the back office. *Id.* The Exchanges note that Users would choose to purchase connections based on factors such as bandwidth, price, termination point, technical preference and consistency. *Id.*

⁵³ *Id.* The Exchanges note that the specifications of FIDS's competitors' circuits are not public. The Exchanges understand that any information FIDS has about its competitors was obtained through anecdotal communications, by observing customers' purchasing choices in the competitive market, and from its own experience as a purchaser of circuits from telecommunications providers to build FIDS's own networks. *Id.* at 9 n.19.

⁵⁴ See *supra* note 43.

⁵⁵ See Amendment No. 1, *supra* note 7, at 9–10.

⁵⁶ *Id.* at 9.

⁵⁷ *Id.*

⁵⁸ *Id.*

third parties that enter through the meet-me-room to provide competing services.⁵⁹ In fact, according to each Exchange, setting meet-me-room fees too high would negatively impact the Exchange's ability to sell its services to Users at the MDC.⁶⁰ With respect to the Telecoms' presence in the Trading Floor buildings, the Exchanges represent that the Telecoms do not pay a fee to connect to the Trading Floor entity's equipment in the same room as the Trading Floor.⁶¹ The Exchanges also represent that the Trading Floor entities do not pay fees to any of the Exchanges for the connection.⁶²

The Exchanges state that the Trading Floor Connections would be offered at the same price as the VCCs currently offered by the Exchanges, and if Users found the fees too high, they have the option to choose alternative options offered by the Telecoms.⁶³ The Exchanges also state that they have no incentive to undercut fees that the Telecoms offer or might offer for competing services because the Telecoms might reassess whether it make sense to participate in the Exchanges' meet-me-rooms, which could negatively impact User participation in colocation and on the Exchanges.⁶⁴

The Exchanges have demonstrated that they are subject to significant competitive forces in setting the terms on which they offer Trading Floor Connections, in particular because substantially similar substitutes are available.⁶⁵ As stated earlier, the Exchanges state that Telecoms are available at both the MDC and the Trading Floor buildings.⁶⁶ The Exchanges have demonstrated that they do not have a competitive advantage compared to the Telecoms with respect to the Trading Floor Connections. Based on the record, the Commission believes that there are sufficiently comparable alternatives to the Trading Floor Connections. Thus, the Exchanges are subject to significant competitive forces that constrain the terms on which the Trading Floor Connections are offered, and the Commission approves the

proposals, as amended, because there is no substantial countervailing basis to find that the terms of the proposals, as amended, violate the Act or rules thereunder.⁶⁷

The Trading Floor Connections are not offered on terms that are unfairly discriminatory or would impose a burden on competition not necessary or appropriate in furtherance of the Act. In particular, the proposed services are available to all market participants equally, and the Exchanges have sufficiently demonstrated that they do not have a competitive advantage compared to the Telecoms.

Based on this, the Commission finds the proposed rule changes, as modified by Amendment No. 1 or Amendment No. 2, as applicable, to be consistent with Section 6(b)(4) of the Act,⁶⁸ which requires that the rules of a national securities exchange provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and Section 6(b)(8), which prohibits any national securities exchange from imposing any burden on competition not necessary or appropriate in furtherance of the Act. Further, because the Trading Floor Connections are designed to offer market participants an additional option for Users to transmit information related to trading and clearing to entities and individuals on the Trading Floors, including market makers and floor brokers, and competitors may offer a similar level of services for the reasons discussed above, the Commission finds the proposals, as amended, to be consistent with the Section 6(b)(5) of the Act, which requires that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.⁶⁹

For the foregoing reasons, the Commission finds that the proposed rule changes of NYSE, NYSE Arca, NYSE Texas and NYSE National, each as modified by Amendment No. 1, and the proposed rule change of NYSE American, as modified by Amendment No. 2, are consistent with the Act.

IV. Solicitation of Comments on the Amendments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 or Amendment No. 2, as applicable, to the proposed rule changes is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Numbers SR-NYSE-2025-12, SR-NYSEAMER-2025-21, SR-NYSEARCA-2025-29, SR-NYSETEX-2025-03, SR-NYSENAT-2025-07 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to File Numbers SR-NYSE-2025-12, SR-NYSEAMER-2025-21, SR-NYSEARCA-2025-29, SR-NYSETEX-2025-03, SR-NYSENAT-2025-07. These file numbers should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchanges. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to File Numbers SR-NYSE-2025-12, SR-NYSEAMER-2025-21, SR-NYSEARCA-2025-29, SR-NYSETEX-2025-03, SR-NYSENAT-2025-07 and should be submitted on or before August 20, 2025.

V. Accelerated Approval of Proposed Rule Changes, as Modified by the Amendments

The Commission finds good cause to approve the proposed rule changes of NYSE, NYSE Arca, NYSE Texas and NYSE National, each as modified by Amendment No. 1, and the proposed rule change of NYSE American, as

⁵⁹ *Id.* at 10.

⁶⁰ *Id.* The Exchanges also state that they are at a competitive disadvantage compared to the Telecoms because the Exchanges are required to file their services and pricing with the Commission pursuant to Section 19(b) of the Exchange Act.

⁶¹ *Id.* at 9.

⁶² *Id.*

⁶³ *Id.* at 10.

⁶⁴ *Id.*

⁶⁵ See ArcaBook Approval Order, *supra* note 33, at 74785; SIFMA Decision, *supra* note 76, at 43-44 (citation omitted) ("We recognize that products need not be identical to be substitutable.")

⁶⁶ See *supra* notes 43-44 and accompanying text.

⁶⁷ See Wireless Order, *supra* note 32.

⁶⁸ 15 U.S.C. 78f(b)(4).

⁶⁹ 15 U.S.C. 78f(b)(5).

modified by Amendment No. 2, prior to the 30th day after the date of publication of notice of the Amendments in the **Federal Register**. The Amendments revise the proposals to provide additional explanation for why the Exchanges believe the proposed service is reasonable. Specifically, the Exchanges, in the Amendments, provide additional support for the assertion that Telecoms provide a substantially similar substitute for the Exchanges' proposed service. The Commission believes that the Amendments provide additional support for why the proposals are consistent with the Act, thereby facilitating the Commission's ability to make the findings set forth above to approve the proposals.

Accordingly, pursuant to Section 19(b)(2) of the Act,⁷⁰ the Commission finds good cause to approve the proposed rule changes of NYSE, NYSE Arca, NYSE Texas and NYSE National, each as modified by Amendment No. 1, and the proposed rule change of NYSE American, as modified by Amendment No. 2, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,⁷¹ that the proposed rule changes (SR-NYSE-2025-12; SR-NYSEAMER-2025-21; SR-NYSEARCA-2025-29; SR-NYSETEX-2025-03; SR-NYSENAT-2025-07), as amended, be, and hereby are approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁷²

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-14358 Filed 7-29-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-103546; File No. SR-CboeEDGX-2025-035]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend Rule 11.21 To Allow an RMO To Enter a Retail Order Onto the Exchange in a Principal Capacity

July 25, 2025.

On May 21, 2025, Cboe EDGX Exchange, Inc. (the "Exchange" or "EDGX") filed with the Securities and

Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to (i) amend Rule 11.21(a)(2) to allow a Retail Member Organization to enter a Retail Order onto the Exchange in a principal capacity, provided the requirements of proposed Rule 11.21(g) are satisfied; (ii) codify in proposed new Rule 11.21(g) additional requirements a Retail Member Organization must comply with in order to enter Retail Orders as principal; and (iii) amend Rule 11.21(b)(6) to require that Retail Member Organizations have in place policies and procedures reasonably designed to ensure compliance with proposed Rule 11.21(g)(1), as well as to ensure that the Retail Member Organization can, upon request by the Exchange, produce documentation evidencing compliance with the requirements of Rule 11.21(g). The proposed rule change was published for comment in the **Federal Register** on June 10, 2025.³ The Commission has not received any comments on the proposed rule change.

Section 19(b)(2) of the Act⁴ provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is July 25, 2025. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change and the issues raised therein. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,⁵ designates September 8, 2025, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed

rule change (File No. SR-CboeEDGX-2025-035).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-14356 Filed 7-29-25; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21199 and #21200; KENTUCKY Disaster Number KY-20022]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the Commonwealth of Kentucky

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Kentucky (FEMA-4875-DR), dated July 22, 2025.

Incident: Severe Storms, Straight-line Winds, and Tornadoes.

DATES: Issued on July 23, 2025.

