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FEDERAL REGISTER

Vol. 87 Monday
No. 99 May 23, 2022

Pages 31093–31356

OFFICE OF THE FEDERAL REGISTER

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Contents

Federal Register

Vol. 87, No. 99

Monday, May 23, 2022

Agriculture Department
See Office of Partnerships and Public Engagement
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 31207

Alcohol and Tobacco Tax and Trade Bureau
RULES
Establishment of Viticultural Area:
West Sonoma Coast, 31164–31182

Army Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 31219

Centers for Disease Control and Prevention
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 31237–31240
Meetings:
Board of Scientific Counselors, National Center for Injury Prevention and Control, 31240–31241

Centers for Medicare & Medicaid Services
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Medicaid and Children's Health Insurance Program, 31242–31243
Medicare and Medicaid Programs:
Application from the National Dialysis Accreditation Commission for Continued Approval of Its End Stage Renal Disease Facility Accreditation Program, 31241–31242

Civil Rights Commission
NOTICES
Meetings:
Arkansas Advisory Committee, 31208–31209

Coast Guard
RULES
Drawbridge Operations:
Rancocas Creek, Burlington County, NJ, 31182–31183
Safety Zones:
Lower Mississippi River, Mile Marker 807, Barfield Bend, TN, 31183–31185
PROPOSED RULES
Safety Zones:
Lake Erie, Cleveland, OH, 31203–31206
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 31248–31252

Commerce Department
See Industry and Security Bureau
See International Trade Administration
See National Oceanic and Atmospheric Administration

Commodity Futures Trading Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Daily Trade and Supporting Data Reports, 31217–31218

Community Living Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
The National Adult Maltreatment Reporting System, 31243–31245

Comptroller of the Currency
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Funding and Liquidity Risk Management, 31297–31298
Request for COVID–19 Vaccine Status and Proof of Vaccination, 31295–31297
Securities Exchange Act Disclosure Rules, 31298–31299

Consumer Product Safety Commission
NOTICES
Meetings; Sunshine Act, 31218

Corporation for National and Community Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
NCCC Service Project Application, 31218–31219

Defense Department
See Army Department
See Navy Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 31219–31221

Drug Enforcement Administration
NOTICES
Importer, Manufacturer or Bulk Manufacturer of Controlled Substances; Application, Registration, etc.:
Scottsdale Research Institute, 31259

Employee Benefits Security Administration
RULES
Annual Information Return/Reports, 31133–31164

Employment and Training Administration
RULES
Exercise of Time-Limited Authority to Increase the Numerical Limitation for Second Half of FY 2022:
H–2B Temporary Nonagricultural Worker Program and Portability Flexibility for H–2B Workers Seeking to Change Employers; Correction, 31095

Energy Department
See Energy Information Administration
See Federal Energy Regulatory Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 31222

Meetings:
Environmental Management Site-Specific Advisory Board, Idaho Cleanup Project, 31222–31223

Energy Information Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 31223–31225

Environmental Protection Agency
RULES
National Emission Standards for Hazardous Air Pollutants: General Provisions; Technical Correction, 31185–31186
Pesticide Tolerance; Exemptions, Petitions, Revocations, etc.:
Fluopicolide, 31186–31190
NOTICES
Proposed Consent Decree:
Clean Air Act Citizen Suit, 31233–31234

Export-Import Bank
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 31234–31235

Federal Aviation Administration
RULES
Airspace Designations and Reporting Points:
Wiggins, MS, 31132–31133
Airworthiness Directives:
Airbus Helicopters and Airbus Helicopters Deutschland GmbH (AHD) Helicopters, 31116–31119
Airbus SAS Airplanes, 31123–31125, 31129–31131
CFM International, S.A. Turbofan Engines, 31119–31123
Piper Aircraft, Inc. Airplanes, 31095–31097
Sikorsky Aircraft Corporation Helicopters, 31125–31129
The Boeing Company Airplanes, 31097–31116
PROPOSED RULES
Airspace Designations and Reporting Points:
Greenwood, SC, 31193–31195
Poughkeepsie, NY, 31192–31193

Federal Election Commission
NOTICES
Meetings; Sunshine Act, 31235

Federal Emergency Management Agency
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Grants Reporting Tool, 31253–31254

Federal Energy Regulatory Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 31226–31228
Annual Change in the Producer Price Index for Finished Goods:
Revisions to Oil Pipeline Regulations Pursuant to the Energy Policy Act of 1992, 31232–31233
Combined Filings, 31225, 31230–31231
Environmental Impact Statements; Availability, etc.:
Northern Natural Gas Co.; Northern Lights 2023 Expansion Project, 31228–31230
Initial Market-Based Rate Filings Including Requests for Blanket Section 204 Authorizations:
Ledyard Windpower, LLC, 31233
Sanford ESS, LLC, 31231–31232
South Portland ESS, LLC, 31226
Vansycle II Wind, LLC, 31226
VESI 10, LLC, 31232

Federal Highway Administration
NOTICES
Final Federal Agency Action:
Proposed Highway Projects in Texas, 31293–31295

Federal Reserve System
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 31235–31236
Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 31236–31237
Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies, 31237

Food and Drug Administration
PROPOSED RULES
Current Good Manufacturing Practice, Certification, Postmarketing Safety Reporting, and Labeling Requirements for Certain Medical Gases, 31302–31356
NOTICES
Charter Amendments, Establishments, Renewals and Terminations:
Gastrointestinal Drugs Advisory Committee; Correction, 31245

Health and Human Services Department
See Centers for Disease Control and Prevention
See Centers for Medicare & Medicaid Services
See Community Living Administration
See Food and Drug Administration
See National Institutes of Health
See Substance Abuse and Mental Health Services Administration
NOTICES
Meetings:
Presidential Advisory Council on Combating Antibiotic–Resistant Bacteria, 31245–31246

Homeland Security Department
See Coast Guard
See Federal Emergency Management Agency
See U.S. Citizenship and Immigration Services
See U.S. Customs and Border Protection
RULES
Exercise of Time-Limited Authority to Increase the Numerical Limitation for Second Half of FY 2022:
H–2B Temporary Nonagricultural Worker Program and Portability Flexibility for H–2B Workers Seeking to Change Employers; Correction, 31095
Ratification of Security Directives, 31093–31094
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Migrant Protection Protocols Disenrollment Request System, 31254–31255

Housing and Urban Development Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Promise Zones Preference Point Certification Form; Correction, 31258–31259

Industry and Security Bureau
PROPOSED RULES
Commerce Control List:
Controls on Certain Marine Toxins, 31195–31203

Internal Revenue Service
RULES
Annual Information Return/Reports, 31133–31164
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Burden Related to the Quarterly Federal Excise Tax Returns, 31299–31300

International Trade Administration
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
Seamless Refined Copper Pipe and Tube from the People's Republic of China and Mexico, 31209–31210

Justice Department
See Drug Enforcement Administration

Labor Department
See Employee Benefits Security Administration
See Employment and Training Administration
See Labor Statistics Bureau
See Mine Safety and Health Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
H–2A Sheepherder Recordkeeping Requirement, 31260
H–2B Application for Temporary Employment Certification, 31259–31260

Labor Statistics Bureau
NOTICES
Meetings:
Technical Advisory Committee, 31260–31261

Mine Safety and Health Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Respirable Coal Mine Dust Sampling, 31261–31268

National Institutes of Health
NOTICES
Meetings:
Center for Scientific Review, 31246
National Institute of Diabetes and Digestive and Kidney Diseases, 31247
National Institute on Aging, 31247
National Library of Medicine, 31247

National Oceanic and Atmospheric Administration
RULES
Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic:
Snapper-Grouper Resources of the South Atlantic; 2022 Red Snapper Commercial and Recreational Fishing Seasons, 31190–31191
NOTICES
Environmental Impact Statements; Availability, etc.:
Identification of One or More Aquaculture Opportunity Area(s) in Southern California, 31210–31213
Fisheries Draft Climate Regional Action Plans (2022–2024), 31215–31216
Meetings:
Fisheries of the Gulf of Mexico; Southeast Data, Assessment, and Review, 31214
New England Fishery Management Council, 31215–31217
Permits; Applications, Issuances, etc.:
Marine Mammals; File No. 25754, 31210
Marine Mammals; File No. 26394, 31213–31214

National Science Foundation
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 31268

Navy Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 31221–31222

Nuclear Regulatory Commission
NOTICES
Meetings; Sunshine Act, 31268–31269

Office of Partnerships and Public Engagement
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Entities Serving Socially Disadvantaged/Veteran Farmers and Ranchers, 31207–31208

Pension Benefit Guaranty Corporation
RULES
Annual Information Return/Reports, 31133–31164

Securities and Exchange Commission
NOTICES
Application and Temporary Order:
Allianz Global Investors U.S., LLC, et al., 31275–31280
Meetings; Sunshine Act, 31283
Self-Regulatory Organizations; Proposed Rule Changes:
Cboe Exchange, Inc., 31287–31290
MIAX PEARL, LLC, 31269–31275
Nasdaq BX, Inc., 31283–31285
Nasdaq GEMX, LLC, 31290–31292
Nasdaq MRX, LLC, 31285–31287
New York Stock Exchange, LLC, 31280–31283

Small Business Administration
NOTICES
Class Waiver of the Nonmanufacturer Rule, 31292–31293

State Department
NOTICES
Culturally Significant Objects Imported for Exhibition:
Park Dae Sung: Virtuous Ink, Contemporary Brush, 31293

Substance Abuse and Mental Health Services Administration
NOTICES
Meetings, 31248

Transportation Department
See Federal Aviation Administration
See Federal Highway Administration

Treasury Department
See Alcohol and Tobacco Tax and Trade Bureau

See Comptroller of the Currency
See Internal Revenue Service

U.S. Citizenship and Immigration Services
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application for Civil Surgeon Designation, 31255–31256
Application to Preserve Residence for Naturalization, 31256–31257
Petition for Nonimmigrant Worker, 31257–31258

U.S. Customs and Border Protection
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application-Permit-Special License Unlading-Lading-Overtime Services, 31252–31253

Separate Parts In This Issue

Part II
Health and Human Services Department, Food and Drug Administration, 31302–31356

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.

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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.

6 CFR
Ch. I 31093

8 CFR
214 31095
274a 31095

14 CFR
39 (7 documents) 31095, 31097, 31116, 31119, 31123, 31125, 31129
71 31132

Proposed Rules:
71 (2 documents) 31192, 31193

15 CFR

Proposed Rules:
740 31195
742 31195
774 31195

20 CFR
655 31095

21 CFR

Proposed Rules:
4 31301
16 31301
201 31301
210 31301
211 31301
213 31301
230 31301
314 31301
514 31301

26 CFR
301 31133

27 CFR
9 31164

29 CFR
2520 31133
4065 31133

33 CFR
117 31182
165 31183

Proposed Rules:
165 31203

40 CFR
63 31185
180 31186

49 CFR
Ch. XII 31093

50 CFR
622 31190

Rules and Regulations

Federal Register
Vol. 87, No. 99
Monday, May 23, 2022

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.

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DEPARTMENT OF HOMELAND SECURITY

6 CFR Chapter I

49 CFR Chapter XII

Ratification of Security Directives

AGENCY: Office of Strategy, Policy, and Plans, Department of Homeland Security (DHS).

ACTION: Notification of ratification of security directives.

SUMMARY: DHS is publishing official notice that the Transportation Security Oversight Board (TSOB) has ratified Transportation Security Administration (TSA) Security Directive 1580–21–01, Security Directive 1582–21–01, Security Directive Pipeline–2021–01A, and Security Directive Pipeline–2021–02B. Security Directive 1580–21–01 requires owners/operators of specified freight railroad carriers to implement certain measures addressing cybersecurity vulnerabilities. Security Directive 1582–21–01 applies these same requirements to owner/operators of specified passenger railroad carriers and rail transit systems. Security Directive Pipeline–2021–01A and Security Directive Pipeline–2021–02B amend earlier cybersecurity directives applicable to owner/operators of critical pipeline systems and facilities. Security Directive Pipeline–2021–01A incorporates a revised definition of a ''cybersecurity incident'' and aligns the definition with the definition applicable across other modes of transportation regulated by TSA. Security Directive Pipeline–2021–02B provides additional flexibility to owner/operators in complying with the mitigation measures required by Security Directive Pipeline-2021–02.

DATES: The TSOB ratified Security Directive 1580–21–01, Security Directive 1582–21–01, and Security Directive Pipeline–2021–01A on December 29, 2021. The TSOB ratified Security Directive Pipeline–2021–02B on January 13, 2022.

FOR FURTHER INFORMATION CONTACT: Thomas McDermott, Acting Assistant Secretary for Cyber, Infrastructure, Risk and Resilience Policy at 202–834–5803 or *thomas.mcdermott@hq.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Cybersecurity Threat

Cybersecurity incidents affecting surface transportation entities are a growing threat that pose a risk to the national and economic security of the United States. In recent years, cyber attackers have maliciously targeted the critical infrastructure of surface transportation modes in the United States, including pipelines, freight railroads, passenger railroads, and rail transit systems, with multiple cyberattack and cyber espionage campaigns.[1] This threat continues to evolve and is ongoing. By targeting the integrated cyber and physical infrastructure of surface transportation entities, these attackers threaten the safe, secure, and uninterrupted daily operation of surface transportation systems relied upon by the U.S. economy with potential to cause nation-wide impact.

B. Security Directive 1580–21–01 and Security Directive 1582–21–01

In response to this persistent threat, TSA issued two security directives on December 2, 2021, requiring specified surface transportation entities to implement urgently needed measures that immediately enhance the cybersecurity of the surface transportation sector.[2] Specifically, the two materially identical security directives—one applicable to specified freight railroad carriers and the other applicable to specified passenger railroad carriers and rail transit systems—require owner/operators to take the following four crucial actions:

- Designate a Cybersecurity Coordinator who is required to be available to TSA and CISA at all times (all hours/all days) to coordinate implementation of cybersecurity practices, manage cybersecurity incidents, and serve as a principal point of contact with TSA and CISA for cybersecurity-related matters;
- Report cybersecurity incidents to CISA;
- Conduct a Cybersecurity Vulnerability Assessment to identify gaps in current cybersecurity measures, identify remediation measures, and develop a plan for the owner/operator to implement the remediation measures to address any identified vulnerabilities and gaps; and
- Develop a Cybersecurity Incident Response Plan to reduce the risk of operational disruption should their Information and/or Operational Technology systems be affected by a cybersecurity incident.

The actions required by these security directives only apply to specified owner/operators of freight railroads, passenger railroads, and rail transit systems that TSA has determined are higher risk.[3] The covered entities are those that the nation depends on to move passengers and transport freight in support of critical sectors, including national defense. Both security directives became effective on December

[1] These activities include the April 2021 breach of New York City's Metropolitan Transportation Authority (the nation's largest mass transit agency) by hackers suspected to be linked to the Chinese government; the December 2020 ''Sunburst'' attack on transit agencies; the August 2020 attack on the Southeastern Pennsylvania Transportation Authority; the 2017 ransomware attack on the Sacramento Regional Transit District; and the November 2016 ransomware attack on the San Francisco Municipal Transportation agency. This threat is ongoing: for example, on November 17, 2021, the Federal Bureau of Investigation, the Cybersecurity and Infrastructure Security Agency (CISA), the Australian Cyber Security Centre, and the United Kingdom's National Cyber Security Centre issued a joint cybersecurity advisory highlighting ongoing malicious cyber activity by an advanced persistent threat group (APT) that these agencies associated with the government of Iran. The advisory states that ''The Iranian government-sponsored APT actors are actively targeting a broad range of victims across multiple U.S. critical infrastructure sectors, including the Transportation Sector and the Healthcare and Public Health Sector, as well as Australian organizations.'' Alert AA21–321A (November 17, 2021).

[2] 49 U.S.C. 114(*l*)(2)(A).

[3] *See* 49 CFR 1580.101 and 1582.101. On December 2, 2021, TSA separately issued an Information Circular (IC) to TSA-regulated owner/operators of freight railroads, passenger railroads, public transportation agencies, and rail transit systems not specifically covered by the security directives and -over-the-road-bus owner/operators regulated under 49 CFR part 1584, recommending that these entities generally implement the same four actions that the security directives require of higher-risk surface transportation entities. *See* Surface Transportation Information Circular–2021–01.

31, 2021 and are set to expire on December 31, 2022.[4]

C. TSA Security Directive Pipeline–2021–01A

On December 2, 2021, TSA also issued a security directive amending a directive issued earlier that year requiring owner/operators of critical pipeline systems and facilities to implement certain cybersecurity measures. On May 26, 2021, TSA issued Security Directive Pipeline-2021–01, which was the first of multiple security directives issued by TSA in 2021 to enhance the cybersecurity of critical pipeline systems in response to the ransomware attack on the Colonial Pipeline Company on May 8, 2021. This first directive required owner/operators to: (1) Report cybersecurity incidents to CISA; (2) appoint a cybersecurity coordinator to be available 24/7 to coordinate with TSA and CISA; and (3) conduct a self-assessment of cybersecurity practices, identify any gaps, and develop a plan and timeline for remediation.[5] This security directive went into effect on May 28, 2021, and was ratified by the TSOB on July 3, 2021. 86 FR 38209. It is set to expire on May 28, 2022.

Security Directive Pipeline–2021–01A, issued on December 2, 2021, amended Security Directive Pipeline–2021–01, updating the definition of cybersecurity incident applicable in the pipeline context to mirror the definition used by the subsequent security directives applicable to specified surface transportation sector entities. TSA's determination to use a modified definition was made following industry input and consultation with DHS cybersecurity experts. The amended definition of cybersecurity incident applicable to critical pipeline owner/operators provides further clarity regarding the nature of incidents that fall within the definition of cybersecurity incident and ensures the consistent identification of incidents that must be reported to CISA across all covered modes of transportation.

D. TSA Security Directive Pipeline–2021–02B

On July 19, 2021 TSA issued the second security directive—Security Directive Pipeline–2021–02—in response to the Colonial Pipeline attack, building on the requirements of Security Directive Pipeline–2021–01 to further enhance the cybersecurity of critical pipeline systems. Security Directive Pipeline–2021–02 required owner/operators of critical pipelines to take the following additional actions:

- Implement specified mitigation measures to reduce the risk of compromise from a cyberattack;
- Develop a Cybersecurity Contingency/Response Plan to reduce the risk of operational disruption or functional degradation of information technology and operational technology systems in the event of a malicious cyber intrusion; and
- Test the effectiveness of their cybersecurity practices through an annual cybersecurity architecture design review conducted by a third party.

Security Directive Pipeline–2021–02 became effective on July 26, 2021 and was ratified by the TSOB on August 17, 2021. 86 FR 52953 (September 24, 2021). It is set to expire on July 26, 2022.

On December 17, 2021, TSA issued Security Directive Pipeline–2021–02B, amending Security Directive Pipeline-2021–02 to provide additional flexibility to owner/operators in complying with the directive's requirements. TSA amended the directive's requirements based on industry feedback and following consultation with CISA. The revisions provide pipeline owner/operators with the necessary flexibility to comply with the directive's requirements, while ensuring that the requirements are met in a uniform and operationally safe manner.[6]

II. TSOB Ratification

TSA has broad statutory responsibility and authority to safeguard the nation's transportation system.[7] The TSOB—a body consisting of the Secretary of Homeland Security, the Secretary of Transportation, the Attorney General, the Secretary of Defense, the Secretary of the Treasury, the Director of National Intelligence, or their designees, and a representative of the National Security Council—reviews certain TSA regulations and security directives consistent with law.[8] TSA issued each of these security directives under 49 U.S.C. 114(*l*)(2)(A), which authorizes TSA to issue emergency regulations or security directives without providing notice or public comment where ''the Administrator determines that a regulation or security directive must be issued immediately in order to protect transportation security . . . .''. Security directives issued pursuant to the procedures in 49 U.S.C. 114(*l*)(2) ''shall remain effective for a period not to exceed 90 days unless ratified or disapproved by the Board or rescinded by the Administrator.'' [9]

Following the issuance of Security Directive 1580–21–01, Security Directive 1582–21–01, and Security Directive Pipeline–2021–01A on December 2, 2021, the chairman of the TSOB convened the board for the purpose of reviewing each directive. Following the issuance of Security Directive Pipeline–2021–02B on December 17, 2021, the chairman again convened the board for the purpose of reviewing that directive. In reviewing the directives, the TSOB reviewed the actions required by Security Directive 1580–21–01 and Security Directive 1582–21–01 to mitigate cybersecurity vulnerabilities in the rail transportation sector; the need for TSA to issue the security directives pursuant to its emergency authority under 49 U.S.C. 114(*l*)(2) to prevent the disruption and degradation of the country's critical rail transportation infrastructure; Security Directive Pipeline–2021–01A's amended definition of cybersecurity incident applicable to owner/operators of critical pipeline systems and facilities; and the flexibilities provided by Security Directive Pipeline–2021–02B. Following its review, the TSOB ratified all four security directives. The TSOB ratified Security Directive 1580–21–01, Security Directive 1582–21–01, and Security Directive Pipeline-2021–01A on December 29, 2021. The TSOB ratified Security Directive Pipeline–2021–02B on January 13, 2022.

John K. Tien,

Deputy Secretary of Homeland Security & Chairman of the Transportation Security Oversight Board.

[FR Doc. 2022–11018 Filed 5–20–22; 8:45 am]

BILLING CODE 9110–9M–P

[4] TSA's security directives are presumptively Sensitive Security Information (SSI) by regulation and are subject to disclosure restrictions. 49 CFR 1520.5(b)(2). The TSA Administrator, however, has determined that it is in the interest of public safety and in furtherance of transportation security that Security Directive 1580–21–01 and Security Directive 1582–21–01 be made publicly available. 49 CFR 1520.5(b).

[5] 86 FR 38209.

[6] Security Directive Pipeline-2021–02B and its specific requirements for operators are designated as Sensitive Security Information (SSI) under TSA regulations. *See* 49 CFR 1520.5(b)(1), (b)(2), (b)(6), (b)(8). Absent a determination by the TSA Administrator to remove the SSI designation in the interest of public safety or in furtherance of transportation security, Security Directive Pipeline 2021–02B, the records produced in compliance with its requirements, and the information contained in these records remain designated as SSI and afforded the protections of such a designation. *See* 49 CFR 1520.5(b).

[7] *See, e.g.,* 49 U.S.C. 114(d), (f), (*l*), (m).

[8] *See, e.g.,* 49 U.S.C. 115; 49 U.S.C. 114(*l*)(2)(B).

[9] 49 U.S.C. 114(*l*)(2)(B).

DEPARTMENT OF HOMELAND SECURITY

8 CFR Parts 214 and 274a

[CIS No. 2719–22]

RIN 1615–AC79

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 655

[DOL Docket No. ETA–2022–0004]

RIN 1205–AC10

Exercise of Time-Limited Authority To Increase the Numerical Limitation for Second Half of FY 2022 for the H–2B Temporary Nonagricultural Worker Program and Portability Flexibility for H–2B Workers Seeking To Change Employers; Correction

AGENCY: U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security (DHS), and Employment and Training Administration and Wage and Hour Division, U.S. Department of Labor (DOL).

ACTION: Temporary final rule; correction.

SUMMARY: On May 18, 2022, the Department of Homeland Security and Department of Labor jointly published a temporary final rule titled ''Exercise of Time-Limited Authority to Increase the Numerical Limitation for Second Half of FY 2022 for the H–2B Temporary Nonagricultural Worker Program and Portability Flexibility for H–2B Workers Seeking To Change Employers.'' The fourth amendatory instruction to the DHS regulatory text contained a typo. This document corrects that typo.

DATES: Effective on May 18, 2022.

FOR FURTHER INFORMATION CONTACT: Samantha Deshommes, Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 5900 Capital Gateway Drive, Camp Springs, MD 20746; telephone 240–721–3000 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: In FR Doc. 2022–10631, appearing in the first column on page 30377 in the **Federal Register** of Wednesday, May 18, 2022, the following correction is made:

§ 274a.12 [Corrected]

■ 1. On page 30377, in the first column, in part 274a, in amendment 4, the instruction ''Effective May 18, 2022 through May 18, 2025, amend § 274a.12 by adding paragraph (b)(31) to read as follows'' is corrected to read ''Effective May 18, 2022 through May 18, 2025, amend § 274a.12 by adding paragraph (b)(32) to read as follows:''.

Christina E. McDonald,

Federal Register Liaison, U.S. Department of Homeland Security.

Laura Dawkins,

Federal Register Liaison, U.S. Department of Labor.

[FR Doc. 2022–11132 Filed 5–20–22; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0021; Project Identifier AD–2020–01283–A; Amendment 39–22060; AD 2022–11–10]

RIN 2120–AA64

Airworthiness Directives; Piper Aircraft, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Piper Aircraft, Inc. (Piper) Model PA–46–600TP airplanes. This AD was prompted by testing that showed that the wing splice assembly could fail before the assembly reaches its established life limit. This AD requires revising the Airworthiness Limitations section (ALS) of the existing maintenance manual (MM) or instructions for continued airworthiness (ICA) to reduce the life limit of the wing splice assembly. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 27, 2022.

ADDRESSES: For service information identified in this final rule, contact Piper Aircraft, Inc., 2926 Piper Drive, Vero Beach, FL 32960; phone: (772) 291–2141; website: *https://www.piper.com.* You may view this service information 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.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0021; 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, 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.

FOR FURTHER INFORMATION CONTACT: Fred Caplan, Aviation Safety Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: (404) 474–5507; email: *frederick.n.caplan@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 serial-numbered Piper Model PA–46–600TP airplanes. The NPRM published in the **Federal Register** on February 1, 2022 (87 FR 5428). The NPRM was prompted by testing that showed that the wing splice assembly, part number (P/N) 46W57A100–001, could fail before reaching its established life limit on Model PA–46–600TP airplanes. The wing splice assembly was certificated with a life limit of 5,132 hours time-in-service (TIS); however, the failures of the test assembly occurred before reaching that established life limit. The stress levels used in the life limit analysis were not adequate. After a new fatigue test article analysis, Piper reduced the life limit of the wing splice assembly P/N 46W57A100–001 from 5,132 hours TIS to 3,767 hours TIS and revised the Airworthiness Limitations section in the MM accordingly.

In the NPRM, the FAA proposed to require revising the Airworthiness Limitations section of the existing MM or ICA to reduce the life limit of the wing splice assembly. Failure of the wing splice assembly, if not addressed, could result in loss of airplane control. The FAA is issuing this AD to address the unsafe condition on these products.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from Piper. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request Regarding Applicability and Cost of Compliance

Piper requested that the FAA update the applicable serial numbers. The applicable serial numbers in the proposed AD were based upon the understanding that airworthiness limitations with the new wing splice assembly life limit would be delivered with new airplanes beginning with serial number 4698186. However, while the AD was in development, airworthiness limitations with the new life limit were actually delivered with new airplanes with serial numbers 4698147, 4698149, and 4698158 and larger.

The FAA agrees and has revised the applicability of this AD accordingly.

Based on its comment regarding the applicable serial numbers, Piper also requested that the FAA revise the estimated Costs of Compliance section. Piper stated that the costs would be reduced because there are fewer affected airplanes.

The FAA agrees that the estimated Costs of Compliance should be updated to reflect the correct number of affected airplanes. However, the FAA's original estimate of the number of affected airplanes was in error. The FAA has corrected that error in the Costs of Compliance section of this final rule, resulting in a higher count of airplanes.

Request Regarding Required Actions

Piper stated that operators cannot physically comply with paragraph (g), Action, of the proposed AD, which proposed to require revising the ALS by reducing the life limit of the wing splice assembly. Piper stated that the ICA are delivered with the airplane in an electronic format on a CD–ROM. Piper requested that the FAA change this action by requiring a logbook entry documenting the change in life limit of the wing splice assembly.

The FAA does not agree that operators are unable to comply with the AD as proposed. While the AD mandates revising the ALS to reduce the life limit, it does not specify any particular method that operators must use to do the revision. One acceptable method is to replace the existing CD–ROM document with a new CD–ROM that includes the new life limit. As long as the ALS of an operator's existing MM or ICA includes the new life limit, then the operator has complied with this AD. The FAA did not change this AD based on this comment.

Request Regarding Related Information

Piper requested that the FAA revise Note 1 to paragraph (g) of the proposed AD to include the December 4, 2020, version of the ALS. Piper stated the initial life limit reduction for wing splice assembly P/N 46W57A100–001 was introduced in the December 4, 2020, version of the ALS. The August 31, 2021, version of the ALS, which was included in the proposed AD, contains the reduced life limit for wing splice assembly P/N 46W57A100–001 and introduces new part numbers for the wing splice assembly (P/N 46W57A100–002) and a service wing assembly (P/N 46W00A700–702).

The FAA agrees that the December 4, 2020, version of the ALS contains the reduced wing splice assembly life limit, but does not agree that a change to this AD is necessary. As previously explained, the AD does not specify any particular method that operators must use to revise the ALS. One acceptable method is incorporating the life limit specified in Piper Aircraft, Inc. PA–46–600TP, M600 Maintenance Manual, Airworthiness Limitations, Page 1, dated December 4, 2020.

The FAA did not change this AD based on this comment.

Conclusion

The FAA reviewed the relevant data, considered the 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 the changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information

The FAA reviewed Piper Aircraft, Inc., PA–46–600TP, M600 Maintenance Manual, Airworthiness Limitations, Section 4–00–00, dated August 31, 2021. This service information specifies the life limits of structural parts for the Model PA–46–600TP airplane and reduces the life limit for the wing splice assembly.

Costs of Compliance

The FAA estimates that this AD affects 139 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 airplane	Cost on U.S. operators
Revise the ALS	1 work-hour × $85 per hour = $85	Not Applicable	$85	$11,815

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, 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:

2022–11–10 Piper Aircraft, Inc.: Amendment 39–22060; Docket No. FAA–2022–0021; Project Identifier AD–2020–01283–A.

(a) Effective Date

This airworthiness directive (AD) is effective June 27, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Piper Aircraft, Inc. Model PA–46–600TP airplanes, serial numbers 4698001, 4698004 through 4698146 inclusive, 4698148, and 4698150 through 4698157 inclusive, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 5711, Wing Spar.

(e) Unsafe Condition

This AD results from testing that showed that the wing splice assembly could fail before the assembly reaches its established life limit. The FAA is issuing this AD to prevent failure of the wing splice assembly before the current established life limit. The unsafe condition, if not addressed, could result in loss of airplane control.

(f) Compliance

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

(g) Action

Within 90 days after the effective date of this AD, revise the Airworthiness Limitations section in the existing maintenance manual or instructions for continued airworthiness by reducing the life limit of the wing splice assembly part number 46W57A100–001 to 3,767 hours time-in-service.