Incident Period: May 16, 2025 through May 17, 2025.

Physical Loan Application Deadline Date: September 22, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: April 22, 2026.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the Commonwealth of Kentucky, dated July 22, 2025, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Allen, Cumberland, Whitley.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 590008)

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 103182 (June 4, 2025), 90 FR 24476.

⁴ 15 U.S.C. 78s(b)(2).

⁵ *Id.*

⁶ 17 CFR 200.30-3(a)(31).

⁷⁰ 15 U.S.C. 78s(b)(2).

⁷¹ See *id.*

⁷² 17 CFR 200.30-3(a)(12).

(Authority: 13 CFR 1234.3(b).)

James Stallings,*Associate Administrator, Office of Disaster Recovery & Resilience.*

[FR Doc. 2025–14422 Filed 7–29–25; 8:45 am]

BILLING CODE 8026–09–P**SMALL BUSINESS ADMINISTRATION****[Disaster Declaration #21204 and #21205; WEST VIRGINIA Disaster Number WV–20019]****Presidential Declaration of a Major Disaster for the State of West Virginia****AGENCY:** U.S. Small Business Administration.**ACTION:** Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of West Virginia (FEMA–4884–DR), dated July 22, 2025.

Incident: Severe Storms, Straight-line Winds, Flooding, Landslides, and Mudslides.

DATES: Issued on July 22, 2025.*Incident Period:* June 14, 2025 through June 15, 2025.*Physical Loan Application Deadline Date:* September 22, 2025.*Economic Injury (EIDL) Loan Application Deadline Date:* April 22, 2026.**ADDRESSES:** Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on July 22, 2025, applications for disaster loans may be submitted online using the MySBA Loan Portal <https://lending.sba.gov> or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Marion, Ohio.

Contiguous Counties (Economic Injury Loans Only):

West Virginia: Brooke, Harrison, Marshall, Monongalia, Taylor,

Wetzel.
Ohio: Belmont, Jefferson.
Pennsylvania: Washington.
The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	5.625
Homeowners without Credit Available Elsewhere	2.813
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere ...	3.625
Non-Profit Organizations without Credit Available Elsewhere	3.625
<i>For Economic Injury:</i>	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for physical damage is 212046 and for economic injury is 212050.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 1234.3(b).)

James Stallings,*Associate Administrator, Office of Disaster Recovery & Resilience.*

[FR Doc. 2025–14418 Filed 7–29–25; 8:45 am]

BILLING CODE 8026–09–P**SMALL BUSINESS ADMINISTRATION****[Disaster Declaration #21201; CALIFORNIA Disaster Number CA–20035 Declaration of Economic Injury]****Administrative Declaration of an Economic Injury Disaster for the State of California****AGENCY:** U.S. Small Business Administration.**ACTION:** Notice.

SUMMARY: This is a notice of an Economic Injury Disaster Loan (EIDL) declaration for the State of California dated July 23, 2025.

Incident: Vehicle Explosion Terrorism Incident.

DATES: Issued on July 23, 2025.*Incident Period:* May 17, 2025 through May 23, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: April 23, 2026.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT:

Sharon Henderson, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's EIDL declaration, applications for disaster loans may be submitted online using the MySBA Loan Portal <https://lending.sba.gov> or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary County: Riverside.

Contiguous Counties:

California: Imperial, Orange, San Bernardino, San Diego.

Arizona: La Paz.

The Interest Rates are:

Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for economic injury is 212010.

The States which received an EIDL Declaration are Arizona, California.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 1234.3(b).)

James Stallings,*Associate Administrator, Office of Disaster Recovery and Resilience.*

[FR Doc. 2025–14350 Filed 7–29–25; 8:45 am]

BILLING CODE 8026–09–P**SMALL BUSINESS ADMINISTRATION****[Disaster Declaration #21202 and #21203; NEW MEXICO Disaster Number NM–20017]****Presidential Declaration of a Major Disaster for the State of New Mexico****AGENCY:** U.S. Small Business Administration.**ACTION:** Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of New Mexico (FEMA–4886–DR), dated July 22, 2025.

Incident: Severe Storms, Flooding and Landslides.

DATES: Issued on July 22, 2025.

Incident Period: June 23, 2025 and continuing.

Physical Loan Application Deadline Date: September 22, 2025.

Economic Injury (EIDL) Loan
Application Deadline Date: April 22, 2026.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President’s major disaster declaration on July 22, 2025, applications for disaster loans may be submitted online using the MySBA Loan Portal <https://lending.sba.gov> or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Lincoln.

Contiguous Counties (Economic Injury Loans Only):

New Mexico: Chaves, De Baca, Guadalupe, Otero, Sierra, Socorro, Torrance.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	5.625
Homeowners without Credit Available Elsewhere	2.813
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere ...	3.625
Non-Profit Organizations without Credit Available Elsewhere	3.625
<i>For Economic Injury:</i>	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for physical damage is 212026 and for economic injury is 212030.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 1234.3(b).)

James Stallings,
Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2025–14420 Filed 7–29–25; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21174 and #21175; TEXAS Disaster Number TX–20057]

Presidential Declaration Amendment of a Major Disaster for the State of Texas

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Texas (FEMA–4879–DR), dated July 6, 2025.

Incident: Severe Storms, Straight-line Winds, and Flooding.

DATES: Issued on July 23, 2025.

Incident Period: July 2, 2025 through July 18, 2025.

Physical Loan Application Deadline Date: September 4, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: April 6, 2026.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President’s major disaster declaration for the State of Texas, dated July 6, 2025, is hereby amended to update the incident period for this disaster as beginning July 2, 2025 and continuing through July 18, 2025.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 1234.3(b).)

James Stallings,
Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2025–14430 Filed 7–29–25; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21206 and #21207; NORTH CAROLINA Disaster Number NC–20020]

Administrative Declaration of a Disaster for the State of North Carolina

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of North Carolina dated July 25, 2025.

Incident: Tropical Depression Chantal—Flooding, and Tornadoes.

DATES: Issued on July 25, 2025.

Incident Period: July 6, 2025 through July 13, 2025.

Physical Loan Application Deadline Date: September 23, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: April 27, 2026.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given as a result of the Administrator’s disaster declaration, applications for disaster loans may be submitted online using the MySBA Loan Portal <https://lending.sba.gov> or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1–800–659–2955 for further assistance. The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Durham, Orange.

Contiguous Counties: North Carolina:

Alamance, Caswell, Chatham, Granville, Person, Wake.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	5.625
Homeowners without Credit Available Elsewhere	2.813
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere ...	3.625

	Percent
Non-Profit Organizations without Credit Available Elsewhere	3.625
<i>For Economic Injury:</i> Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for physical damage is 21206B and for economic injury is 212070.

The States which received an EIDL Declaration are North Carolina.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 1234.3(b).)

Randle Logan,

*Acting Deputy Associate Administrator,
Office of Disaster Recovery and Resilience.*

[FR Doc. 2025-14432 Filed 7-29-25; 8:45 am]

BILLING CODE 8026-09-P

SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration #21176 and #21177;
TEXAS Disaster Number TX-20058]**

**Presidential Declaration Amendment of
a Major Disaster for Public Assistance
Only for the State of Texas**

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 5.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Texas (FEMA-4879-DR), dated July 6, 2025.

Incident: Severe Storms, Straight-line Winds, and Flooding.

DATES: Issued on July 23, 2025.

Incident Period: July 2, 2025 through July 18, 2025.

Physical Loan Application Deadline Date: September 4, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: April 6, 2026.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Texas,

dated July 6, 2025 is hereby amended to update the incident period for this disaster as beginning July 2, 2025 and continuing through July 18, 2025.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 1234.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2025-14428 Filed 7-29-25; 8:45 am]

BILLING CODE 8026-09-P

SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration #21199 and #21200;
KENTUCKY Disaster Number KY-20022]**

**Presidential Declaration of a Major
Disaster for Public Assistance Only for
the Commonwealth of Kentucky**

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Kentucky (FEMA-4875-DR), dated July 22, 2025.

Incident: Severe Storms, Straight-line Winds, and Tornadoes.

DATES: Issued on July 22, 2025.

Incident Period: May 16, 2025 through May 17, 2025.