Note 1 to paragraph (g): Section 4–00–00 of Piper Aircraft, Inc. PA–46–600TP, M600 Maintenance Manual, Airworthiness Limitations, Page 1, dated August 31, 2021, contains the life limit in paragraph (g) of this AD.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Atlanta ACO 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 certification office, send it to the attention of the person identified in paragraph (i)(1) of this AD.

(2) 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.

(i) Related Information

(1) For more information about this AD, contact Fred Caplan, Aviation Safety Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: (404) 474–5507; email: *frederick.n.caplan@faa.gov.*

(2) For service information identified in this AD, contact Piper Aircraft, Inc., 2926 Piper Drive, Vero Beach, FL, 32960; phone: (772) 291–2141; website: *https://www.piper.com.*

(j) Material Incorporated by Reference

None.

Issued on May 17, 2022.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–10863 Filed 5–20–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0509; Project Identifier AD–2022–00338–T; Amendment 39–22038; AD 2022–09–18]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all The Boeing Company Model 707, 717, and 727 airplanes; Model DC–8, DC–9, and DC–10 airplanes; Model MD–10 and MD–11 airplanes; Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), DC–9–87 (MD–87), and MD–88 (collectively described, in the preamble of this AD, as MD–80) airplanes; and Model MD–90–30 airplanes. This AD was prompted by a determination that radio altimeters cannot be relied on to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band), and a recent determination that during approach, landings, and go-arounds, as a result of this interference, certain airplane systems may not properly function, resulting in increased flightcrew workload while on approach with the flight director, autothrottle, or autopilot engaged. This AD requires revising the limitations and operating procedures sections of the existing airplane flight manual (AFM) to incorporate specific operating procedures for, depending on the airplane model, instrument landing system (ILS) approaches, non-precision approaches, ground spoiler deployment, and go-around and missed approaches, when in the presence of 5G C-Band interference as identified by Notices to Air Missions (NOTAMs). The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 23, 2022.

The FAA must receive comments on this AD by July 7, 2022.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0509; 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, any comments received, and other information. The street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Eric Igama, Aerospace Engineer, Systems and Equipment Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5388; email: *Roderick.Igama@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

In March 2020, the United States Federal Communications Commission (FCC) adopted final rules authorizing flexible use of the 3.7–3.98 GHz band for next generation services, including 5G and other advanced spectrum-based services.[1] Pursuant to these rules, C-Band wireless broadband deployment was permitted to occur in phases with the opportunity for operations in the lower 0.1 GHz of the band (3.7–3.8 GHz) in certain markets beginning on January 19, 2022. This AD refers to ''5G C-Band'' interference, but wireless broadband technologies, other than 5G, may use the same frequency band.[2] These other uses of the same frequency band are within the scope of this AD since they would introduce the same risk of radio altimeter interference as 5G C-Band.

The radio altimeter is an important aircraft instrument, and its intended function is to provide direct height-above-terrain/water information to a variety of aircraft systems. Commercial aviation radio altimeters operate in the 4.2–4.4 GHz band, which is separated by 0.22 GHz from the C-Band telecommunication systems in the 3.7–3.98 GHz band. The radio altimeter is more precise than a barometric altimeter and for that reason is used where aircraft height over the ground needs to be precisely measured, such as autoland, manual landings, or other low altitude operations. The receiver on the radio altimeter is typically highly accurate, however it may deliver erroneous results in the presence of out-of-band radio frequency emissions from other frequency bands. The radio altimeter must detect faint signals reflected off the ground to measure altitude, in a manner similar to radar. Out-of-band signals could significantly degrade radio altimeter functions during critical phases of flight, if the altimeter is unable to sufficiently reject those signals.

The FAA issued AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) (AD 2021–23–12) to address the effect of 5G C-Band interference on all transport and commuter category airplanes equipped with a radio (also known as radar) altimeter. AD 2021–23–12 requires revising the limitations section of the existing AFM to incorporate limitations prohibiting certain operations, which require radio altimeter data to land in low visibility conditions, when in the presence of 5G C-Band interference as identified by NOTAM. The FAA issued AD 2021–23–12 because radio altimeter anomalies that are undetected by the automation or pilot, particularly close to the ground (*e.g.*, landing flare), could lead to loss of continued safe flight and landing.

Since the FAA issued AD 2021–23–12, Boeing has continued to evaluate potential 5G C-Band interference on aircraft systems that rely on radio altimeter inputs. Boeing issued Boeing Multi Operator Message MOM–MOM–22–0038–01B(R1), dated February 2, 2022 (for Model 707 and 727 operators); Boeing Multi Operator Message MOM–MOM–22–0030–01B(R3), dated March 22, 2022 (for Model MD–10, MD–11, MD–80, and 717 operators); Boeing Multi Operator Message MOM–MOM–22–0040–01B, dated January 17, 2022 (for Model DC–8, DC–9, and DC–10 operators); Boeing MD–10 Flight Crew Operations Manual Bulletin 2–10C, ''Operation in airspace affected by 5G signal interference,'' dated March 18, 2022; Boeing MD–11 Flight Crew Operations Manual Bulletin 2–18C, ''Operation in airspace affected by 5G signal interference,'' dated March 18, 2022; and Boeing MD–80 Flight Crew Operations Manual Bulletin 80–2–019B, ''Operation in airspace affected by 5G signal interference,'' dated February 1, 2022; and Boeing 717 Flight Crew Operating Manual Bulletin FAB2 717–2–016C, ''Operation in airspace affected by 5G signal interference,'' dated March 18, 2022.

Based on Boeing's data, the FAA identified an additional hazard presented by 5G C-Band interference on The Boeing Company Model 707 and 727 airplanes; Model 717–200 airplanes; Model DC–8–10, DC–8–20, DC–8–30, and DC–8–40 airplanes; DC–8–50, DC–8–60, DC–8–60F, DC–8–70, DC–8–70F series airplanes; Model DC–8F–54 and DC–8F–55 airplanes; Model DC–9–10, DC–9–20, DC–9–30, DC–9–40, and DC–9–50 series airplanes; Model DC–10–10, DC–10–10F, DC–10–15, DC–10–30, DC–10–30F (KC–10A and KDC–10), DC–10–40, and DC–10–40F airplanes; Model MD–10–10F and MD–10–30F airplanes; Model MD–11 and MD–11F airplanes; Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), DC–9–87 (MD–87), and MD–88 (collectively described, in this preamble, as MD–80[3]) airplanes; and Model MD–90–30 airplanes. The FAA determined that anomalies due to 5G C-Band interference may affect multiple other airplane systems using radio altimeter data, regardless of the approach type or weather. These anomalies may not be evident until very low altitudes. Impacted systems depend on the airplane model and include, but are not limited to, flight guidance, autothrottle system, flight controls, traffic alert and collision avoidance system (TCAS), ground proximity warning system (GPWS), windshear advisory and guidance system (WAGS), and central aural warning system (CAWS).

The effects on these impacted systems include:

- *Flight Guidance (for Model 717, MD–10, and MD–11 airplanes):* Glideslope guidance sensitivity may be affected when conducting Category I ILS approaches to barometric altitude (BARO) minimums. During missed approach, pilot inputs into the flight control panel (FCP) may not result in commands to the flight director to provide speed or heading guidance, and may not provide altitude capture guidance. Simulator testing for Model MD–11 airplanes showed that in some cases the system will bias the flight director bars out of view when presented with the expected erroneous radio altimeter data, providing immediate and compelling information to the flightcrew to perform a go-around. If the flight director bars remain in view, appropriate guidance is still displayed, and other systems' effects are sufficient to elicit proper pilot response to land (if visual) or conduct a go-around. Similar effects are expected for Model 717 and MD–10 airplanes due to similar system architecture.
- *Flight Guidance (for Model 707, 727, DC–8, DC–9, DC–10, MD–80, and MD–90 airplanes):* Glideslope guidance sensitivity may be affected when conducting Category I ILS approaches to BARO minimums.
- *Flight Guidance (for Model 717, MD–10, MD–11, MD–80, and MD–90 airplanes):* As specified in the operating procedures in paragraph (h) of this AD, non-precision approaches can be flown using LNAV/VNAV with flight directors, autopilot, and autothrottle to published BARO minimums.
- *Autothrottle System (for Model 717, MD–10, and MD–11 airplanes):* RETARD, FMA RETARD, ALIGN, and FLARE functions and indications may be unreliable and may occur early, late, or not at all. If the autothrottle system

[1] The FCC's rules did not make C-Band wireless broadband available in Alaska, Hawaii, and the U.S. Territories.

[2] The regulatory text of the AD uses the term ''5G C-Band'' which, for purposes of this AD, has the same meaning as ''5G'', ''C-Band'' and ''3.7–3.98 GHz.''

[3] This preamble groups these models under the term ''MD–80'' in order to reflect the title and affected models of the ''MD–80'' bulletin described in the previous paragraph. The regulatory applicability of this AD, however, and required AFM changes, address the individual models of that ''MD–80'' group.

is not in the FLARE mode, LO SPD protection can engage and advance with autothrottles ON or OFF.

• *Autothrottle System (for Model 707, 727, DC–8, DC–9, DC–10, MD–80, and MD–90 airplanes):* Potentially erroneous autothrottle commands.

• *Flight Controls (for Model 717, MD–10, and MD–11 airplanes):* Auto ground spoiler function may require manual extension. For Model MD–11 airplanes, longitudinal stability augmentation system (LSAS) and low altitude stability enhancement (LASE) may not function properly. The pitch attitude hold (PAH) may not wash out on schedule. Positive nose lowering (PNL) and pitch rate damping (PRD) may not be available during landing. Pitch attitude protection (PAP) may activate early, or not at all. If PAP is activated early, it may resist increasing pitch attitude, necessitating additional column pull force.

• *TCAS:* May be unreliable and resolution advisories and voice warnings may not be inhibited below 1,000 feet above ground level (AGL).

• *Enhanced ground proximity warning system (E–GPWS) and WAGS:* May be unreliable and activate early, late, or not at all.

• *CAWS:* CAWS annunciations may not provide proper aural warnings or altitude callouts and/or radio altimeter displayed values during flare.

• Other simultaneous flight deck effects associated with the 5G C-Band interference could increase pilot workload.

These erroneous indications and annunciations, as well as conflicting information, may be provided to the flightcrew during critical phases of flight. There may also be a lack of cues present to elicit prompt go-around or recovery initiation. These effects could lead to reduced ability of the flightcrew to maintain safe flight and landing of the airplane and are an unsafe condition.

To address this unsafe condition, this AD mandates procedures for operators to incorporate specific operating procedures for, depending on the airplane model, ILS approaches, non-precision approaches, ground spoiler deployment, and go-around and missed approaches, when in the presence of 5G C-Band interference as identified by NOTAMs.

Finally, the FAA notes that AD 2021–23–12 remains in effect and prohibits certain ILS approaches. Thus, this AD addresses procedures applicable only to those ILS approaches not already prohibited by AD 2021–23–12.

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

FAA's Determination

The FAA is issuing this AD because the agency has determined the unsafe condition described previously is likely to exist or develop in other products of these same type designs.

AD Requirements

This AD requires revising the limitations and operating procedures sections of the existing AFM to incorporate specific operating procedures for, depending on the airplane model, ILS approaches, non-precision approaches, ground spoiler deployment, and go-around and missed approaches, when in the presence of 5G C-Band interference as identified by NOTAMs.

Compliance With AFM Revisions

Section 91.9 prohibits any person from operating a civil aircraft without complying with the operating limitations specified in the AFM. FAA regulations also require operators to furnish pilots with any changes to the AFM (14 CFR 121.137) and pilots in command to be familiar with the AFM (14 CFR 91.505).

Interim Action

The FAA considers this AD to be an interim action. If final action is later identified, the FAA might consider further rulemaking.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this rule because the FAA determined that radio altimeters cannot be relied on to perform their intended function if they experience interference from wireless broadband operations in the 5G C-Band. The FAA recently determined that as a result of this interference, certain airplane systems may not properly function during approach, landings, and go-arounds, resulting in increased flightcrew workload while on approach with the flight director, autothrottle, or autopilot engaged. This increased flightcrew workload could lead to reduced ability of the flightcrew to maintain safe flight and landing of the airplane. The urgency is based on the hazard presented by 5G C-Band interference and on the ongoing C-Band wireless broadband deployment. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forgo notice and comment.

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include Docket No. FAA–2022–0509 and Project Identifier AD–2022–00338–T at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as

confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Eric Igama, Aerospace Engineer, Systems and Equipment Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5388; email: *Roderick.Igama@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 476 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
AFM revision	1 work-hour × $85 per hour = $85	$0	$85	$40,460

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, and

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

Adoption of 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:

2022–09–18 The Boeing Company: Amendment 39–22038; Docket No. FAA–2022–0509; Project Identifier AD–2022–00338–T.

(a) Effective Date

This airworthiness directive (AD) is effective May 23, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company airplanes identified in paragraphs (c)(1) through (9) of this AD, certificated in any category.

(1) Model 707–100 Long Body, –200, –100B Long Body, and –100B Short Body series airplanes, and Model 707–300, –300B, –300C, and –400 series airplanes.

(2) Model 717–200 airplanes.

(3) Model 727, 727C, 727–100, 727–100C, 727–200, and 727–200F series airplanes.

(4) Model DC–8–11, DC–8–12, DC–8–21, DC–8–31, DC–8–32, DC–8–33, DC–8–41, DC–8–42, DC–8–43, DC–8–51, DC–8–52, DC–8–53, DC–8–55, DC–8F–54, DC–8F–55, DC–8–61, DC–8–62, DC–8–63, DC–8–61F, DC–8–62F, DC–8–63F, DC–8–71, DC–8–72, DC–8–73, DC–8–71F, DC–8–72F, and DC–8–73F airplanes.

(5) Model DC–9–11, DC–9–12, DC–9–13, DC–9–14, DC–9–15, DC–9–15F, DC–9–21, DC–9–31, DC–9–32, DC–9–32 (VC–9C), DC–9–32F, DC–9–32F (C–9A, C–9B), DC–9–33F, DC–9–34, DC–9–34F, DC–9–41, and DC–9–51 airplanes.

(6) Model DC–10–10, DC–10–10F, DC–10–15, DC–10–30, DC–10–30F (KC–10A and KDC–10), DC–10–40, and DC–10–40F airplanes.

(7) Model MD–10–10F and MD–10–30F airplanes.

(8) Model MD–11 and MD–11F airplanes.

(9) Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), DC–9–87 (MD–87), MD–88, and MD–90–30 airplanes.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by a determination that radio altimeters cannot be relied on to perform their intended function if they experience interference from wireless broadband operations in the 3.7–3.98 GHz frequency band (5G C-Band), and a determination that during approach, landings, and go-arounds, as a result of this interference, certain airplane systems may not properly function, resulting in increased flightcrew workload while on approach with the flight director, autothrottle, or autopilot engaged. The FAA is issuing this AD to address 5G C-Band interference that could result in increased flightcrew workload and could lead to reduced ability of the flightcrew to maintain safe flight and landing of the airplane.

(f) Compliance

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

(g) Revision of Existing Airplane Flight Manual (AFM)—Limitations

(1) For airplanes identified in paragraphs (c)(1) and (c)(3) through (6) of this AD: Within 2 days after the effective date of this AD, revise the Limitations Section of the existing AFM to include the information specified in figure 1 to paragraph (g)(1) of this AD. This may be done by inserting a copy of figure 1 to paragraph (g)(1) of this AD into the Limitations Section of the existing AFM.

BILLING CODE 4910–13–P

Figure 1 to paragraph (g)(1) – *AFM Limitations Revision for Model 707, 727, DC-8, DC-9 (except DC-9-81 (MD-81), DC-9-82 (MD-82), DC-9-83 (MD-83), and DC-9-87 (MD-87)), and DC-10*

(Required by AD 2022-09-18)

Radio Altimeter 5G C-Band Interference, Approach Procedures
The following limitations are required for ILS approaches on runways in U.S. airspace in the presence of 5G C-Band wireless broadband interference as identified by NOTAM (NOTAMs will be issued to state the specific airports or approaches where the radio altimeter is unreliable due to the presence of 5G C-Band wireless broadband interference).

ILS Approaches
Operators must use the Radio Altimeter 5G C-Band Interference, ILS Approaches procedure contained in the Operating Procedures Section of this AFM.

(2) For airplanes identified in paragraphs (c)(2), (7), and (8) of this AD: Within 2 days after the effective date of this AD, revise the Limitations Section of the existing AFM to include the information specified in figure 2 to paragraph (g)(2) of this AD. This may be done by inserting a copy of figure 2 to paragraph (g)(2) of this AD into the Limitations Section of the existing AFM.

Figure 2 to paragraph (g)(2) – *AFM Limitations Revision for Model 717, MD-10, and MD-11*

(Required by AD 2022-09-18)

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around Procedures
The following limitations are required for approaches, landings, or go-arounds on runways, in U.S. airspace in the presence of 5G C-Band wireless broadband interference as identified by NOTAM (NOTAMs will be issued to state the specific airports or approaches where the radio altimeter is unreliable due to the presence of 5G C-Band wireless broadband interference).

ILS and Non Precision Approaches, Landing, and Go-Around
Operators must use the Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around procedures contained in the Operating Procedures Section of this AFM.

(3) For airplanes identified in paragraph (c)(9) of this AD: Within 2 days after the effective date of this AD, revise the Limitations Section of the existing AFM to include the information specified in figure 3 to paragraph (g)(3) of this AD. This may be done by inserting a copy of figure 3 to paragraph (g)(3) of this AD into the Limitations Section of the existing AFM.

Figure 3 to paragraph (g)(3) – *AFM Limitations Revision for Model DC-9-81 (MD-81), DC-9-82 (MD-82), DC-9-83 (MD-83), DC-9-87 (MD-87), MD-88, and MD-90-30*

(Required by AD 2022-09-18)

Radio Altimeter 5G C-Band Interference, Approach Procedures

The following limitations are required for approaches in U.S. airspace in the presence of 5G C-Band wireless broadband interference as identified by NOTAM (NOTAMs will be issued to state the specific airports or approaches where the radio altimeter is unreliable due to the presence of 5G C-Band wireless broadband interference).

ILS and Non Precision Approaches

Operators must use the Radio Altimeter 5G C-Band Interference, Approaches procedures contained in the Operating Procedures Section of this AFM.

(h) Revision of Existing AFM—Operating Procedures

(1) For airplanes identified in paragraphs (c)(1) and (3) through (6) of this AD: Within 2 days after the effective date of this AD, revise the Operating Procedures Section of the existing AFM to include the information specified in figure 4 to paragraph (h)(1) of this AD. This may be done by inserting a copy of figure 4 to paragraph (h)(1) of this AD into the Operating Procedures Section of the existing AFM.

Note 1 to paragraph (h)(1): Guidance for accomplishing the actions required by paragraph (h)(1) of this AD can be found in Boeing Multi Operator Message MOM–MOM–22–0038–01B(R1), dated February 2, 2022; and Boeing Multi Operator Message MOM–MOM–22–0040–01B, dated January 17, 2022.

Figure 4 to paragraph (h)(1) – *AFM Operating Procedures Revision for Model 707, 727, DC-8, DC-9 (except DC-9-81 (MD-81), DC-9-82 (MD-82), DC-9-83 (MD-83), and DC-9-87 (MD-87)), and DC-10*

(Required by AD 2022-09-18)

Radio Altimeter 5G C-Band Interference, ILS Approaches

ILS Approaches

For ILS approaches not prohibited by AD 2021-23-12, disconnect the autopilot and autothrottles, and place both flight director switches to OFF prior to glideslope intercept.

(2) For airplanes identified in paragraph (c)(2) of this AD: Within 2 days after the effective date of this AD, revise the Operating Procedures Section of the existing AFM to include the information specified in figure 5 to paragraph (h)(2) of this AD. This may be done by inserting a copy of figure 5 to paragraph (h)(2) of this AD into the Operating Procedures Section of the existing AFM.

Note 2 to paragraph (h)(2): Guidance for accomplishing the actions required by paragraph (h)(2) of this AD can be found in Boeing Multi Operator Message MOM–MOM–22–0030–01B(R3), dated March 22, 2022; and Boeing 717 Flight Crew Operating Manual Bulletin FAB2 717–2–016C, ''Operation in airspace affected by 5G signal interference,'' dated March 18, 2022.

Figure 5 to paragraph (h)(2) – *AFM Operating Procedures Revision for Model 717*

(Required by AD 2022-09-18)

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

ILS Approaches

For ILS approaches not prohibited by AD 2021-23-12, disconnect the autopilot prior to glideslope intercept.

Note: Possible erroneous radio altimeter indications may affect autothrottles and flight director guidance; manually intervene if necessary.

Non-Precision Approaches

Non-precision instrument approaches can be conducted using LNAV/VNAV with flight directors, autopilot, and autothrottle to published BARO minimums.

Landing

For landing, the Auto Ground Spoiler function may require manual extension. If manual extension is required, calculate landing distance requirements as specified in Appendix 3, Auto Ground Spoiler System Inop, of this AFM.

During Go-Around and Missed Approach

If go-around is required, initial flight director pitch guidance will provide proper speed and pitch targets, but, under certain 5G interference conditions, the flight director cannot be commanded from the Flight Control Panel (FCP) to provide speed or heading guidance, and may not provide altitude capture guidance. If this guidance is not available, manually comply with missed approach procedures, including altitude constraints.

(3) For airplanes identified in paragraph (c)(7) of this AD: Within 2 days after the effective date of this AD, revise the Operating Procedures Section of the existing AFM to include the information specified in figure 6 to paragraph (h)(3) of this AD. This may be done by inserting a copy of figure 6 to paragraph (h)(3) of this AD into the Operating Procedures Section of the existing AFM.

Note 3 to paragraph (h)(3): Guidance for accomplishing the actions required by paragraph (h)(3) of this AD can be found in Boeing Multi Operator Message MOM–MOM–22–0030–01B(R3), dated March 22, 2022; and Boeing MD–10 Flight Crew Operations Manual Bulletin 2–10C, ''Operation in airspace affected by 5G signal interference,'' dated March 18, 2022.

Figure 6 to paragraph (h)(3) – *AFM Operating Procedures Revision for Model MD-10*

(Required by AD 2022-09-18)

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

ILS Approaches

For ILS approaches not prohibited by AD 2021-23-12, disconnect the autopilot prior to glideslope intercept.

Note: Possible erroneous radio altimeter indications may affect autothrottles and flight director guidance; manually intervene if necessary.

Non-Precision Approaches

Non-precision instrument approaches can be conducted using LNAV/VNAV with flight directors, autopilot, and autothrottle to published BARO minimums.

Landing

For landing, the Auto Ground Spoiler function may require manual extension. If manual extension is required, calculate landing distance requirements according to the following tables, as applicable.

SERIES 10
50/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MANUAL SPOILERS

Weight 1000 LB		260	280	300	320	340	360	380	400
S.L.	DRY	2800	2900	3030	3160	3290	3410	3540	3660
STD=15°C	WET	3670	3810	3990	4190	4370	4540	4730	4900
2000 FT	DRY	2920	3030	3170	3310	3450	3580	3720	3840
STD=11°C	WET	3840	3990	4190	4400	4600	4780	4980	5170
4000 FT	DRY	3060	3170	3320	3480	3620	3760	3920	4050
STD=7°C	WET	4040	4190	4410	4630	4850	5040	5260	5460
6000 FT	DRY	3210	3330	3490	3650	3820	3960	4130	4270
STD=3°C	WET	4240	4410	4650	4890	5120	5330	5570	5780
8000 FT	DRY	3360	3490	3670	3840	4020	4180	4360	4520
STD=-1°C	WET	4460	4650	4900	5160	5410	5640	5900	6130
10000 FT	DRY	3530	3670	3860	4060	4250	4420	4610	4780
STD=-5°C	WET	4690	4910	5180	5460	5730	5980	6260	6510

NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop. (Includes Air Run Distance)

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-7	-10
ABOVE standard day	+37	+44

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-46	-96
DOWNHILL	+257	+459

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-20	-34
TAILWIND	+50	+68

SERIES 10
35/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MANUAL SPOILERS

Weight 1000 LB		260	280	300	320	340	360	380	400
S.L.	DRY	2800	2900	3030	3170	3300	3420	3560	3680
STD=15°C	WET	3710	3850	4050	4250	4450	4620	4820	4990
2000 FT	DRY	2930	3030	3180	3330	3470	3600	3740	3870
STD=11°C	WET	3890	4040	4260	4480	4680	4870	5080	5270
4000 FT	DRY	3070	3180	3330	3490	3640	3790	3940	4080
STD=7°C	WET	4090	4260	4480	4720	4940	5150	5370	5580
6000 FT	DRY	3210	3340	3500	3670	3840	3990	4160	4310
STD=3°C	WET	4300	4490	4730	4980	5220	5440	5690	5910
8000 FT	DRY	3380	3510	3680	3870	4050	4210	4400	4560
STD=-1°C	WET	4530	4730	4990	5260	5530	5770	6030	6280
10000 FT	DRY	3550	3690	3880	4090	4280	4460	4650	4830
STD=-5°C	WET	4790	5000	5280	5580	5860	6120	6410	6670
NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop. (Includes Air Run Distance)									

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-7	-10
ABOVE standard day	+17	+25

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-47	-99
DOWNHILL	+125	+300

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-20	-34
TAILWIND	+30	+51

SERIES 30
50/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MANUAL SPOILERS

Weight 1000 LB		340	360	380	400	420	440	460	480
S.L.	DRY	3380	3530	3670	3800	3910	4050	4210	4370
STD=15°C	WET	4500	4700	4900	5100	5270	5470	5690	5920
2000 FT	DRY	3550	3710	3850	4000	4120	4270	4440	4610
STD=11°C	WET	4740	4960	5180	5390	5570	5790	6030	6280
4000 FT	DRY	3740	3900	4060	4220	4350	4510	4710	4910
STD=7°C	WET	5010	5250	5480	5710	5910	6150	6440	6720
6000 FT	DRY	3930	4110	4280	4450	4590	4770	5010	5240
STD=3°C	WET	5290	5550	5800	6050	6260	6520	6860	7200
8000 FT	DRY	4140	4330	4510	4720	4910	5120	5390	5650
STD=-1°C	WET	5590	5860	6130	6430	6710	7020	7390	7770
10000 FT	DRY	4370	4570	4770	5010	5260	5510	5800	6110
STD=-5°C	WET	5910	6210	6500	6840	7200	7560	7970	8410

NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop. (Includes Air Run Distance)

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-10	-14
ABOVE standard day	+23	+34

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-54	-116
DOWNHILL	+168	+380

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-25	-41
TAILWIND	+79	+63

SERIES 30
35/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MANUAL SPOILERS

Weight 1000 LB		340	360	380	400	420	440	460	480
S.L.	DRY	3500	3650	3810	3950	4070	4220	4390	4560
STD=15°C	WET	4700	4920	5140	5360	5540	5760	6010	6250
2000 FT	DRY	3680	3840	4010	4160	4300	4460	4640	4820
STD=11°C	WET	4960	5190	5440	5670	5870	6110	6380	6640
4000 FT	DRY	3870	4040	4230	4400	4540	4720	4930	5150
STD=7°C	WET	5250	5500	5770	6020	6240	6500	6810	7120
6000 FT	DRY	4080	4270	4460	4650	4800	4990	5250	5510
STD=3°C	WET	5550	5830	6110	6390	6620	6910	7270	7640
8000 FT	DRY	4300	4500	4710	4930	5140	5370	5650	5930
STD=-1°C	WET	5870	6170	6480	6800	7100	7430	7840	8240
10000 FT	DRY	4540	4760	4990	5250	5500	5780	6090	6400
STD=-5°C	WET	6210	6540	6870	7250	7610	8010	8460	8900

NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop. (Includes Air Run Distance)

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-10	-15
ABOVE standard day	+26	+37

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-58	-120
DOWNHILL	+179	+411

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-26	-42
TAILWIND	+86	+68

During Go-Around and Missed Approach

If go-around is required, initial flight director pitch guidance will provide proper speed and pitch targets, but, under certain 5G interference conditions, the flight director cannot be commanded from the Flight Control Panel (FCP) to provide speed or heading guidance, and may not provide altitude capture guidance. If this guidance is not available, manually comply with missed approach procedures, including altitude constraints.

(4) For airplanes identified in paragraph (c)(8) of this AD: Within 2 days after the effective date of this AD, revise the Operating Procedures Section of the existing AFM to include the information specified in figure 7 to paragraph (h)(4) of this AD. This may be done by inserting a copy of figure 7 to paragraph (h)(4) of this AD into the Operating Procedures Section of the existing AFM.

Note 4 to paragraph (h)(4): Guidance for accomplishing the actions required by paragraph (h)(4) of this AD can be found in Boeing Multi Operator Message MOM–MOM–22–0030–01B(R3), dated March 22, 2022; and Boeing MD–11 Flight Crew Operations Manual Bulletin 2–18C, ''Operation in airspace affected by 5G signal interference,'' dated March 18, 2022.

Figure 7 to paragraph (h)(4) – *AFM Operating Procedures Revision for Model MD-11*

(Required by AD 2022-09-18)

Radio Altimeter 5G C-Band Interference, Approach, Landing, and Go-Around

ILS Approaches

For ILS approaches not prohibited by AD 2021-23-12, disconnect the autopilot prior to glideslope intercept.

Note: Possible erroneous radio altimeter indications may affect autothrottles and flight director guidance; manually intervene if necessary.

Non-Precision Approaches

Non-precision instrument approaches can be conducted using LNAV/VNAV with flight directors, autopilot, and autothrottle to published BARO minimums.

Landing

For landing, the Auto Ground Spoiler function may require manual extension. If manual extension is required, calculate landing distance requirements according to the following tables, as applicable.

50/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MAN SPOILERS

General Electric CF6-80C2 Engines

Weight 1000 LB		360	380	400	420	440	460	480	500
S.L.	DRY	4315	4480	4650	4803	4949	5126	5274	5453
STD=15°C	WET	5156	5388	5604	5805	6008	6240	6443	6677
2000 FT	DRY	4520	4695	4876	5039	5195	5384	5542	5734
STD=11°C	WET	5466	5688	5927	6140	6355	6605	6827	7084
4000 FT	DRY	4738	4925	5118	5292	5459	5661	5830	6036
STD=7°C	WET	5777	6021	6275	6510	6743	7007	7241	7527
6000 FT	DRY	4975	5175	5381	5568	5747	5963	6145	6367
STD=3°C	WET	6125	6392	6658	6917	7166	7449	7710	7999
8000 FT	DRY	5229	5443	5663	5864	6057	6290	6486	6725
STD=-1°C	WET	6497	6787	7084	7354	7628	7939	8212	8538
10000 FT	DRY	5505	5734	5972	6188	6418	6693	6931	7208
STD=-5°C	WET	6920	7220	7544	7842	8155	8532	8853	9223

NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop (includes air run distances).