Physical Loan Application Deadline Date: September 22, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: April 22, 2026.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on July 22, 2025, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal <https://lending.sba.gov> or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1-800-659-2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Adair, Barren, Breathitt, Butler, Caldwell, Carlisle, Casey, Christian, Clay, Clinton, Crittenden, Estill, Jackson, Knott, Knox, LaRue, Laurel, Lee, Livingston, Logan, Lyon, Marshall, McCreary, Menifee, Metcalfe, Owsley, Powell, Pulaski, Rockcastle, Russell, Spencer, Todd, Trigg, Union, Warren, Wayne.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i> Non-Profit Organizations with Credit Available Elsewhere ...	3.625
Non-Profit Organizations without Credit Available Elsewhere	3.625
<i>For Economic Injury:</i> Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for physical damage is 21199C and for economic injury is 212000.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 1234.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2025-14423 Filed 7-29-25; 8:45 am]

BILLING CODE 8026-09-P

SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration #21197 and #21198;
KENTUCKY Disaster Number KY-20021]**

**Presidential Declaration Amendment of
a Major Disaster for Public Assistance
Only for the Commonwealth of
Kentucky**

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Kentucky (FEMA-4864-DR), dated July 22, 2025.

Incident: Severe Storms, Straight-line Winds, Tornadoes, Flooding, Landslides, and Mudslides.

DATES: Issued on July 23, 2025.

Incident Period: April 2, 2025 through May 16, 2025.

Physical Loan Application Deadline Date: September 22, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: April 22, 2026.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President’s major disaster declaration for Private Non-Profit organizations in the Commonwealth of Kentucky, dated July 22, 2025, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Anderson, Ballard, Bracken, Bullitt, Carlisle, Clay, Crittenden, Daviess, Fulton, Hardin, Harrison, Jessamine, Leslie, Lewis, Lincoln, Livingston, Madison, Marshall, McCracken, Mercer, Monroe, Ohio, Oldham, Robertson, Simpson, Todd.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 1234.3(b).)

James Stallings,
Associate Administrator, Office of Disaster Recovery & Resilience.
[FR Doc. 2025–14427 Filed 7–29–25; 8:45 am]
BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21197 and #21198; KENTUCKY Disaster Number KY–20021]

Presidential Declaration of a Major Disaster for Public Assistance Only for the Commonwealth of Kentucky

AGENCY: U.S. Small Business Administration.
ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Kentucky (FEMA–4864–DR), dated July 22, 2025.

Incident: Severe Storms, Straight-line Winds, Tornadoes, Flooding, Landslides, and Mudslides.

DATES: Issued on July 22, 2025.
Incident Period: April 2, 2025 through May 16, 2025.

Physical Loan Application Deadline Date: September 22, 2025.
Economic Injury (EIDL) Loan Application Deadline Date: April 22, 2026.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President’s major disaster declaration on July 22, 2025, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal <https://lending.sba.gov> or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Allen, Barren, Breathitt, Breckinridge, Butler, Caldwell, Calloway, Campbell, Carroll, Carter, Casey, Christian, Clark, Edmonson, Elliott, Estill, Floyd, Franklin, Gallatin, Garrard, Graves, Grayson, Green, Greenup, Hancock, Hart, Henderson, Hickman, Hopkins, Jackson, Jefferson, Johnson, Kenton, LaRue, Lawrence, Lee, Logan, Lyon, Magoffin, Marion, Martin, McLean, Meade, Metcalfe, Morgan, Muhlenberg, Nelson, Nicholas, Owen, Owsley, Pendleton, Perry, Powell, Rockcastle, Spencer, Taylor, Trigg, Trimble, Union, Warren, Washington, Webster, Wolfe, Woodford.

The Interest Rates are:	
	Percent
<i>For Physical Damage:</i>	
Non-Profit Organizations with Credit Available Elsewhere ...	3.625
Non-Profit Organizations without Credit Available Elsewhere	3.625
<i>For Economic Injury:</i>	
Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for physical damage is 211976 and for economic injury is 211980.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 1234.3(b).)

James Stallings,
Associate Administrator, Office of Disaster Recovery & Resilience.
[FR Doc. 2025–14426 Filed 7–29–25; 8:45 am]
BILLING CODE 8026–09–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36866]

OPSEU Pension Plan Trust Fund, Jaguar Transport Holdings, LLC, and Jaguar Rail Holdings, LLC—Control Exemption—Central Washington Railroad Company, LLC

OPSEU Pension Plan Trust Fund (OPTrust), Jaguar Transport Holdings, LLC (JTH), and Jaguar Rail Holdings, LLC (JRH) (collectively, Jaguar), each a noncarrier, have filed a verified notice of exemption under 49 CFR 1180.2(d)(2) to acquire control of Central Washington Railroad Company, LLC (CWAR). CWAR¹ is an existing Class III railroad common carrier.²

According to the verified notice, OPTrust indirectly controls JTH, which, in turn, directly controls JRH. JTH currently controls, indirectly, 11 Class III railroads. Of the 11 railroads currently under JTH’s indirect control, eight³ are controlled directly by JRH. JRH also indirectly controls two⁴ other railroads through WYCO. JTH indirectly controls West Memphis Base Railroad, L.L.C., through Jaguar Transport, LLC, a separate JTH subsidiary affiliated with JRH.⁵

Pursuant to a Unit Purchase Agreement, Jaguar proposes to acquire

¹ The verified notice indicates that CWAR was formerly a corporation—Central Washington Railroad Company—that has reconstituted as a limited liability company).

² See *Cent. Wash. R.R.—Lease & Operation Exemption—The Burlington N. & Santa Fe Ry, FD 34640* (STB served Jan. 21, 2005).

³ Those carriers, and the states in which they operate, are: (1) Southwestern Railroad, Inc. (New Mexico, Texas, and Oklahoma); (2) Texas & Eastern Railroad, LLC (Texas); (3) Wyoming and Colorado Railroad, Inc. (WYCO) (Oregon); (4) Missouri Eastern Railroad, LLC (Missouri); (5) Charlotte Western Railroad, LLC (North Carolina); (6) Kinston Railroad LLC (North Carolina); (7) Waterloo Railroad LLC (Iowa); and (8) Kansas City West Bottoms Railroad, LLC (Missouri and Kansas).

⁴ Those carriers, and the states in which they operate, are: (1) Cimarron Valley Railroad, L.C. (Kansas, Colorado, and Oklahoma); and (2) Washington Eastern Railroad, LLC (Washington).

⁵ Concurrent with this acquisition of control notice of exemption, Jaguar is filing a separate notice of exemption to authorize Jaguar’s acquisition of control of another Class III rail carrier, Columbia Basin Railroad Company, LLC (CBRW), in Docket No. FD 36865. CWAR’s lines and CBRW’s lines are each located in the State of Washington, but CWAR’s and CBRW’s railroad networks do not connect or intersect.

control of CWAR.⁶ According to the verified notice, the primary purpose of the transaction is for Jaguar to add CWAR to its various short line holdings. The verified notice further states that the transaction will promote Jaguar's investment objectives and sustain its railroads' efficiency, financial strength, and ability to meet customer needs. Jaguar also states that the agreement does not include any provision that would limit the future interchange of traffic with a third-party connecting carrier.

Jaguar represents that its acquisition of control of CWAR is not a transaction where: (1) CWAR would connect with any of the Jaguar railroads, (2) Jaguar plans through its acquisition of control of CWAR to connect to any of the Jaguar railroads, or to connect any of the Jaguar railroads to one another; or (3) a Class I carrier is involved. The proposed transaction is therefore exempt from the prior approval requirements of 49 U.S.C. 11323 pursuant to 49 CFR 1180.2(d)(2).

This transaction may be consummated on or after August 13, 2025, the effective date of the exemption (30 days after the verified notice was filed).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. However, 49 U.S.C. 11326(c) does not provide for labor protection for transactions under 49 U.S.C. 11324 and 11325 that involve only Class III rail carriers. Because this transaction involves Class III rail carriers only, the Board, under the statute, may not impose labor protective conditions for this transaction.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than August 6, 2025.

All pleadings, referring to Docket No. FD 36866, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423-0001. In addition, one copy of each pleading must be served on Jaguar's representative, Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker

Drive, Suite 800, Chicago, IL 60606-3208.

According to Jaguar, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at www.stb.gov.