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-12	-14
ABOVE standard day	+25	+35

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-84	-137
DOWNHILL	+229	+444

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-32	-46
TAILWIND	+83	+132

35/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MAN SPOILERS

General Electric CF6-80C2 Engines

Weight 1000 LB		360	380	400	420	440	460	480	500
S.L.	DRY	4632	4803	4974	5155	5340	5496	5685	5855
STD=15°C	WET	5577	5795	6020	6257	6502	6717	6969	7197
2000 FT	DRY	4856	5039	5221	5414	5613	5780	5983	6165
STD=11°C	WET	5890	6131	6373	6631	6893	7128	7394	7642
4000 FT	DRY	5096	5291	5486	5693	5906	6085	6304	6500
STD=7°C	WET	6249	6509	6763	7037	7317	7571	7864	8133
6000 FT	DRY	5357	5566	5775	5998	6227	6420	6655	6867
STD=3°C	WET	6631	6914	7190	7489	7798	8060	8380	8674
8000 FT	DRY	5637	5862	6087	6326	6574	6782	7037	7317
STD=-1°C	WET	7047	7348	7660	7980	8308	8600	8943	9324
10000 FT	DRY	5943	6185	6428	6687	6963	7267	7546	7854
STD=-5°C	WET	7513	7841	8166	8522	8888	9294	9675	10074

NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 80 KIAS, then reverse idle to 60 KIAS, then forward idle to stop (includes air run distances).

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-13	-16
ABOVE standard day	+29	+39

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-94	-155
DOWNHILL	+275	+522

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-35	-50
TAILWIND	+95	+143

50/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MAN SPOILERS

Pratt & Whitney PW-4460/PW-4462 Engines

Weight 1000 LB		360	380	400	420	440	460	480	500
S.L.	DRY	4316	4476	4641	4791	4963	5113	5262	5443
STD=15°C	WET	5050	5269	5498	5710	5922	6157	6371	6626
2000 FT	DRY	4526	4697	4875	5036	5190	5377	5535	5728
STD=11°C	WET	5343	5585	5824	6053	6282	6531	6760	7035
4000 FT	DRY	4751	4935	5125	5297	5463	5663	5832	6038
STD=7°C	WET	5664	5914	6185	6425	6673	6943	7189	7477
6000 FT	DRY	4993	5190	5394	5580	5757	5973	6154	6375
STD=3°C	WET	6003	6284	6566	6826	7094	7392	7651	7969
8000 FT	DRY	5253	5465	5684	5883	6075	6307	6503	6741
STD=-1°C	WET	6382	6677	6983	7266	7550	7869	8158	8494
10000 FT	DRY	5534	5762	5998	6214	6443	6718	6955	7232
STD=-5°C	WET	6783	7107	7440	7749	8076	8457	8797	9182

NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 60 KIAS, then forward idle to stop (includes air run distances).

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-11	-13
ABOVE standard day	+25	+34

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-83	-138
DOWNHILL	+228	+443

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-33	-45
TAILWIND	+83	+128

35/EXT ESTIMATED LANDING DISTANCES (FEET)
USE MAN SPOILERS

Pratt & Whitney PW-4460/PW-4462 Engines

Weight 1000 LB		360	380	400	420	440	460	480	500
S.L.	DRY	4622	4790	4958	5138	5326	5484	5677	5850
STD=15°C	WET	5422	5661	5902	6154	6422	6647	6923	7169
2000 FT	DRY	4856	5035	5215	5406	5605	5773	5979	6165
STD=11°C	WET	5755	6005	6265	6533	6812	7062	7353	7626
4000 FT	DRY	5105	5298	5491	5696	5908	6087	6307	6506
STD=7°C	WET	6102	6386	6659	6950	7251	7511	7825	8121
6000 FT	DRY	5373	5581	5788	6009	6238	6430	6665	6879
STD=3°C	WET	6493	6787	7084	7397	7724	8013	8345	8656
8000 FT	DRY	5662	5885	6109	6347	6594	6802	7056	7285
STD=-1°C	WET	6907	7220	7543	7887	8236	8548	8916	9254
10000 FT	DRY	5975	6216	6458	6716	6992	7296	7575	7882
STD=-5°C	WET	7353	7703	8047	8423	8815	9243	9646	10082

NOTE: Standard day, no wind, zero slope, three engines at maximum reverse thrust to 60 KIAS, then forward idle to stop (includes air run distances).

CORRECTIONS:

Temperature: Valid from STD -20°C to STD +40°C

FEET PER °C	DRY	WET
BELOW standard day	-11	-15
ABOVE standard day	+28	+39

Slope: Valid from -2% downhill to +2% uphill

FEET PER 1% SLOPE	DRY	WET
UPHILL	-93	-151
DOWNHILL	+273	+524

Wind: Valid from -10 knot tailwind to +20 knot headwind

FEET PER KNOT	DRY	WET
HEADWIND	-35	-48
TAILWIND	+94	+140

During Go-Around and Missed Approach

If go-around is required, initial flight director pitch guidance will provide proper speed and pitch targets, but, under certain 5G interference conditions, the flight director cannot be commanded from the Flight Control Panel (FCP) to provide speed or heading guidance, and may not provide altitude capture guidance. If this guidance is not available, manually comply with missed approach procedures, including altitude constraints.

(5) For airplanes identified in paragraph (c)(9) of this AD: Within 2 days after the effective date of this AD, revise the Operating Procedures Section of the existing AFM to include the information specified in figure 8 to paragraph (h)(5) of this AD. This may be done by inserting a copy of figure 8 to paragraph (h)(5) of this AD into the Operating Procedures Section of the existing AFM.

Note 5 to paragraph (h)(5): Guidance for accomplishing the actions required by paragraph (h)(5) of this AD can be found in Boeing Multi Operator Message MOM–MOM–22–0030–01B(R3), dated March 22, 2022; and Boeing MD–80 Flight Crew Operations Manual Bulletin 80–2–019B, ''Operation in airspace affected by 5G signal interference,'' dated February 1, 2022.

Figure 8 to paragraph (h)(5) – *AFM Operating Procedures Revision for Model DC-9-81 (MD-81), DC-9-82 (MD-82), DC-9-83 (MD-83), DC-9-87 (MD-87), MD-88, and MD-90-30*

(Required by AD 2022-09-18)

Radio Altimeter 5G C-Band Interference, Approaches

ILS Approaches

For ILS approaches not prohibited by AD 2021-23-12, disconnect the autopilot and autothrottles, and place both flight director switches to OFF prior to glideslope intercept.

Note: Possible erroneous radio altimeter indications may affect autopilot, autothrottles, and flight director guidance; manually intervene if necessary.

Non-Precision Approaches

Non-precision instrument approaches can be conducted using LNAV/VNAV with flight directors, autopilot, and autothrottle to published BARO minimums.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO 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 certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) AMOCs approved for AD 2021–23–12, Amendment 39–21810 (86 FR 69984, December 9, 2021) providing relief for specific radio altimeter installations are approved as AMOCs for the provisions of this AD.

(j) Related Information

(1) For more information about this AD, contact Eric Igama, Aerospace Engineer, Systems and Equipment Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5388; email: *Roderick.Igama@faa.gov.*

(2) For service information identified in this AD that is not incorporated by reference, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110 SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.*

(k) Material Incorporated by Reference

None.

Issued on April 28, 2022.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–11058 Filed 5–18–22; 4:15 pm]

BILLING CODE 4910–13–C

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0519; Project Identifier MCAI–2022–00589–R; Amendment 39–22050; AD 2022–10–51]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters and Airbus Helicopters Deutschland GmbH (AHD) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for Airbus Helicopters Model AS350B, AS350B1, AS350B2, AS350B3, AS350BA, AS350D, AS355E, AS355F, AS355F1, AS355F2, AS355N, AS355NP, EC130B4, and EC130T2 helicopters; and Airbus Helicopters Deutschland GmbH (AHD) Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, EC135T3, MBB–BK 117 C–2, MBB–BK 117 D–2, and MBB–BK 117 D–3 helicopters. This AD was prompted by a supplier report of a non-conformity occurring during production. This AD requires removing certain flight control Flexball cables from service and prohibits installing those flight control Flexball cables on any helicopter, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. This AD also requires reporting certain information. The FAA previously sent an emergency AD to all known U.S. owners and operators of these helicopters. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 7, 2022. Emergency AD 2022–10–51, issued on May 3, 2022, which contained the requirements of this amendment, was effective with actual notice.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 7, 2022.

The FAA must receive comments on this AD by July 7, 2022.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For EASA material incorporated by reference (IBR) in this final rule, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* For Airbus Helicopters service information identified in this final rule, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *https://www.airbus.com/helicopters/services/technical-support.html.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. Service information that is IBRed is also available in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0519.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0519; 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 EASA emergency AD, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Kristi Bradley, Program Manager, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *kristin.bradley@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On May 3, 2022, the FAA issued Emergency AD 2022–10–51 for Airbus Helicopters Model AS350B, AS350B1, AS350B2, AS350B3, AS350BA, AS350D, AS355E, AS355F, AS355F1, AS355F2, AS355N, AS355NP, EC130B4, and EC130T2 helicopters; and Airbus Helicopters Deutschland GmbH (AHD) Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, EC135T3, MBB–BK 117 C–2, MBB–BK 117 D–2, and MBB–BK 117 D–3 helicopters. Emergency AD 2022–10–51 requires removing certain part-numbered and serial-numbered flight control Flexball cables from service and prohibits installing those flight control Flexball cables on any helicopter. Emergency AD 2022–10–51 also requires reporting certain information to Airbus Helicopters or AHD, as applicable. The FAA sent the emergency AD to all known U.S. owners and operators of these helicopters. That action was prompted by EASA Emergency AD 2022–0077–E, dated April 29, 2022 (EASA AD 2022–0077–E), to correct an unsafe condition for Airbus Helicopters (AH), formerly Eurocopter, Eurocopter France, Aerospatiale, Model AS 350 B, AS 350 B1, AS 350 B2, AS 350 B3, AS 350 BA, AS 350 BB, AS 350 D, AS 355 E, AS 355 F, AS 355 F1, AS 355 F2, AS 355 N, AS 355 NP, EC 130 B4, and EC 130 T2 helicopters, all serial numbers (S/Ns); and Airbus Helicopters Deutschland GmbH (AHD), formerly Eurocopter Deutschland GmbH, Eurocopter España S.A., Model EC 135 T1, EC 135 T2, EC 135 T2+, EC 135 T3, EC 135 P1, EC 135 P2, EC 135 P2+, EC 135 P3, EC 635 T1, EC 635 T2+, EC 635 T3, EC 635 P2+, EC 635 P3, MBB–BK 117 D–2, MBB–BK 117 D–3, MBB–BK 117 D–3m, and MBB–BK 117 C–2 helicopters, all S/Ns.

The FAA is issuing this AD to address non-conforming flight control Flexball cables, which, if not addressed, could result in increased friction inside the flight control Flexball cables, jamming of the flight controls, and subsequent loss of control of the helicopter. See EASA AD 2022–0077–E for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0077–E requires replacing affected flight control Flexball cables with a serviceable part and prohibits installing an affected flight control Flexball cable on any helicopter.

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.

Other Related Service Information

The FAA reviewed Airbus Helicopters Emergency Alert Service Bulletin (EASB) AS350 67.00.81, AS355 67.00.49, and EC130 67A023, which are co-published as one document along with AS550 67.00.45 (military) and AS555 67.00.34 (military), EASB EC135–67A–043, EASB EC135H–67A–016, EASB MBB–BK117 C–2–67A–032, and EASB MBB–BK117 D–2–67A–021, each Revision 0 and dated April 29, 2022. This service information specifies procedures for determining if an affected Flexball is installed. If an affected Flexball is installed, or if it cannot be determined if an affected Flexball is installed, this service information specifies procedures for replacing the Flexball, returning the removed Flexball to the supplier, and completing and emailing a reply form sheet to Airbus Helicopters Customer Support or Airbus Helicopters Service Bulletin Germany, depending on your model helicopter.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its emergency AD. The FAA is issuing this AD after evaluating all pertinent information and determining that the unsafe condition exists and is likely to exist or develop on other helicopters of the same type designs.

Requirements of This AD

This AD requires accomplishing the actions specified in EASA AD 2022–0077–E, described previously, as IBRed, except for any differences identified as exceptions in the regulatory text of this AD and except as discussed under ''Differences Between this AD and the EASA AD.''

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, EASA AD 2022–0077–E is IBRed in this FAA final rule. This AD, therefore, requires compliance with EASA AD 2022–0077–E in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in EASA AD 2022–0077–E does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2022–0077–E. Service information referenced in EASA AD 2022–0077–E for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0519 after this final rule is published.

Differences Between This AD and the EASA AD

EASA AD 2022–0077–E applies to Airbus Helicopters Model AS 350 BB helicopters and Airbus Helicopters Deutschland GmbH (AHD) Model EC 635 T1, EC 635 T2+, EC 635 T3, EC 635 P2+, EC 635 P3, and MBB–BK 117 D–3m helicopters. This AD does not apply to those model helicopters because those models are not FAA type-certificated and are not included on the U.S. type certificate data sheet (TCDS), except where the TCDS explains that the Model EC635T2+ helicopter having serial number 0858 was converted from Model EC635T2+ to Model EC135T2+. The service information referenced in EASA AD 2022–0077–E specifies sending removed Flexball cables to the supplier; whereas, this AD requires removing an affected part from service. EASA AD 2022–0077–E specifies that a single ferry flight without passengers is allowed to a maintenance location where the action required by the AD can be accomplished; whereas this AD may allow a special flight permit or continuous authorization flight for a single flight, provided that there are no passengers onboard and that there is no noticeable increase in friction in the flight control system. EASA AD 2022–0077–E does not require reporting information; whereas, this AD does.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that required the immediate adoption of Emergency AD 2022–10–51, issued on May 3, 2022, to all known U.S. owners and operators of these helicopters. The FAA found that the risk to the flying public justified waiving notice and comment prior to adoption of this rule because the affected component is part of the flight control system and is critical to the control of a helicopter. A non-conforming flight control Flexball cable, if not corrected, could result in jamming of the flight controls during various operations and phases of flight, and over various terrains. Additionally, the FAA has no information pertaining to how quickly the condition may propagate to failure. In light of this, the initial actions required by this AD must be accomplished before next flight. These conditions still exist, therefore, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forego notice and comment.

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0519; Project Identifier MCAI–2022–00589–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Kristi Bradley, Program Manager, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *kristin.bradley@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects up to 1,785 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Replacing a flight control Flexball cable takes about 8 work-hours and parts cost about $804 to $13,555, depending on part number, for an estimated cost of $1,484 to $14,235 per helicopter and up to $437,780 to $4,199,325 for the U.S. fleet (there are up to 295 affected flight control Flexball cables installed in the U.S. fleet). Reporting information takes about 0.5 work-hour for an estimated cost of $43 per helicopter and up to $76,755 for the U.S. fleet.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

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, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866, and

(2) Will not affect intrastate aviation in Alaska.

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:

2022–10–51 Airbus Helicopters and Airbus Helicopters Deutschland GmbH (AHD): Amendment 39–22050; Docket No. FAA–2022–0519; Project Identifier MCAI–2022–00589–R.

(a) Effective Date

The FAA issued Emergency Airworthiness Directive (AD) 2022–10–51 on May 3, 2022, directly to affected owners and operators. As a result of such actual notice, that AD was effective for those owners and operators on the date it was provided. This AD contains the same requirements as that emergency AD and, for those who did not receive actual notice, is effective on June 7, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the helicopters identified in paragraphs (c)(1) and (2) of this AD, certificated in any category.

(1) Airbus Helicopters Model AS350B, AS350B1, AS350B2, AS350B3, AS350BA, AS350D, AS355E, AS355F, AS355F1, AS355F2, AS355N, AS355NP, EC130B4, and EC130T2 helicopters.

Note 1 to paragraph (c)(1): Helicopters with an AS350B3e designation are Model AS350B3 helicopters.

(2) Airbus Helicopters Deutschland GmbH (AHD) Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, EC135T3, MBB–BK 117 C–2, MBB–BK 117 D–2, and MBB–BK 117 D–3 helicopters.

Note 2 to paragraph (c)(2): Helicopters with an EC135P3H designation are Model EC135P3 helicopters. Helicopters with an EC135T3H designation are Model EC135T3 helicopters. Helicopters with an MBB–BK117 C–2e designation are Model MBB–BK117 C–2 helicopters.

(d) Subject

Joint Aircraft System Component (JASC) Code: 2700, Flight Control System.

(e) Unsafe Condition

This AD was prompted by a supplier report of a non-conformity occurring during

production. The FAA is issuing this AD to address non-conforming flight control Flexball cables. The unsafe condition, if not addressed, could result in increased friction inside the flight control Flexball cables, jamming of the flight controls, and subsequent loss of control of the helicopter.

(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) Emergency AD 2022–0077–E, dated April 29, 2022 (EASA AD 2022–0077–E).

(h) Exceptions to EASA AD 2022–0077–E

(1) Where EASA AD 2022–0077–E refers to its effective date, this AD requires using the effective date of this AD.

(2) Where the service information referenced in EASA AD 2022–0077–E specifies returning a part to the supplier, this AD requires removing an affected part from service.

(3) The note to paragraph (1) of EASA AD 2022–0077–E does not apply to this AD; instead, see the provisions in paragraph (j) of this AD.

(4) This AD does not mandate compliance with the ''Remarks'' section of EASA AD 2022–0077–E.

(i) Reporting Requirement

Within 10 days after accomplishing the actions required by paragraph (g) of this AD, report the information requested in Appendix 1 to this AD to the email address identified in paragraph (i)(1) or (2) of this AD, depending on your helicopter model.

(1) For Model AS350B, AS350B1, AS350B2, AS350B3, AS350BA, AS350D, AS355E, AS355F, AS355F1, AS355F2, AS355N, AS355NP, EC130B4, and EC130T2 helicopters: *customersupport.helicopters@airbus.com.*

(2) For Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, EC135T3, MBB–BK 117 C–2, MBB–BK 117 D–2, and MBB–BK 117 D–3 helicopters: *support.technical-bulletins.ahd@airbus.com.*

(j) Special Flight Permit

A special flight permit or continuous authorization flight for a single flight may be issued, provided that there are no passengers onboard and that there is no noticeable increase in friction in the flight control system.

(k) Alternative Methods of Compliance (AMOCs)

(1) 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, send it to the attention of the person identified in paragraph (l) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

(2) 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.

(l) Related Information

For more information about this AD, contact Kristi Bradley, Program Manager, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *kristin.bradley@faa.gov.*

(m) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) Emergency AD 2022–0077–E, dated April 29, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0077–E, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find the EASA material on the EASA website at *https://ad.easa.europa.eu.*

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. This material may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0519.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Appendix 1 to Airworthiness Directive 2022–10–51

Conformity of the Flexballs (sample format)

Provide the following information by email as follows:

For Model AS350B, AS350B1, AS350B2, AS350B3, AS350BA, AS350D, AS355E, AS355F, AS355F1, AS355F2, AS355N, AS355NP, EC130B4, and EC130T2 helicopters: *customersupport.helicopters@airbus.com.*

For Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, EC135T3, MBB–BK 117 C–2, MBB–BK 117 D–2, and MBB–BK 117 D–3 helicopters: *support.technical-bulletins.ahd@airbus.com.*

Helicopter Model and Serial Number:

Flexball Part Number:

Flexball Serial Number:

Issued on May 9, 2022.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–11067 Filed 5–19–22; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–1183; Project Identifier AD–2021–01193–E; Amendment 39–22029; AD 2022–09–09]

RIN 2120–AA64

Airworthiness Directives; CFM International, S.A. Turbofan Engines

Editorial Note: Rule document 2022–10447 was originally published on pages 29651 through 29654 in the issue of Monday, May 16, 2022. In that publication on page 29653, in the third column, in paragraph 2(a), ''June 20, 2022'' should read ''June 21, 2022''. The corrected document is published here in its entirety.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all CFM International, S.A. (CFM) LEAP–1A23, LEAP–1A24, LEAP–1A24E1, LEAP–1A26, LEAP–1A26CJ, LEAP–1A26E1, LEAP–1A29, LEAP–1A29CJ, LEAP–1A30, LEAP–1A32, LEAP–1A33, LEAP–1A33B2, and LEAP–1A35A model turbofan engines. This AD was prompted by the detection of melt-related freckles in the billet, which may reduce the life of certain compressor rotor stages 6–10 spools, high pressure turbine (HPT) rotor interstage seals, HPT rotor stage 2 disks, low pressure turbine (LPT) stage 1 disks, LPT stage 2 disks, LPT stage 3 disks, and LPT stage 4 disks. This AD requires revising the airworthiness limitations section (ALS) of the applicable CFM LEAP–1A Engine Shop Manual (ESM) and the operator's existing approved continuous airworthiness maintenance program (CAMP) to incorporate reduced life limits for these parts. This AD also requires the removal of certain LPT stage 4 disks identified by serial number (S/N) prior to their new life limits. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 21, 2022.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of June 21, 2022.

ADDRESSES: For service information identified in this final rule, contact CFM International, S.A., Aviation Operations Center, 1 Neumann Way, M/D Room 285, Cincinnati, OH 45125; phone: (877) 432–3272; email: *fleetsupport@ge.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1183.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1183; 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, 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.

FOR FURTHER INFORMATION CONTACT: Mehdi Lamnyi, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7743; fax: (781) 238–7199; email: *Mehdi.Lamnyi@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 all CFM LEAP–1A23, LEAP–1A24, LEAP–1A24E1, LEAP–1A26, LEAP–1A26CJ, LEAP–1A26E1, LEAP–1A29, LEAP–1A29CJ, LEAP–1A30, LEAP–1A32, LEAP–1A33, LEAP–1A33B2, and LEAP–1A35A model turbofan engines. The NPRM published in the **Federal Register** on January 18, 2022 (87 FR 2563). The NPRM was prompted by the manufacturer's detection of melt-related freckles in the billet, which may reduce the life of certain compressor rotor stages 6–10 spools, HPT rotor interstage seals, HPT rotor stage 2 disks, LPT stage 1 disks, LPT stage 2 disks, LPT stage 3 disks, and LPT stage 4 disks (life-limited parts (LLPs)). Through the manufacturer's investigation, it was determined that these LLPs may have subsurface anomalies that developed during the manufacturing process, resulting in a lower life capability. In the NPRM, the FAA proposed to require revising the ALS of the CFM LEAP–1A ESM, as applicable to each affected engine model, and the operator's existing approved CAMP to incorporate reduced life limits for certain LLPs. In the NPRM, the FAA also proposed to require operators to remove certain LPT stage 4 disks, identified by S/N, before reaching their new life limits. The LPT stage 4 disks, identified by S/N in Figure 1 to paragraph (g)(2) of the NPRM, were discovered by the manufacturer after publication of the ALS revision.

After the NPRM was issued, CFM revised its service information by including additional part numbers for newly manufactured parts that did not exist prior to NPRM publication. Accordingly, the FAA has revised paragraph (g)(1)(iii) of this AD to require operators to update the ALS of the applicable CFM LEAP–1A ESM and the operator's existing approved CAMP to include CFM Low Pressure Turbine Rotor Life Limits LEAP 1A–05–11–04–01A–0B1B–C, Issue 010–00, dated February 15, 2022, instead of CFM Low Pressure Turbine Rotor Life Limits LEAP 1A–05–11–04–01A–0B1B–C, Issue 009–00, dated June 1, 2021.

The FAA has also added a credit for previous actions paragraph to this AD, providing credit to operators that incorporated CFM Low Pressure Turbine Rotor Life Limits LEAP 1A–05–11–04–01A–0B1B–C, Issue 009–00, dated June 1, 2021, into the ALS of the applicable ESM and the operator's existing approved CAMP prior to the effective date of this AD.

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

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from two commenters. The commenters were American Airlines (AA) and Air Line Pilot Association, International (ALPA). The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Include Future Revisions to ESM

AA requested that the FAA add ''. . . or later'' to the following ALS references in paragraph (g) of this AD to allow for the use of future revisions;

(i) CFM High Pressure Compressor Rotor Life Limits LEAP 1A–05–11–02–01A–0B1B–C, Issue 010–00, dated September 15, 2021, or later;

(ii) CFM High Pressure Turbine Rotor Life Limits LEAP 1A–05–11–03–01A–0B1B–C, Issue 007–00, dated September 15, 2021, or later; and

(iii) CFM Low Pressure Turbine Rotor Life Limits LEAP 1A–05–11–04–01A–0B1B–C, Issue 009–00, dated June 1, 2021, or later.

AA stated that they are currently using Issues 7, 9, and 10 of the referenced service information and their ALS and CAMP are already in compliance with this AD. AA also stated that CFM continues to update the referenced service information and Issues 7, 9, and 10 will be further revised. As a result, the requirements of this AD will cause AA to use outdated service information.

The FAA disagrees with adding ''or later'' when referencing the service information in paragraph (g) of this AD. Future revisions of the service information have not yet been published by the manufacturer or reviewed by the FAA. A request for an alternative method of compliance can be submitted to the FAA if future revisions of the service information referenced in paragraph (g) of this AD are published. Additionally, if future revisions of the service information are published by the manufacturer and approved by the FAA, the FAA may consider further rulemaking.

Request To Add Credit for Previous Actions

AA requested that the FAA add a new paragraph (h)(3) to this AD to allow credit for previous actions associated with the required actions proposed in paragraph (g)(1)(iii) of the NPRM, similar to the credit paragraphs proposed in (h)(1) and (h)(2) of the NPRM. AA requested that the new paragraph (h)(3) provide credit to operators if CFM Low Pressure Turbine Rotor Life Limits LEAP 1A–05–11–04–01A–0B1B–C, Issue 008–00 was incorporated into the ALS of the applicable ESM and the operator's existing approved CAMP prior to the effective date of this AD.

The FAA notes that CFM Low Pressure Turbine Rotor Life Limits LEAP 1A–05–11–04–01A–0B1B–C, Issue 009–00, dated June 1, 2021, was the first issue of this service information to include the reduced life limits for that module as a result of the investigation into melt-related freckles in the billet. Issue 008–00 and earlier issues do not include the reduced life limits so the FAA will not provide credit for issues released prior to Issue 009–00. Since the FAA issued the NPRM, the manufacturer published CFM Low Pressure Turbine Rotor Life

Limits LEAP 1A–05–11–04–01A–0B1B–C, Issue 010–00, dated February 15, 2022. As a result, the FAA has added paragraph (h)(3) to this AD, providing credit for actions required by paragraph (g)(1)(iii) of this AD if CFM Low Pressure Turbine Rotor Life Limits LEAP 1A–05–11–04–01A–0B1B–C, Issue 009–00, dated June 1, 2021, was incorporated into the ALS of the applicable ESM and the operator's existing approved CAMP prior to the effective date of this AD.

Support for the AD

ALPA expressed support for the AD as written.

Conclusion

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 and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed CFM High Pressure Compressor Rotor Life Limits LEAP 1A–05–11–02–01A–0B1B–C, Issue 010–00, dated September 15, 2021 (CFM LEAP 1A–05–11–02–01A–0B1B–C); CFM High Pressure Turbine Rotor Life Limits LEAP 1A–05–11–03–01A–0B1B–C, Issue 007–00, dated September 15, 2021 (CFM LEAP 1A–05–11–03–01A–0B1B–C); and CFM Low Pressure Turbine Rotor Life Limits LEAP 1A–05–11–04–01A–0B1B–C, Issue 010–00, dated February 15, 2022 (CFM LEAP 1A–05–11–04–01A–0B1B–C). CFM LEAP 1A–05–11–02–01A–0B1B–C provides the new life limits for the high-pressure compressor, CFM LEAP 1A–05–11–03–01A–0B1B–C provides the new life limits for the HPT rotor, and CFM LEAP 1A–05–11–04–01A–0B1B–C provides the new life limits for the LPT rotor. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Other Related Service Information

The FAA reviewed CFM LEAP 1A–05–11–02–01A–0B1B–C, Issue 009–00, dated July 26, 2021; CFM LEAP 1A–05–11–03–01A–0B1B–C, Issue 006–00, dated July 26, 2021, and CFM LEAP 1A–05–11–04–01A–0B1B–C, Issue 009, dated June 1, 2021. This service information provides the new life limits for the LLPs.

The FAA also reviewed CFM Service Bulletin (SB) LEAP–1A–72–00–0413–01A–930A–D, Issue 004–00, dated December 11, 2021 (CFM SB LEAP–1A–72–00–0413–01A–930A–D). CFM SB LEAP–1A–72–00–0413–01A–930A–D specifies procedures for removing and replacing the LLPs, and provides new life limits for certain S/Ns of the LLPs.

Costs of Compliance

The FAA estimates that this AD affects 256 engines installed on airplanes of U.S. registry. The FAA estimates that 256 engines installed on airplanes of U.S. registry require revising the ALS of the CFM LEAP–1A ESM and the operator's existing approved CAMP.

The FAA estimates that zero airplanes of U.S. registry require replacement of the LPT stage 4 disk.

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
Revise ALS of Engine Manual and the operator's existing approved CAMP.	1 work-hour × $85 per hour = $85	$0	$85	$21,760

The FAA estimates the following costs to replace the LPT stage 4 disk:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace LPT Stage 4 disk	225 work-hours × $85 per hour = $19,125	$129,000	$148,125	$0

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:

2022–09–09 CFM International, S.A.: Amendment 39–22029; Docket No. FAA–2021–1183; Project Identifier AD–2021–01193–E.

(a) Effective Date

This airworthiness directive (AD) is effective June 21, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to CFM International, S.A. (CFM) LEAP–1A23, LEAP–1A24, LEAP–1A24E1, LEAP–1A26, LEAP–1A26CJ, LEAP–1A26E1, LEAP–1A29, LEAP–1A29CJ, LEAP–1A30, LEAP–1A32, LEAP–1A33, LEAP–1A33B2, and LEAP–1A35A model turbofan engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7230, Turbine Engine Compressor Section, and JASC Code 7250, Turbine Section.

(e) Unsafe Condition

This AD was prompted by the detection of melt-related freckles in the billet, which may reduce the life of certain compressor rotor stages 6–10 spools, high pressure turbine (HPT) rotor interstage seals, HPT rotor stage 2 disks, low pressure turbine (LPT) stage 1 disks, LPT stage 2 disks, LPT stage 3 disks, and LPT stage 4 disks. The FAA is issuing this AD to prevent the failure of the high-pressure compressor, HPT rotor, and LPT rotor. The unsafe condition, if not addressed, could result in release of uncontained debris, damage to the engine, and damage to the airplane.