Decided: July 25, 2025.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2025-14383 Filed 7-29-25; 8:45 am]

BILLING CODE 4915-01-P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36865]

OPSEU Pension Plan Trust Fund, Jaguar Transport Holdings, LLC, and Jaguar Rail Holdings, LLC—Control Exemption—Columbia Basin Railroad Company, LLC

OPSEU Pension Plan Trust Fund (OPTrust), Jaguar Transport Holdings, LLC (JTH), and Jaguar Rail Holdings, LLC (JRH) (collectively, Jaguar), each a noncarrier, have filed a verified notice of exemption under 49 CFR 1180.2(d)(2) to acquire control of Columbia Basin Railroad Company, LLC (CBRW). CBRW¹ is an existing Class III railroad common carrier.²

According to the verified notice, OPTrust indirectly controls JTH, which, in turn, directly controls JRH. JTH currently controls, indirectly, 11 Class III railroads. Of the 11 railroads currently under JTH's indirect control, eight³ are controlled directly by JRH. JRH also indirectly controls two⁴ other railroads through WYCO. JTH indirectly controls West Memphis Base Railroad, L.L.C., through Jaguar Transport, LLC, a

¹ The verified notice indicates that CBRW was formerly a corporation—Columbia Basin Railroad Company, Inc.—that has reconstituted as a limited liability company.

² See *Columbia Basin R.R.—Acquisition & Operation Exemption—BNSF Ry.*, FD 35066 (STB served Nov. 16, 2007).

³ Those carriers, and the states in which they operate, are: (1) Southwestern Railroad, Inc. (New Mexico, Texas, and Oklahoma); (2) Texas & Eastern Railroad, LLC (Texas); (3) Wyoming and Colorado Railroad, Inc. (WYCO) (Oregon); (4) Missouri Eastern Railroad, LLC (Missouri); (5) Charlotte Western Railroad, LLC (North Carolina); (6) Kinston Railroad, LLC (North Carolina); (7) Waterloo Railroad LLC (Iowa); and (8) Kansas City West Bottoms Railroad, LLC (Missouri and Kansas).

⁴ Those carriers, and the states in which they operate, are: (1) Cimarron Valley Railroad, L.C. (Kansas, Colorado, and Oklahoma); and (2) Washington Eastern Railroad, LLC (Washington).

separate JTH subsidiary affiliated with JRH.⁵

Pursuant to a Unit Purchase Agreement, Jaguar proposes to acquire control of CBRW.⁶ According to the verified notice, the primary purpose of the transaction is for Jaguar to add CBRW to its various short line holdings. The verified notice further states that the transaction will promote Jaguar's investment objectives and sustain its railroads' efficiency, financial strength, and ability to meet customer needs. Jaguar also states that the agreement does not include any provision that would limit the future interchange of traffic with a third-party connecting carrier.

Jaguar represents that its acquisition of control of CBRW is not a transaction where: (1) CBRW would connect with any of the Jaguar railroads, (2) Jaguar plans through its acquisition of control of CBRW to connect CBRW to any of the Jaguar railroads, or to connect any of the Jaguar railroads to one another; or (3) a Class I carrier is involved. The proposed transaction is therefore exempt from the prior approval requirements of 49 U.S.C. 11323 pursuant to 49 CFR 1180.2(d)(2).

This transaction may be consummated on or after August 13, 2025, the effective date of the exemption (30 days after the verified notice was filed).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. However, 49 U.S.C. 11326(c) does not provide for labor protection for transactions under 49 U.S.C. 11324 and 11325 that involve only Class III rail carriers. Because this transaction involves Class III rail carriers only, the Board, under the statute, may not impose labor protective conditions for this transaction.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than August 6, 2025.

⁵ Concurrent with this acquisition of control notice of exemption, Jaguar is filing a separate notice of exemption to authorize Jaguar's acquisition of control of another Class III rail carrier, Central Washington Railroad Company, LLC (CWAR), in Docket No. FD 36866. CWAR's lines and CBRW's lines are each located in the State of Washington, but CWAR's and CBRW's railroad networks do not connect or intersect.

⁶ Public and confidential versions of the agreement were filed with the verified notice. The confidential version was submitted under seal concurrent with a motion for protective order, which was granted on July 25, 2025.

⁶ Public and confidential versions of the agreement were filed with the verified notice. The confidential version was submitted under seal concurrent with a motion for protective order, which was granted on July 25, 2025.

All pleadings, referring to Docket No. FD 36865, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423-0001. In addition, one copy of each pleading must be served on Jaguar's representative, Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606-3208.

According to Jaguar, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at www.stb.gov.

July 25, 2025.

Decided: By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Kenyatta Clay,
Clearance Clerk.

[FR Doc. 2025-14382 Filed 7-29-25; 8:45 am]

BILLING CODE 4915-01-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA-2021-0024]

Notice of Petition for Waiver of Compliance

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This document provides the public notice that Sandersville Railroad Company (SAN) petitioned FRA for relief from certain regulations concerning bridge safety standards.

DATES: FRA must receive comments on the petition by August 29, 2025. FRA will consider comments received after that date to the extent practicable.

ADDRESSES:

Comments: Comments related to this docket may be submitted by going to <https://www.regulations.gov> and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number. All comments received will be posted without change to <https://www.regulations.gov>; this includes any personal information. Please see the Privacy Act heading in the **SUPPLEMENTARY INFORMATION** section of this document for Privacy Act information related to any submitted comments or materials.

Docket: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT:

Alan Craine, Railroad Safety Specialist, FRA Track and Structures Division, telephone: 202-740-4908, email: alan.craine@dot.gov.

SUPPLEMENTARY INFORMATION: Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that by letter received July 7, 2025, SAN petitioned FRA for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 237 (Bridge Safety Standards). FRA assigned the petition Docket Number FRA-2021-0024.

Specifically, SAN requests relief from § 237.31, *Adoption of bridge management programs*, for its weigh-in-motion scale that is considered a "railroad bridge" under § 237.5, *Definitions*.¹ In support of its request, SAN states that it has no "actual bridges" and that "the reoccurring costs of maintaining the Bridge Management Program for a single scale with 2 inches of ground clearance could be invested in structural or operational improvements that would benefit safety without negatively impacting the risk of human casualties, environmental damage, or disrupting the Nation's railroad transportation system." SAN adds that the scale's structural integrity is essential for its operation and accuracy and that the scale is inspected weekly by track inspectors.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

Communications received by August 29, 2025 will be considered by FRA

¹ By letter received February 1, 2021, SAN sought the same relief, and FRA denied the request by letter dated August 19, 2021. See <https://www.regulations.gov/document/FRA-2021-0024-0001> and <https://www.regulations.gov/document/FRA-2021-0024-0007>.

before final action is taken. Comments received after that date will be considered if practicable.

Privacy Act

Anyone can search the electronic form of any written communications and comments received into any of FRA's dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacy-notice> for the privacy notice of [regulations.gov](https://www.regulations.gov).

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2025-14352 Filed 7-29-25; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA-2025-0094]

Nix Coach Interiors, LLC—Receipt of Petition for Temporary Exemption From Shoulder Belt Requirements for Side-Facing Seats on Motorcoaches

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice of receipt of petition for temporary exemption; request for comment.

SUMMARY: NHTSA has received a request for a temporary exemption from Nix Coach Interiors, LLC, (petitioner) seeking a temporary exemption from a shoulder belt requirement of Federal Motor Vehicle Safety Standard (FMVSS) No. 208, "Occupant crash protection," for side-facing seats on motorcoaches. The petitioner seeks an exemption to allow them to install Type 1 seat belts (lap belt only) at side-facing seating positions, instead of Type 2 seat belts (lap and shoulder belts) required by FMVSS No. 208. The petitioner states that, absent the requested exemption, it will otherwise be unable to sell a motor vehicle whose overall level of safety is equivalent to or exceeds the overall

level of safety of non-exempted motor vehicles. NHTSA is publishing this document to notify the public of the receipt of the petition and to request comment on it, in accordance with statutory and administrative provisions.

DATES: If you would like to comment, you should submit your comment no later than September 29, 2025.

FOR FURTHER INFORMATION CONTACT:

Callie Roach, Attorney Advisor, Office of the Chief Counsel, NCC-200, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, callie.roach@dot.gov, (202) 597-1312; or Devon Fray, Honors Attorney, Office of the Chief Counsel, NCC-200, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, devon.fray@dot.gov.

ADDRESSES: You may submit your comment, identified by the docket number in the heading of this document, by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *Fax:* (202) 493-2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12-140, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays. To be sure someone is there to help you, please call (202) 366-9322 before coming.

Instructions: All submissions must include the agency name and docket number.

Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. Please see the Privacy Act discussion below. NHTSA will consider all comments received before the close of business on the comment closing date indicated above. To the extent possible, NHTSA will also consider comments filed after the closing date.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> at any time or to 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m. Monday through Friday, except Federal Holidays. Telephone: (202) 366-9826. To be sure someone is

there to help you, please call (202) 366-9322 before coming.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, the agency encourages commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please see below.

Confidential Business Information: If you wish to submit any information under a claim of confidentiality, you must submit your request directly to NHTSA's Office of the Chief Counsel. Requests for confidentiality are governed by part 512. NHTSA is currently treating electronic submission as an acceptable method for submitting confidential business information to the agency under part 512. If you would like to submit a request for confidential treatment, you may email your submission to Dan Rabinovitz in the Office of the Chief Counsel at Daniel.Rabinovitz@dot.gov or you may contact Dan for a secure file transfer link. At this time, you should not send a duplicate hardcopy of your electronic CBI submissions to DOT headquarters. If you claim that any of the information or documents provided to the agency constitute confidential business information within the meaning of 5 U.S.C. 552(b)(4), or are protected from disclosure pursuant to 18 U.S.C. 1905, you must submit supporting information together with the materials that are the subject of the confidentiality request, in accordance with part 512, to the Office of the Chief Counsel. Your request must include a cover letter setting forth the information specified in our confidential business information regulation (49 CFR 512.8) and a certificate, pursuant to § 512.4(b) and part 512, appendix A. In addition, you should submit a copy, from which you have deleted the claimed confidential business information, to the Docket at the address given above.

SUPPLEMENTARY INFORMATION:

I. Background

a. Authority and Procedures for Temporary Exemptions

The National Traffic and Motor Vehicle Safety Act (Safety Act), codified as 49 U.S.C. Chapter 301, authorizes the Secretary of Transportation to exempt, on a temporary basis, under specified circumstances, and on terms the Secretary considers appropriate, motor vehicles from a motor vehicle safety standard or bumper standard. This authority and circumstances are set forth in 49 U.S.C. 30113. The Secretary has delegated the authority for implementing this section to NHTSA.¹

The Safety Act authorizes the Secretary to grant, in whole or in part, a temporary exemption to a vehicle manufacturer if the Secretary makes one of four specified findings.² The Secretary must also look comprehensively at the request for exemption and find that the exemption is consistent with the public interest and with the objectives of the Safety Act.³ The Secretary must evaluate the petition for exemption under at least one of the following bases:

- (i) Compliance would cause substantial economic hardship, and the manufacturer tried to comply in good faith;
- (ii) the exemption would make easier the development or field evaluation of a new motor vehicle safety feature, and the safety level is equal to the safety level of the standard;
- (iii) the exemption would make the development or field evaluation of a low-emission motor vehicle easier, and the safety level of the vehicle is not unreasonably lowered; or
- (iv) compliance would prevent the manufacturer from selling a motor vehicle with an overall safety level at least equal to the overall safety level of nonexempt vehicles.⁴

NHTSA established 49 CFR part 555, *Temporary Exemption from Motor Vehicle Safety and Bumper Standards*, to implement the statutory provisions concerning temporary exemptions, including renewals of temporary exemptions. Under Part 555 subpart A, a vehicle manufacturer seeking an exemption or renewal of an exemption must submit a petition for exemption containing specified information. The requirements in 49 CFR 555.5 state that the petitioner must set forth the basis of the petition by providing the information required under 49 CFR

¹ 49 CFR 1.95.

² 49 U.S.C. 30113(b)(3).

³ 49 U.S.C. 30113(b)(3)(A).

⁴ 49 U.S.C. 30113(b)(3)(B).

555.6, and the reasons why the exemption would be in the public interest and consistent with the objectives of the Safety Act. Nix Coach Interiors, LLC's petition, which was submitted on the basis that the applicant is otherwise unable to sell a vehicle whose overall level of safety or impact protection is at least equal to that of a nonexempt vehicle must include the information specified in 49 CFR 555.6(d). A manufacturer is eligible for an exemption on this basis only if NHTSA determines the exemption is for not more than 2,500 vehicles to be sold in the U.S. in any 12-month period. An exemption on this basis may be granted for not more than two years but may be renewed upon reapplication.⁵

b. FMVSS No. 208

On November 25, 2013, NHTSA published a final rule amending FMVSS No. 208 to require seat belts for each passenger seating position in all new over-the-road buses (OTRBs) regardless of gross vehicle weight rating (GVWR), and all other buses with GVWRs greater than 11,793 kilograms (kg) (26,000 pounds (lb)) (with certain exclusions).⁶

In the notice of proposed rulemaking (NPRM) preceding the final rule (75 FR 50958, August 18, 2010), NHTSA proposed to permit manufacturers the option of installing either a Type 1 (lap belt) or a Type 2 (lap and shoulder belt) on side-facing seats.⁷ The proposed option was consistent with an existing provision in FMVSS No. 208 that allows lap belts for side-facing seats on buses with a GVWR of 4,536 kg (10,000 lb) or less. NHTSA proposed the option because the agency was unaware of any demonstrable increase in associated risks using lap belts when compared to using lap and shoulder belts on side-facing seats. In the NPRM, NHTSA noted that "a study commissioned by the European Commission regarding side-facing seats on minibuses and motorcoaches found that due to different seat belt designs, crash modes and a lack of real-world data, it cannot be determined whether a lap belt or a lap/shoulder belt would be the most effective."⁸

However, after the NPRM was published, the Motorcoach Enhanced Safety Act of 2012 was enacted as part

of the Moving Ahead for Progress in the 21st Century Act ((MAP-21), Public Law 112-141 (July 6, 2012)). Section 32703(a) of MAP-21 directed the Secretary of Transportation (with authority delegated to NHTSA) to "prescribe regulations requiring safety belts to be installed in motorcoaches at each designated seating position."⁹ As MAP-21 defined "safety belt" to mean an integrated lap and shoulder belt, the final rule amended FMVSS No. 208 to require lap and shoulder belts at all designated seating positions, including side-facing seats, on OTRBs.¹⁰

Even as it did so, however, the agency reiterated its view that "the addition of a shoulder belt at [side-facing seats on light vehicles] is of limited value, given the paucity of data related to side facing seats."¹¹ The agency also noted that Australian Design Rule ADR 5/04, "Anchorages for Seatbelts" specifically prohibits shoulder belts for side-facing seats.¹² Given that background, and believing there would be few side-facing seats on OTRBs, NHTSA stated in the November 2013 final rule that manufacturers may petition NHTSA for a temporary exemption under 49 CFR part 555 to install lap belts instead of lap and shoulder belts at side-facing seats.¹³ NHTSA further explained that a manufacturer could seek such an exemption on the basis that the applicant is otherwise unable to sell a vehicle whose overall level of safety is at least equal to that of a nonexempted vehicle, stating that the agency would be receptive to an argument that, for side-facing seats, lap belts provide an equivalent level of safety to lap and shoulder belts.¹⁴

Since issuing the November 2013 final rule, NHTSA has granted temporary exemptions to sixteen final stage manufacturers of entertainer buses

for the same shoulder belt requirement in FMVSS No. 208 for side-facing seats on entertainer buses.¹⁵

In a recent decision notice granting one of these exemptions,¹⁶ NHTSA's rationale for granting the exemption cited the uncertainties about shoulder belts on side-facing seats, the relatively small number of side-facing seats on buses subject to the November 2013 final rule, and that FMVSS No. 208 does not require shoulder belts on side-facing seats on any other vehicle type.¹⁷ NHTSA stated that it believes the potential safety risk at issue is theoretical, as explained in the in November 2013 final rule, and that the agency could not affirmatively conclude, based on available information, that shoulder belts on side-facing seats are associated with a demonstrated risk of serious neck injuries in front crashes. NHTSA also stated that it believes a shoulder belt is of limited value on side-facing seats for the reasons explained in the final rule and further explained that it believed granting the exemption is consistent with the public interest and the Safety Act.

II. Receipt of Petition

In accordance with 49 U.S.C. 30113 and the procedures in 49 CFR part 555, a final-stage manufacturer of entertainer motorcoaches has submitted a petition asking NHTSA for a temporary exemption from the shoulder belt requirement of FMVSS No. 208 for side-facing seats on its vehicles. The petitioner seeks an exemption to allow them the option of installing Type 1 seat belts (lap belt only) at side-facing seating locations, instead of Type 2 seat belts (lap and shoulder belts) as required by FMVSS No. 208. The basis

⁹ MAP-21 states at § 32702(6) that "the term 'motorcoach' has the meaning given the term 'over-the-road bus' in section 3038(a)(3) of the Transportation Equity Act for the 21st Century (49 U.S.C. 5310 note), but does not include a bus used in public transportation provided by, or on behalf of, a public transportation agency; or a school bus, including a multifunction school activity bus." Section 3038(a)(3) (49 U.S.C. 5310 note) states: "The term 'over-the-road bus' means a bus characterized by an elevated passenger deck located over a baggage compartment."