(f) Compliance

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

(g) Required Actions

(1) Within 60 days after the effective date of this AD, revise the airworthiness limitations section (ALS) of the applicable CFM LEAP–1A Engine Shop Manual (the ESM) and the operator's existing approved continuous airworthiness maintenance program (CAMP) by incorporating the following service information:

(i) CFM High Pressure Compressor Rotor Life Limits LEAP 1A–05–11–02–01A–0B1B–C, Issue 010–00, dated September 15, 2021; and

(ii) CFM High Pressure Turbine Rotor Life Limits LEAP 1A–05–11–03–01A–0B1B–C, Issue 007–00, dated September 15, 2021; and

(iii) CFM Low Pressure Turbine Rotor Life Limits LEAP 1A–05–11–04–01A–0B1B–C, Issue 010–00, dated February 15, 2022.

(2) Before the LPT stage 4 disk, part number (P/N) 362–039–520–0, with serial numbers identified in Figure 1 to paragraph (g)(2) of this AD (Figure 1) accumulates the cycles in Figure 1, or within 100 cycles after the effective date of this AD, whichever occurs later, remove the affected LPT stage 4 disk from service and replace with a part eligible for installation.

FIGURE 1 TO PARAGRAPH (g)(2)—LIFE LIMITS FOR LPT STAGE 4 DISKS, P/N 362–039–520–0

LPT stage 4 disk serial No.	Life limit for LEAP–1A23, –1A24, –1A24E1, –1A26, –1A26E1, –1A29, –1A30, –1A32, –1A33, –1A33B2, and –1A35A	Life limit for LEAP–1A26CJ and –1A29CJ
PC975638 ..... PC975635.	2,500 cycles	1,400 cycles.

(h) Credit for Previous Actions

(1) You may take credit for the action required by paragraph (g)(1)(i) of this AD if the following service information was incorporated into the ALS of the applicable ESM and the operator's existing approved CAMP prior to the effective date of this AD: CFM High Pressure Compressor Rotor Life Limits LEAP 1A–05–11–02–01A–0B1B–C, Issue 009–00, dated July 26, 2021.

(2) You may take credit for the action required by paragraph (g)(1)(ii) of this AD if the following service information was incorporated into the ALS of the applicable ESM and the operator's existing approved CAMP prior to the effective date of this AD: CFM High Pressure Turbine Rotor Life Limits LEAP 1A–05–11–03–01A–0B1B–C, Issue 006–00, dated July 26, 2021.

(3) You may take credit for the action required by paragraph (g)(1)(iii) of this AD if the following service information was incorporated into the ALS of the applicable ESM and the operator's existing approved CAMP prior to the effective date of this AD: CFM Low Pressure Turbine Rotor Life Limits LEAP 1A–05–11–04–01A–0B1B–C, Issue 009–00, dated June 1, 2021.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO 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 certification office, send it to the attention of the person identified in paragraph (j) of this AD. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(2) 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) Related Information

For more information about this AD, contact Mehdi Lamnyi, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7743; fax: (781) 238–7199; email: *Mehdi.Lamnyi@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) CFM High Pressure Compressor Rotor Life Limits LEAP 1A–05–11–02–01A–0B1B–C, Issue 010–00, dated September 15, 2021.

(ii) CFM High Pressure Turbine Rotor Life Limits LEAP 1A–05–11–03–01A–0B1B–C, Issue 007–00, dated September 15, 2021.

(iii) CFM Low Pressure Turbine Rotor Life Limits LEAP 1A–05–11–04–01A–0B1B–C, Issue 010–00, dated February 15, 2022.

(3) For service information identified in this AD, contact CFM International, S.A., Aviation Operations Center, 1 Neumann Way, M/D Room 285, Cincinnati, OH 45125; phone: (877) 432–3272; email: *fleetsupport@ge.com.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For

information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on April 15, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. R1–2022–10447 Filed 5–20–22; 8:45 am]

BILLING CODE 0099–10–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0086; Project Identifier MCAI–2021–01035–T; Amendment 39–22026; AD 2022–09–06]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

Editorial Note: Rule document 2022–10460 was originally published on pages 29654 through 29657 in the issue of Monday, May 16, 2022. In that publication on page 29655, in the first column, in the **DATES**, ''June 20, 2022'' should read ''June 21, 2022''. Also, in that publication, on page 29656, in the first column, paragraph 2(a), ''June 20, 2022'' should read ''June 21, 2022''. The corrected document is published here in its entirety.

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2021–13–06, which applied to certain Airbus SAS Model A350–941 and –1041 airplanes. AD 2021–13–06 required revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. Since the FAA issued AD 2021–13–06, the FAA has determined that new or more restrictive airworthiness limitations are necessary. This AD continues to require the actions in AD 2021–13–06 and requires revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 21, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 21, 2022.

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of September 3, 2021 (86 FR 40934, July 30, 2021).

ADDRESSES: For material incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu*; internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://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 in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0086.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0086; 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.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225; email *dan.rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0208, dated September 15, 2021 (EASA AD 2021–0208) (also referred to as the MCAI), to correct an unsafe condition for all Airbus SAS Model A350–941 and –1041 airplanes.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2021–13–06, Amendment 39–21611 (86 FR 40934, July 30, 2021) (AD 2021–13–06). AD 2021–13–06 applied to certain Airbus SAS Model A350–941 and –1041 airplanes. The NPRM published in the **Federal Register** on February 9, 2022 (87 FR 7397). The NPRM was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The NPRM proposed to continue to require the actions in AD 2021–13–06 and require revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations, as specified in EASA AD 2021–0208.

The FAA is issuing this AD to address hazardous or catastrophic airplane system failures. See the MCAI for additional background information.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from the Air Line Pilots Association, International (ALPA) who supported the NPRM without change.

Conclusion

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

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0208 describes new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This AD also requires EASA AD 2020–0211, dated October 5, 2020, and EASA AD 2021–0026, dated January 20, 2021, which the Director of the Federal Register approved for incorporation by reference as of September 3, 2021 (86 FR 40934, July 30, 2021).

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

The FAA estimates the total cost per operator for the retained actions from

AD 2021–13–06 to be $7,650 (90 work-hours × $85 per work-hour).

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate.

The FAA estimates the total cost per operator for the new proposed actions to be $7,650 (90 work-hours × $85 per work-hour).

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) 2021–13–06, Amendment 39–21611 (86 FR 40934, July 30, 2021); and

■ b. Adding the following new AD:

2022–09–06 Airbus SAS: Amendment 39–22026; Docket No. FAA–2022–0086; Project Identifier MCAI–2021–01035–T.

(a) Effective Date

This airworthiness directive (AD) is effective June 21, 2022.

(b) Affected ADs

(1) This AD replaces AD 2021–13–06, Amendment 39–21611 (86 FR 40934, July 30, 2021) (AD 2021–13–06).

(2) This AD affects AD 2019–20–01, Amendment 39–19754 (84 FR 55495, October 17, 2019) (AD 2019–20–01).

(c) Applicability

This AD applies to Airbus SAS Model A350–941 and –1041 airplanes, certificated in any category, with an original airworthiness certificate or original export certificate of airworthiness issued on or before July 20, 2021.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Reason

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address hazardous or catastrophic airplane system failures.

(f) Compliance

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

(g) Retained Maintenance or Inspection Program Revision, With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2021–13–06, with no changes. For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before July 22, 2020: 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 2020–0211, dated October 5, 2020 (EASA AD 2020–0211); and EASA AD 2021–0026, dated January 20, 2021 (EASA AD 2021–0026). Where EASA AD 2021–0026 affects the same airworthiness limitations (tasks and life limits) as those in EASA AD 2020–0211, the airworthiness limitations referenced in EASA AD 2021–0026 prevail. Accomplishing the revision of the existing maintenance or inspection program required by paragraph (j) of this AD terminates the requirements of this paragraph.

(h) Retained Exceptions to EASA AD 2020–0211 and EASA AD 2021–0026, With No Changes

This paragraph restates the requirements of paragraph (h) of AD 2021–13–06, with no changes. For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before July 22, 2020:

(1) Where EASA AD 2020–0211 and EASA AD 2021–0026 refers to its effective date, this AD requires using September 3, 2021 (the effective date of AD 2021–13–06).

(2) The requirements specified in paragraphs (1) and (2) of EASA AD 2020–0211 and EASA AD 2021–0026 do not apply to this AD.

(3) Paragraph (3) of EASA AD 2020–0211 and EASA AD 2021–0026 specifies revising ''the approved AMP [aircraft maintenance program]'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, to incorporate the ''limitations, tasks and associated thresholds and intervals'' specified in paragraph (3) of EASA AD 2020–0211 and EASA AD 2021–0026 within 90 days after September 3, 2021 (the effective date of AD 2021–13–06).

(4) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2020–0211 and EASA AD 2021–0026 is at the applicable ''thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2020–0211 and EASA AD 2021–0026, or within 90 days after September 3, 2021 (the effective date of AD 2021–13–06), whichever occurs later.

(5) The provisions specified in paragraphs (4) and (5) of EASA AD 2020–0211 do not apply to this AD.

(6) The provisions specified in paragraph (4) of EASA AD 2021–0026 do not apply to this AD.

(7) The ''Remarks'' section of EASA AD 2020–0211 and EASA AD 2021–0026 does not apply to this AD.

(i) Retained Provisions for Alternative Actions and Intervals, With a New Exception

This paragraph restates the requirements of paragraph (i) of AD 2021–13–06, with a new exception. For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before July 22, 2020: Except as required by paragraph (j) of this AD, after the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections)

and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2020–0211 or EASA AD 2021–0026.

(j) New Maintenance or Inspection Program Revision

Except as specified in paragraph (k) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2021–0208, dated September 15, 2021. Accomplishing the revision of the existing maintenance or inspection program required by this paragraph terminates the requirements of paragraph (g) of this AD.

(k) Exceptions to EASA AD 2021–0208

(1) Where EASA AD 2021–0208 refers to its effective date, this AD requires using the effective date of this AD.

(2) The requirements specified in paragraphs (1) and (2) of EASA AD 2021–0208 do not apply to this AD.

(3) Paragraph (3) of EASA AD 2021–0208 specifies to revise ''the AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(4) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2021–0208 is at the applicable ''limitations'' as incorporated by the requirements of paragraph (3) of EASA AD 2021–0208, or within 90 days after the effective date of this AD, whichever occurs later.

(5) The provisions specified in paragraphs (4) and (5) of EASA AD 2021–0208 do not apply to this AD.

(6) The ''Remarks'' section of EASA AD 2021–0208 does not apply to this AD.

(7) Where EASA AD 2021–0208 refers to Airbus A350 Airworthiness Limitations Section (ALS) Part 4, Revision 6 and Variation 6.1, replace the text ''Airbus A350 Airworthiness Limitations Section (ALS) Part 4, Revision 6 and Variation 6.1,'' with ''Airbus A350 Airworthiness Limitations Section (ALS) Part 4, Revision 6 and Variation 6.1; for any airworthiness limitations (tasks and life limits) that are in both documents, the airworthiness limitations (tasks and life limits) specified in Variation 6.1 prevail.''

(l) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2021–0208.

(m) Terminating Action for Certain Requirements of AD 2019–20–01

Accomplishing the actions required by paragraph (g) or (j) of this AD terminates the repetitive greasing task for batch 02 group of affected thrust reverser actuators required by paragraph (g) of AD 2019–20–01.

(n) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, 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 Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (o) of this AD. Information may be emailed to: *9-AVS-AIR-730-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, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(o) Related Information

For more information about this AD, contact Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225; email *dan.rodina@faa.gov.*

(p) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on June 21, 2022.

(i) European Union Aviation Safety Agency (EASA) AD 2021–0208, dated September 15, 2021.

(ii) [Reserved]

(4) The following service information was approved for IBR on September 3, 2021 (86 FR 40934, July 30, 2021).

(i) European Union Aviation Safety Agency (EASA) AD 2020–0211, dated October 5, 2020.

(ii) European Union Aviation Safety Agency (EASA) AD 2021–0026, dated January 20, 2021.

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

(6) 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.

(7) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on April 15, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. R1–2022–10460 Filed 5–20–22; 8:45 am]

BILLING CODE 0099–10–D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0146; Project Identifier AD–2021–00449–R; Amendment 39–22054; AD 2022–11–04]

RIN 2120–AA64

Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2020–26–13, which applied to certain Sikorsky Aircraft Corporation (Sikorsky) Model S–92A helicopters. AD 2020–26–13 required establishing the life limit for certain part-numbered horizontal stabilizer root fittings FWD (forward root fittings) and certain part-numbered stabilizer strut fittings. AD 2020–26–13 also required repetitively inspecting certain parts, and depending on the inspection results, removing parts from service. Finally AD 2020–26–13 prohibited installing certain stabilizer assemblies on any helicopter. Since the FAA issued AD 2020–26–13, the manufacturer notified the FAA that due to an error in the service information, certain part numbers in AD 2020–26–13 are incorrect. Also, the FAA determined that additional inspections are required to address the unsafe condition. This AD retains certain requirements and the prohibition for installing certain stabilizer assemblies on any helicopter from AD 2020–26–13, corrects certain part numbers, and requires additional repetitive inspections. The actions of this AD are intended to address an unsafe condition on these products.

DATES: This AD is effective June 27, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of February 1, 2021 (85 FR 84201, December 28, 2020).

ADDRESSES: For service information identified in this final rule, contact Sikorsky's Engineering Group at Sikorsky Aircraft Corporation, 124 Quarry Road, Trumbell, CT 06611, United States; phone: (800) 946–4337; email: *wcs_cust_service_eng.gr-sik@lmco.com;* website: *www.sikorsky360.com.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0146.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov in* Docket No. FAA–2022–0146; 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 AD, any service information that is incorporated by reference, 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.

FOR FURTHER INFORMATION CONTACT: Dorie Resnik, Aerospace Engineer, Aviation Safety Section, Boston ACO Branch, Compliance & Airworthiness Division, 1200 District Avenue, Burlington, MA 01803; telephone (781) 238–7693; 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 to supersede AD 2020–26–13, Amendment 39–21368 (85 FR 84201, December 28, 2020) (AD 2020–26–13). AD 2020–26–13 applied to Sikorsky Model S–92A helicopters with forward root fitting part number (P/N) 92209–07111–101 or 92070–20125–101; or stabilizer strut fitting P/N 92209–07404–041, 92209–07403–041, or 92070–20117–041 installed on horizontal stabilizer assembly (stabilizer assembly) P/N 92070–20117–045, 92070–20117–046, 92070–20125–041, 92070–20125–042, 92070–20125–043, 92070–20125–044, 92205–07400–043, or 92205–07400–045. The NPRM published in the **Federal Register** on February 23, 2022 (87 FR 10115). The NPRM was prompted by the discovery that incorrect P/Ns were identified in the Applicability and the Required Actions paragraphs of AD 2020–26–13. Additionally, after the FAA issued AD 2020–26–13, Sikorsky notified the FAA that an additional repetitive inspection of certain parts of the stabilizer strut assembly is required to prevent the unsafe condition. Finally, after the FAA issued AD 2020–26–13, Sikorsky requested and the FAA approved a global Alternative Method of Compliance (AMOC) to allow only removing parts from service that are cracked, corroded, or have fretting, deformation, or wear rather than require removing the upper and lower support strut rod ends, including lug and conical fitting and both upper and lower attachment fittings on the stabilizer from service.