¹⁰ For side-facing seats on buses other than OTRBs, in the final rule NHTSA permitted either lap or lap/shoulder belts at the manufacturer's option.

¹¹ 78 FR at 70448 (quoting the agency's Anton's Law final rule, which required lap/shoulder belts in forward-facing rear seating positions of light vehicles, 59 FR 70907).

¹² Fildes, B., Digges, K., "Occupant Protection in Far Side Crashes," Monash University Accident Research Center, Report No. 294, April 2010, pg. 57.

¹³ *Id.*

¹⁴ *Id.*

¹⁵ The first petition was submitted by Hemphill Brothers Leasing Company, LLC (Hemphill). (Notice of receipt of petition, 84 FR 11735 (March 28, 2019); notice of grant of petition, 84 FR 61966 (November 14, 2019)). In its original petition, Hemphill stated that thirty-nine "other petitioners" were covered by it. Later, NHTSA granted the thirteen petitions submitted by All Access Coach Leasing LLC, Amadas Coach, Creative Mobile Interiors, D&S Classic Coach Inc., Farber Specialty Vehicles, Florida Coach, Inc., Geomarc, Inc., Integrity Interiors LLC, Nitetrain Coach Company, Inc., Pioneer Coach Interiors LLC, Roberts Brothers Coach Company, Russell Coachworks LLC, and Ultra Coach Inc. (Notice of receipt of the petitions, 85 FR 51550 (August 20, 2020); notice of grant of petitions, 87 FR 33299 (June 1, 2022)). NHTSA then granted an exemption to Beat the Street Interiors, Inc. (BTS). (Notice of receipt of petition, 88 FR 25445 (April 26, 2023); notice of grant of petition, 88 FR 78093 (November 14, 2023)). Most recently, NHTSA granted an exemption to Legacy Limousines and Luxury Coaches. (Notice of receipt of petition, 89 FR 87722 (November 4, 2024); notice of grant of petition, 90 FR 7234 (January 21, 2025)).

¹⁶ 88 FR 25445.

¹⁷ 88 FR 25445.

⁵ 555.8(b) and 555.8(e).

⁶ 78 FR 70415 (November 25, 2013); response to petitions for reconsideration, 81 FR 19902 (April 6, 2016). The final rule became effective November 28, 2016 for buses manufactured in a single stage, and a year later for buses manufactured in more than one stage.

⁷ 75 FR at 50971.

⁸ 75 FR at 50971-50972 (citing http://ec.europa.eu/enterprise/automotive/projects/safety_consider_long_stg.pdf).

of the petition is that compliance would prevent the petitioner from selling a motor vehicle whose overall level of safety is equivalent to or exceeds the overall level of safety of non-exempted motor vehicles (49 CFR 555.6(d)).

A copy of this petition has been placed in the docket listed in the heading of this notice. To view the petition, go to <http://www.regulations.gov> and enter the docket number in the heading.

a. Brief Overview of the Petition

The petitioner states that it is a final-stage manufacturer of entertainer-type motorcoaches and is responsible for ensuring the completed vehicle meets the FMVSS. The petitioner also states that it typically receives a bus shell¹⁸ from an incomplete vehicle manufacturer and customizes it to meet the needs of its entertainer clients, politician clients, celebrity clients, and other specialized customers. The petitioner states that it “builds out the complete interior of the vehicle” of the bus shell, which might include: roof escape hatch; fire suppression systems (interior living space, rear tires, electrical panels, bay storage compartments, and generator); ceiling, side walls and flooring; seating; electrical system, generator, inverter and house batteries; interior lighting; interior entertainment equipment; heating, ventilation and cooling system; galley with potable water, cooking equipment, refrigerators, and storage cabinets; bathroom and showers; and sleeping positions.

Pursuant to 49 CFR 555.6(d), an application must provide “[a] detailed analysis of how the vehicle provides the overall level of safety or impact protection at least equal to that of nonexempted vehicles.”

The petitioner reiterates, as part of their justification that the vehicles provide an overall level of safety equivalent to that of a nonexempted vehicle, statements made in NHTSA’s 2013 final rule. Specifically, the petitioner cites NHTSA’s statement that it believed “the addition of a shoulder belt at this seat position is of limited value, given the paucity of data related to side facing seats.” Amongst other concerns, the petitioner also cites NHTSA’s conclusion in the 2013 final

rule that: “[t]here is not sufficient information that substantiates concerns about lap/shoulder belts on side-facing seats to a degree that would support prohibiting such belts.” Additional details are provided in the petition, which may be located in the docket identified at the top of this document.

Pursuant to 49 CFR 555.5(b)(7), petitioner must state why granting an exemption allowing it to install Type 1 instead of Type 2 seat belts in side-facing seats would be in the public interest and consistent with the objectives of the Safety Act. The petitioner states that granting it an exemption would be in the public interest as it would allow the petitioner the option to install Type 1 lap belts at sideways-facing seating positions. This would be in line with NHTSA’s analysis in development of the 2013 final rule, which found that “such belts presented no demonstrable increase in associated risk,” and that “Type 2 belts at side-facing seats might cause serious neck injuries.”

In support of the petition, the petitioner also states that fewer than 100 entertainer-type motorcoaches with side-facing seats are manufactured in the U.S. market each year and indicated that the number of exempted vehicles the petitioner would manufacture would be well below the limit.

The petitioner also indicates that it expects to seek to renew this exemption, if granted, at the end of the exemption period. In support of this intention, the petitioner notes the agency’s apparent lack of research, testing, or analysis to justify the use of Type 2 belts on side-facing seats in over-the-road-buses.

IV. Comment Period

The agency seeks comments from the public on the merits of the petition requesting a temporary exemption from FMVSS No. 208’s shoulder belt requirement for side-facing seats. The petitioner seeks to install lap belts at the side-facing seats; they do not seek to be completely exempted from a belt requirement. Further, the petitioner’s request does not pertain to forward-facing designated seating positions on their vehicles. Under FMVSS No. 208, forward-facing seating positions on motorcoaches must have Type 2 lap and shoulder belts, and the petitioner is not seeking an exemption from that requirement for forward-facing seats. After considering public comments and other available information, NHTSA will publish a notice of final action on the petition in the **Federal Register**.

Authority: 49 U.S.C. 30113; delegation of authority at 49 CFR 1.95 and 501.5.

Peter Simshauser,
Chief Counsel.

[FR Doc. 2025–14384 Filed 7–29–25; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Financial Crimes Enforcement Network (FinCEN) Information Collection Requests

AGENCY: Financial Crimes Enforcement Network, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to comment on proposed or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Comments should be received on or before August 29, 2025 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

Copies of the submissions may be obtained from Melody Braswell by emailing PRA@treasury.gov, calling (202) 622–1035, or viewing the entire information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION: CRIMES ENFORCEMENT NETWORK (FINCEN)

1. *Title:* Prohibition on Correspondent Accounts for Foreign Shell Banks; Records Concerning Owners of Foreign Banks and Agents for Service of Legal Process.

OMB Control Number: 1506–0043.
Form Number: Optional form—certification regarding correspondent accounts for foreign banks.

Abstract: FinCEN is issuing this notice to renew the OMB control number for regulations prohibiting a covered financial institution from maintaining correspondent accounts for foreign shell banks and requiring a covered financial institution to maintain

¹⁸ The petition describes the bus shell as generally containing the following components: exterior frame; driver’s seat; dash cluster, speedometer, emissions light and emissions diagnosis connector; exterior lighting, headlights, marker lights, turn signal lights, and brake lights; exterior glass, windshield and side lights with emergency exits; windshield wiper system; braking system; tires, tire pressure monitoring system and suspension; and engine and transmission.

records identifying the owners of certain foreign banks and agents residing in the United States who have agreed to accept service of legal process for records regarding correspondent accounts.

Affected Public: Businesses or other for-profit institutions, and non-profit institutions.

Type of Review: Renewal without change of a currently approved information collection.

Estimated Number of Potential Respondents: 12,637.

Estimated Number of Expected Respondents: 104.

Frequency of Response: As required.

Estimated Total Number of Annual Responses: 18,408.

Estimated Time per Response: 4 hours.

Estimated Total Annual Burden Hours: 73,632 hours.

2. Title: Additional records to be made and retained by casinos.

OMB Control Number: 1506–0054.

Abstract: FinCEN is issuing this notice to renew the OMB control number for regulations requiring additional records to be made and retained by casinos.

Affected Public: Businesses or other for-profit institutions.

Type of Review: Renewal without change of a currently approved information collection.

Estimated Number of Respondents: 1292.

Frequency of Response: As required.

Estimated Total Number of Annual Responses: 2,183,460.

Estimated Average Recordkeeping Time per Response: 5 hours.

Estimated Total Annual Burden Hours: 118,863 hours.

3. Title: Reports of transactions with foreign financial agencies.

OMB Control Number: 1506–0055.

Abstract: FinCEN is issuing this notice to renew the OMB control number for regulations requiring reports of transactions with designated FFAs.

Affected Public: Businesses or other for-profit institutions, and non-profit institutions.

Type of Review: Renewal without change of a currently approved information collection.

Estimated Number of Potential Respondents: 1292.

Estimated Number of Expected Respondents: 40.

Frequency of Response: As required.

Estimated Total Number of Annual Responses: 2,183,460.

Estimated Average Time per Response: 301 hours.

Estimated Total Annual Burden Hours: 118,863 hours.

4. Title: Reporting obligations on foreign bank relationships with Iranian-linked financial institutions designated under IEEPA and IRGC-linked persons designated under IEEPA.

OMB Control Number: 1506–0066.

Form Number: Optional form—certification for purposes of section 104(e) of CISADA.

Abstract: FinCEN is issuing this notice to renew the OMB control number for the CISADA regulations that require, upon receiving a CISADA Request, a U.S. bank that maintains a correspondent account for a specified foreign bank to inquire with the foreign bank and report to FinCEN with respect to transactions or other financial services provided by that foreign bank to Iranian-linked financial institutions and IRGC-linked persons.

Affected Public: Businesses or other for-profit institutions, and non-profit institutions.

Type of Review: Renewal without change of a currently approved information collection.

Estimated Number of Respondents: 9,384.

Frequency of Response: As required.

Estimated Total Number of Annual Responses: 72.

Estimated Average Time per Response: 45 minutes.

Estimated Total Annual Burden Hours: 156 hours.

Authority: 44 U.S.C. 3501 *et seq.*

Melody Braswell,

Treasury PRA Clearance Officer.

[FR Doc. 2025–14405 Filed 7–29–25; 8:45 am]

BILLING CODE 4810–02–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Homeowner Assistance Fund (HAF) Program Quarterly and Annual Report Forms

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to comment on the proposed information collections listed below, in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments should be received on or before August 29, 2025 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

Copies of the submissions may be obtained from Melody Braswell by emailing PRA@treasury.gov, calling (202) 622–1035, or viewing the entire information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

Title: The Homeowner Assistance Fund (HAF) Quarterly and Annual Reports, instructions and Treasury’s Portal User Guide.

OMB Control Number: 1505–0269.

Type of Review: Extension without change of a currently approved collection.

Description: The HAF authorized by the American Rescue Plan Act, provides \$9.961 billion to support homeowners facing financial hardship associated with COVID–19. HAF funds were distributed to states, U.S. Territories, and Indian Tribes. Funds from HAF may be used for assistance with mortgage payments, homeowner’s insurance, utility payments, and other specified purposes. HAF grantees must submit quarterly and annual report forms on their utilization of HAF award funds. The information can be submitted electronically via Treasury’s Portal. The information collection will permit Treasury to effectively monitor the HAF grantees’ compliance with the requirements of the HAF Award Terms.

Form: None.

Affected Public: State, Tribal and Territorial Governments.

Estimated Number of Respondents: 1,442.

Frequency of Response: As required.

Estimated Total Number of Annual Responses: 1,698.

Estimated Average Time per Response: 3 hours.

Estimated Total Annual Burden Hours: 5,527 hours.

(Authority: 44 U.S.C. 3501 *et seq.*)

Melody Braswell,

Treasury PRA Clearance Officer.

[FR Doc. 2025–14424 Filed 7–29–25; 8:45 am]

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Reader Aids

Federal Register

Vol. 90, No. 144

Wednesday, July 30, 2025

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FEDERAL REGISTER PAGES AND DATE, JULY

27973-28868	1
28869-29392	2
29393-29716	3
29717-29984	7
29985-30196	8
30197-30554	9
30555-30824	10
30825-31130	11
31131-31582	14
31583-31852	15
31853-33262	16
33263-33870	17
33871-34164	18
34165-34346	21
34347-34582	22
34583-34760	23
34761-35222	24
35223-35384	25
35385-35588	28
35589-35826	29
35827-35964	30

CFR PARTS AFFECTED DURING JULY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR	June 30, 2025	29409
Proclamations:	5 CFR	
10955	755	35223
10956	1201	34347
10957	1605	30825
10958	1655	30203
10959		
Executive Orders:	Proposed Rules:	
13338 (revoked by EO	300	31594
14312)	550	31594
13399 (revoked by EO	731	29512
14312)	2419	30019
13460 (revoked by EO		
14312)	7 CFR	
13572 (revoked by EO	1b	29632, 33871, 34165
14312)	9	30555
13573 (revoked by EO	372	29632, 33871, 34165
14312)	400	30555
13582 (revoked by EO	520	29632, 33871, 34165
14312)	636	30555
13606 (amended by	650	29632, 33871, 34165
EO 14312)	760	30555, 30561, 35234
13894 (amended by	761	30555
EO 14312)	762	30555
14311	767	30555
14312	799	29632, 33871, 34165
14313	1405	31583
14314	1410	30555
14315	1424	31583
14316	1429	31583
14317	1465	30555
14318	1467	30555
14319	1468	30555
14320	1560	33871
14321	1570	33871
14322	1767	33872
	1970	29632, 33871, 34165
Administrative Orders:	3407	29632, 33871, 34165
Notices:	4280	30555
Notice of July 10,	5001	30555
2025		
Notice of July 15,	9 CFR	
2025	424	27973
Notice of July 21,	10 CFR	
2025	12	33263
Notice of July 21,	13	33263
2025	52	28869
Notice of July 25,	72	35589
2025	170	35397
Orders:	171	35397
Order of July 8,	205	29676, 31131
2025	207	31131
Presidential Permits:	460	28873
Presidential Permit of	590	31132
July 29, 2020	600	31133
(superseded and	626	31134
revoked by Permit of	708	31136
June 30, 2025)	800	31137
29405	1000	31138
Presidential Permit of	1003	31139
June 30, 2025	1021	29676
29405	1040	31140
Presidential Permit of		

1042.....31141
Proposed Rules:
50 34190, 34609, 35441,
35445
52 28911
72 35640

12 CFR

3.....30780
6.....30780
208.....30780
217.....30780
252.....30780
303.....29413
324.....30780
Ch. VII.....30596
1082.....34165

Proposed Rules:

Ch. I.....35241
24.....34086
25.....34086
35.....34086
Ch. II.....35241
207.....34086
228.....34086
Ch. III.....35241
303.....33898, 35449
314.....35449
335.....35449
340.....35449
345.....33898, 34086
346.....34086
347.....35449
354.....33910
363.....35449
380.....35449
1293.....35475

13 CFR

301.....28878
302.....29417

Proposed Rules:

107.....29794

14 CFR

1.....35034
21.....35034
22.....35034
36.....35034
39.....27975, 27977, 27979,
28879, 28882, 28885, 29717,
30575, 30577, 30581, 30583,
30585, 30588, 31583, 34165,
34168, 34171, 34174, 34176,
34178, 34348, 34352, 35594,
35827, 35829, 35831
43.....35034
45.....35034
61.....35034
65.....35034
71.....29419, 29420, 29422,
29719, 30204, 30590, 31141,
31853, 33267, 34180, 35234
73.....31143, 31854, 34593
91.....27981, 35034
95.....31855
97.....31865, 31866, 34761
119.....35034
147.....35034

Proposed Rules:

39.....28237, 28913, 28916,
29512, 29802, 29804, 30024,
30027, 30030, 30829, 34386,
34388, 34391, 34612, 34774,
35483, 35486, 35642
71.....30831, 34777, 35251

15 CFR**Proposed Rules:**

970.....29806
971.....29806

17 CFR

232.....27987
240.....27990

18 CFR

40.....28889, 35599
380.....29423
385.....29423

19 CFR

12.....35397

20 CFR

660.....27992
661.....27992
662.....27992
663.....27992
664.....27992
665.....27992
666.....27992
667.....27992
668.....27992
669.....27992
670.....27992
671.....27992
672.....27992

Proposed Rules:

651.....28919
652.....28239
653.....28919
655.....28919
658.....28919

21 CFR

16.....35407
73.....31586
145.....33268
155.....33268
1308.....35236

Proposed Rules:

131.....33334
133.....33334
135.....33334
136.....33339
139.....33339
145.....33346
146.....33334
155.....33346
161.....33339
169.....33339
172.....35645
184.....33334
573.....35645
1308.....35253

22 CFR

120.....29720
126.....29720

23 CFR

771.....29426
1300.....31590

26 CFR

1.....30825
301.....33895

Proposed Rules:

1.....28946

28 CFR

85.....29445

Proposed Rules:

25.....34394
107.....34394

29 CFR

2.....27995
37.....27999
95.....28002
96.....28002
97.....28002
99.....28002
1911.....27996, 30205
1912.....27996, 30205
2509.....28004
2550.....28007, 28009
4044.....28899

Proposed Rules:

29.....28947
30.....28947
38.....28245
42.....28247
403.....28251
404.....28255
501.....28919
525.....29817
552.....28976
775.....28985
776.....28985
779.....28985
782.....28985
783.....28985
784.....28985
789.....28985
793.....28985
794.....28985
1904.....28257
1910.....28263, 28267, 28272,
28277, 28282, 28286, 28291,
28295, 28302, 28307, 28312,
28316, 28321, 28325, 28330,
28336, 28349, 28354, 28363
1915.....28263, 28267, 28272,
28277, 28282, 28286, 28291,
28295, 28302, 28307, 28312,
28316, 28321, 28325, 28330,
28336
1917.....28263, 28267, 28272,
28277, 28286, 28291, 28295,
28302, 28307, 28312, 28316,
28321, 28325, 28330, 28336,
28349, 28354, 28358, 28362
1918.....28263, 28267, 28272,
28277, 28286, 28291, 28295,
28302, 28307, 28312, 28316,
28321, 28325, 28330, 28336,
28349
1926.....28263, 28267, 28272,
28277, 28286, 28291, 28295,
28302, 28307, 28312, 28316,
28321, 28325, 28330, 28336,
28354, 28366
1928.....28330, 28336
1975.....28370
2510.....35646
2520.....35646
2550.....35646

30 CFR

250.....34596
556.....34353
938.....35407
948.....35417

Proposed Rules:

47.....28375
48.....28383, 34405
56.....28390, 28392, 28395

57.....28395, 28400, 28403,
28406, 34405
72.....28418
75.....28395, 28406, 28421,
28424, 28426, 28429, 28432,
28438, 28440, 28443, 28454,
34405, 34406, 34407
77.....28395

31 CFR

528.....28012
587.....34596, 34597
591.....34598
594.....30205, 34600
597.....30205
1010.....30826

32 CFR

199.....35422
310.....35434
651.....29450
775.....29453
935.....34763
989.....28021

Proposed Rules:

310.....34197, 35488

33 CFR

100.....28901, 29985, 31868,
34181, 35616, 35835
165.....28901, 28903, 29457,
29459, 29725, 29726, 29728,
29986, 29987, 29988, 30208,
31868, 31870, 31872, 33896,
34356, 34358, 34600, 35436,
35437, 35617, 35836
230.....29461
320.....29465
325.....29465, 31593
333.....29465

Proposed Rules:

100.....34200
117.....34778
165.....30603, 35839

34 CFR

Ch. III.....35439
668.....29734

Proposed Rules:

75.....34203
Ch. II.....33349, 33353
Ch. VI.....35261, 35652

36 CFR

220.....29632, 33871, 34165
242.....34142, 34152

37 CFR

1.....29990

38 CFR

9.....28904

Proposed Rules:

17.....34407

39 CFR

955.....29485
962.....33272

Proposed Rules:

3030.....30606
3050.....31158

40 CFR

9.....34184, 34602
52.....29737, 29742, 29743,

29745, 29934, 29993, 30591, 30593, 31872, 31877, 31881, 31882, 34763, 34766, 34768, 34770 59.....28904 62.....29749 63.....29485, 29997 80.....29751 81.....34770, 35619 180.....31890, 31894, 33277, 34602, 35620 257.....34358 300.....29491 721.....33283, 34184, 34602, 35624 725.....35624 745.....30211	495.....32352 498.....29108, 30217, 30833 512.....28342, 32352	43 CFR 46.....29498 51.....34142, 34152 1850.....33299 3200.....33301, 33303, 33305, 33307, 33308 3500.....33310 3710.....33313 3730.....33314, 34366 3800.....33316, 33318 3810.....33320 3820.....33321, 33323, 34368 3830.....33325, 33327, 33328 3834.....33330	45 CFR Proposed Rules: 180.....33476	46 CFR 315.....28024 317.....28027 324.....28027 325.....28027 326.....28027 328.....28027 329.....28027 330.....28027 332.....28027 335.....28027 336.....28027 337.....28027 338.....28027 339.....28027 340.....28029 345.....28029 346.....28029 347.....28029	Proposed Rules: 327.....28504 355.....28513 356.....28519	47 CFR 1.....28032, 29760, 31145, 35238 54.....30213 73.....33332, 33333, 34185, 35238 74.....35238 76.....31145, 35238	Proposed Rules: 0.....31945 1.....31945 2.....31945 9.....31945 27.....31595 51.....29830 54.....29830 61.....29830 69.....29830 73.....30032, 33911	48 CFR 9.....29773	Proposed Rules: 11.....34208 12.....34208 52.....34208 235.....33911 252.....33911, 33912	49 CFR 172.....28044 173.....28044 174.....28044 179.....28044 180.....28044 190.....28044 191.....28047, 28050 192.....28054, 28057, 28061, 28064, 28068, 28072, 28075, 28079, 28082, 28086, 28090, 28094, 28097, 28101, 28105, 28108, 28112 195.....28050, 28101, 28105, 28108, 28112, 28116, 28119 209.....28123 211.....28128 212.....28130 213.....28134 214.....28136 215.....28138 216.....28140 217.....28123 218.....28142 219.....28123, 28144 220.....28146 221.....28148 222.....28150 223.....28123, 28153 224.....28123, 28155 225.....28123, 28156, 34370 227.....28123, 28158 228.....28160, 28162 229.....28164 230.....28123, 28165 231.....28168 232.....28171 233.....28173 234.....28174 235.....28176 236.....28178, 28180 237.....28183 238.....28123, 28185 239.....28123, 28188 240.....28123 241.....28123, 28190 242.....28123 243.....28123, 28192 244.....28123, 28194 245.....28123 246.....28123 264.....29426 270.....28195 271.....29198 272.....28201 520.....29507 571.....28909 572.....28909 601.....28203 604.....28210 605.....28223 609.....28227	611.....28229 622.....29426 625.....28235	Proposed Rules: 107.....28524, 28528, 28531, 28534 171.....28534, 28540, 28544, 28548, 28552, 28556 172.....28534, 28544, 28560, 28563, 28566, 28571 173.....28534, 28544, 28548, 28552, 28566, 28571, 28574, 28578 174.....28556 177.....28541 180.....28585 190.....28590 192.....28593, 28597, 28600, 28603, 28606 209.....28609, 28612, 28622 213.....28622, 28626 214.....28629 215.....28633, 28636, 28639 217.....28622 219.....28622 222.....28643, 28646 225.....28648, 28651, 28654 227.....28622 229.....28622, 28658, 28660 230.....28622 232.....28622, 28660, 28667 237.....28669 238.....28622, 28660 239.....28622 240.....28622, 28672, 28676 241.....28622 242.....28622, 28676, 28684 392.....30217 393.....30217, 34822 571.....34822 602.....28688 633.....28690 650.....28693 671.....28695 672.....28697 675.....28700	50 CFR 17.....30004, 34372 100.....34142 217.....30215, 31756 223.....31800 226.....31800 300.....29774, 34384 622.....30827, 34186 635.....29792 648.....30828 660.....34186 679.....29774, 31899, 33896, 33897	Proposed Rules: 17.....28701, 31951 217.....34974, 35762 218.....32118 226.....30833
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