In the NPRM, the FAA proposed to expand the applicability of AD 2020–26–13 by adding an additional part-numbered stabilizer assembly. The NPRM also proposed to correct paragraph (g)(4) of the Required Actions so that the installation of the titanium stabilizer strut fitting is terminating action for the 50-hour time-in-service (TIS) inspections of the aluminum stabilizer strut fitting. The NPRM also proposed to require an additional repetitive inspection of certain parts of the stabilizer strut assembly. Finally, the NPRM proposed to incorporate the FAA approved global AMOC.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comments from Sikorsky stating that in the section titled ''Actions Since AD 2020–26–13 Was Issued'' of the NPRM, the part number specified (92070–20117–04) is incorrect and should be 92070–20117–041. The FAA acknowledges this comment; however, the part number is not used in the ''Background'' section of this final rule. In light of this, the commenter's request no longer applies.

Conclusion

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

Related Service Information Under 1 CFR Part 51

This AD continues to require S–92 Maintenance Manual, SA S92A–AMM–000, Temporary Revision (TR) 55–33, dated March 24, 2020 (TR 55–33), which the Director of the Federal Register approved for incorporation by reference as of February 1, 2021 (85 FR 84201, December 28, 2020).

This service information 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.

Other Related Service Information

The FAA reviewed S–92 Maintenance Manual SA S92A–AWL–000, TR No. 4–58, dated October 2, 2017 (TR 4–58), and S–92 Maintenance Manual SA S92A–AWL–000, TR No. 4–66 dated November 20, 2019 (TR 4–66). This service information revises Task 4–00–00–200–000, Table 1 Replacement Schedule, dated November 30, 2015. Both TR 4–58 and 4–66 revise the Airworthiness Limitations Schedule by removing certain part-numbered components, introducing new part-numbered components, and establishing replacement intervals and recurring inspections for the forward root fitting and the horizontal stabilizer strut fitting. TR 4–58 also specifies inspecting the horizontal stabilizer and attaching hardware at a recurring interval of 250 hours TIS.

Differences Between This AD and the Service Information

The service information requires returning affected parts to a Sikorsky specialist; this AD does not.

Costs of Compliance

The FAA estimates that this AD affects 82 helicopters of U.S. registry. Labor costs are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Visually inspecting the stabilizer assembly and attached hardware takes about 3 work-hours for an estimated cost of $255 per helicopter and $20,910 for the U.S. fleet per inspection cycle.

If required, replacing a hat bushing and both upper fittings and lower fittings takes about 1 work-hour and parts cost about $10,000 for an estimated cost of $10,085 per replacement.

If required, replacing the upper and lower support strut rod ends, including lug and conical fitting, takes about 1 work-hour and parts cost about $10,000 for an estimated cost of $10,085 per replacement.

If required, replacing Mylar washers takes about 0.5 work-hour and parts cost about $76 for an estimated cost of $119 per replacement.

If required, performing a fluorescent penetrant inspection takes about 3 work-hours for an estimated cost of $255 per inspection.

If required, replacing a stabilizer assembly takes about 6 work-hours and parts cost about $312,000 for an estimated cost of $312,510 per replacement.

If required, replacing a forward root fitting takes about 10 work-hours and parts cost about $25,000 for an estimated cost of $25,850 per replacement.

If required, replacing a stabilizer strut fitting takes about 10 work-hours and parts cost about $10,000 for an estimated cost of $10,850 per replacement.

If required, replacing a forward root fitting and an aft attachment fitting takes about 20 work-hours and parts cost about $50,000 for an estimated cost of $51,700 per replacement.

If required, removing wear or corrosion and applying corrosion preventative compound takes about 0.5 work-hour and parts cost a nominal amount for an estimated cost of $43 per action.

If required, replacing a stabilizer attachment bolt and barrel nut set takes about 1 work-hour and parts cost about $500 for an estimated cost of $585 per replacement.

If required, replacing a fastener takes about 0.1 work-hour and parts cost a nominal amount for an estimated cost of $9 per fastener.

If required, removing the abrasion-resistant Teflon coating to inspect each forward and aft attachment fitting mating surface takes about 5 work-hours for an estimated cost of $425 per inspection.

If required, applying alodine or equivalent and applying abrasion-resistant Teflon coating takes about 5 work hours with minimal parts cost for an estimated cost of $425 per application.

According to Sikorsky, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all costs in this cost estimate.

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 AD 2020–26–13, Amendment 39–21368 (85 FR 84201, December 28, 2020); and

■ b. Adding the following new airworthiness directive:

2022–11–04 Sikorsky Aircraft Corporation: Amendment 39–22054; Docket No. FAA–2022–0146; Project Identifier AD–2021–00449–R.

(a) Effective Date

This airworthiness directive (AD) is effective June 27, 2022.

(b) Affected ADs

This AD replaces AD 2020–26–13, Amendment 39–21368 (85 FR 84201, December 28, 2020) (AD 2020–26–13).

(c) Applicability

This AD applies to Sikorsky Aircraft Corporation Model S–92A helicopters, certificated in any category, with the following installed: Horizontal stabilizer root fitting FWD (forward root fitting) part number (P/N) 92209–07111–101 or 92070–20125–101; or stabilizer strut fitting P/N 92209–07403–041 or 92070–20117–041 installed on horizontal stabilizer assembly (stabilizer assembly) P/N 92070–20117–045, 92070–20117–046, 92070–20125–041, 92070–20125–042, 92070–20125–043, 92070–20125–044, 92205–07400–043, 92205–07400–045, or 92205–07400–047.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by incidents of fatigue cracks in a forward root fitting and life limit recalculations for forward root fitting P/N 92209–07111–101 and 92070–20125–101. The FAA is issuing this AD to prevent a forward root fitting from remaining in service beyond its life limit, detect fatigue cracking in a forward root fitting, and prevent increased load and stress cracking in the stabilizer root fitting aft. The unsafe condition, if not addressed, could result in failure of a stabilizer root fitting, separation of the stabilizer assembly from the helicopter, and subsequent loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) Within 50 hours time-in-service (TIS) after the effective date of this AD:

(i) Determine the total hours TIS of the forward root fitting P/N 92209–07111–101 or 92070–20125–101. If the total hours TIS of the forward root fitting is unknown, use the total hours TIS of the stabilizer assembly instead.

(A) If the forward root fitting has accumulated 7,900 or more total hours TIS, before further flight, remove the forward root fitting from service.

(B) If the forward root fitting has accumulated less than 7,900 total hours TIS,

before exceeding 7,900 total hours TIS, remove the forward root fitting from service.

(ii) Thereafter following paragraph (g)(1)(i) of this AD, remove the forward root fitting from service before accumulating 7,900 total hours TIS.

(iii) For stabilizer assemblies with stabilizer strut fitting P/N 92070–20117–041 installed, perform the following actions:

(A) Determine the total hours TIS of stabilizer strut fitting P/N 92070–20117–041.

(B) If the stabilizer strut fitting has accumulated 19,100 or more total hours TIS, before further flight, remove the stabilizer strut fitting from service.

(C) If the stabilizer strut fitting has accumulated less than 19,100 total hours TIS, before exceeding 19,100 total hours TIS, remove the stabilizer strut fitting from service.

(iv) Thereafter following paragraph (g)(1)(iii) of this AD, remove the stabilizer strut fitting from service before accumulating 19,100 total hours TIS.

(2) For helicopters with stabilizer strut fitting P/N 92070–20117–041 or 92209–07403–041 installed, within 50 hours TIS after the effective date of this AD and thereafter at intervals not to exceed 50 hours TIS:

(i) Remove the support strut and using a cheese cloth (or similar cloth) and isopropyl alcohol, clean the upper and lower support strut rod ends, horizontal stabilizer attachment fitting, and the tail rotor pylon attachment fitting.

(ii) If installed, visually inspect the surface of each Mylar washer P/N 92070–20117–104 (Mylar washer). The surface should be smooth and continuous. If there is any visible damage such as any tear or scrape, remove the Mylar washer from the peelable-ply washer P/N 92070–20117–105 (peelable-ply washer) and remove the Mylar washer from service as follows:

(A) Dampen a low-lint cloth with 3M 6041 adhesive remover and place on the top of the Mylar washer.

(B) Allow the adhesive remover to soften the Mylar washer and peel the Mylar washer back.

(C) Repeat with more solvent until the Mylar washer and adhesive are removed.

(D) Clean the peelable-ply washer with cheese cloth moistened with isopropyl alcohol and adhere a new Mylar washer to the peelable-ply washer.

Note 1 to paragraph (g)(2)(ii): Stabilizer assembly P/Ns 92070–20125–041, 92070–20125–042, 92070–20125–043, and 92070–20125–044 do not utilize the Mylar washer. The inspection of the Mylar washer is not required on helicopters with stabilizer assembly P/N 92070–20125–041, 92070–20125–042, 92070–20125–043, or 92070–20125–044 installed.

(iii) Using a 10X or higher power magnifying glass, a flashlight, and a mirror, visually inspect the hat bushing and both upper fittings and lower fittings for a crack, corrosion, fretting, deformation, and wear. If there is a crack, corrosion, fretting, deformation, or wear on any part, before further flight, remove the part from service.

(iv) Using a 10X or higher power magnifying glass, a flashlight, and a mirror, visually inspect both upper and lower support strut rod ends, including each lug and conical fitting, and both upper and lower attachment fittings on the stabilizer and pylon including the bushings for a crack, corrosion, fretting, deformation, and wear. If there is a crack, corrosion, fretting, deformation, or wear on any part, before further flight, remove the part from service.

(3) Within 250 hours TIS or one year, whichever occurs first after the effective date of this AD, and thereafter at intervals not to exceed 250 hours TIS or one year, whichever occurs first:

(i) Remove the stabilizer assembly and visually inspect each stabilizer attachment bolt and barrel nut set for corrosion, a crack, and damage to the threads. For the purposes of this inspection, damage may be indicated by uneven threads, missing threads, or cross-threading.

(A) If there is corrosion within allowable limits, before further flight, treat for corrosion in accordance with FAA-approved procedures.

(B) If there is corrosion that exceeds allowable limits, or a crack, or damage to the threads, before further flight, remove the bolt and barrel nut set from service.

(ii) Inspect the forward root fitting and the aft attachment fitting by:

(A) Gaining access to the inside of the horizontal stabilizer.

(B) Using Brulin Cleaner SD 1291 (or equivalent) and a low-lint cloth, remove all traces of sealing compound, oil, and dirt from the stabilizer mounting surfaces.

(C) Using a 10X or higher magnifying glass, inspect for any crack, wear, and corrosion.

(*1*) If there is a crack, before further flight, remove the affected forward root fitting and the affected aft attachment fitting from service.

(*2*) If there is wear or corrosion that exceeds allowable limits, before further flight, remove the affected forward root fitting and the affected aft attachment fitting from service.

(*3*) If there is wear or corrosion within allowable limits, before further flight, treat for corrosion in accordance with FAA-approved procedures.

(D) Visually inspect each attachment fitting bolt hole and fastener hole for a crack, wear, and corrosion.

(*1*) If there is a crack, before further flight, remove the affected forward root fitting and the affected aft attachment fitting from service.

(*2*) If there is wear or corrosion that exceeds allowable limits, before further flight, remove the affected forward root fitting and the affected aft attachment fitting from service.

(*3*) If there is wear or corrosion within allowable limits, before further flight, treat for corrosion in accordance with FAA approved procedures.

(E) Inspect for loose or working fasteners. If there is a loose or working fastener, before further flight, remove the fastener from service.

(iii) As an alternative means to inspect for cracks in paragraphs (g)(3)(i) and (ii) of this AD, perform a florescent penetrant inspection (FPI).

(iv) Visually inspect each forward and aft attachment fitting mating surface for wear of the abrasion-resistant Teflon coating and degradation. For the purposes of this inspection, degradation may be indicated by fretting. Refer to Figure 204, of S–92 Maintenance Manual, SA S92A–AMM–000, Temporary Revision 55–33, Task 55–11–01–210–004, dated March 24, 2020 (TR 55–33), for a depiction of the area to be inspected. For the purposes of this inspection, wear may be indicated by less than 100% coverage of the abrasion-resistant Teflon coating. If there is wear to the abrasion-resistant Teflon coating or degradation, before further flight:

(A) Chemically strip the abrasion-resistant Teflon coating from the entire mounting pad in accordance with paragraph 7.A.(7)(a) of TR 55–33.

(B) FPI or eddy current inspect for a crack. If there is a crack, before further flight, remove the stabilizer assembly from service.

(C) If there is no crack, treat the affected area by applying alodine or equivalent. Apply abrasion-resistant Teflon coating in accordance with paragraphs 7.A.(7)(d) through (e) of TR 55–33.

(4) Installing stabilizer strut fitting P/N 92209–07404–041 is a terminating action for the requirements in paragraph (g)(2) of this AD.

(5) As of the effective date of this AD, do not install stabilizer assembly P/N 92205–07400–043, 92205–07400–045, or 92205–07400–047 on any helicopter.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston ACO 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 certification office, send it to the attention of the person identified in paragraph (i) of this AD.

(2) 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.

(i) Related Information

For more information about this AD, contact Dorie Resnik, Aerospace Engineer, Boston ACO Branch, 1200 District Avenue, Burlington, Massachusetts 01803; telephone 781–238–7693; email *9-AVS-AIR-BACO-COS@faa.gov.*

(j) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on February 1, 2021 (85 FR 84201, December 28, 2020).

(i) S–92 Maintenance Manual, SA S92A–AMM–000, Temporary Revision (TR) 55–33, dated March 24, 2020.

(ii) [Reserved]

(4) For Sikorsky Aircraft Corporation service information identified in this AD, contact Sikorsky's Engineering Group at Sikorsky Aircraft Corporation, 124 Quarry Road, Trumbell, CT 06611, United States; phone: (800) 946–4337; email: *wcs_cust_service_eng.gr-sik@lmco.com;* website: *www.sikorsky360.com.*

(5) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(6) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on May 16, 2022.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–10952 Filed 5–20–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0518; Project Identifier MCAI–2021–00822–T; Amendment 39–22046; AD 2022–10–08]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus SAS Model A320–214, –251N, and –271N airplanes. This AD was prompted by reports that damaged seat rail covers were detected in the forward and aft seat fixation area of some airplanes during initial delivery. This AD requires a one-time detailed inspection of the affected passenger seats and corrective actions if necessary, as specified in a European Union Aviation Safety Agency (EASA). The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective June 7, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 7, 2022.

The FAA must receive comments on this AD by July 7, 2022.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For material incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://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 in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0518.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0518; 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 AD, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3229; email *vladimir.ulyanov@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0518; Project Identifier MCAI–2021–00822–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3229; email *vladimir.ulyanov@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0166, dated July 13, 2021 (EASA AD 2021–0166) (also referred to as the MCAI), to correct an unsafe condition for certain Airbus SAS Model A320–214, –251N, and –271N airplanes.

This AD was prompted by reports that damaged seat rail covers were detected in the forward and aft seat fixation area of some airplanes during initial delivery. The FAA is issuing this AD to

address deformation or compression of the seat rail covers caused by improper transportation, handling or installation on the airplane. This condition, if not addressed, could lead to seat track detachment, possibly resulting in injury to passengers. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0166 specifies procedures for a detailed inspection of the affected parts and corrective actions. Corrective actions include replacement of the seat or the seat rail covers. 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.

FAA's Determination

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 described above. The FAA is issuing this AD after determining that the unsafe condition described previously is likely to exist or develop on other products of these same type designs.

Requirements of This AD

This AD requires accomplishing the actions specified in EASA AD 2021–0166 described previously, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, EASA AD 2021–0166 is incorporated by reference in this AD. This AD requires compliance with EASA AD 2021–0166 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in EASA AD 2021–0166 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2021–0166.

Service information required by EASA AD 2021–0166 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0518 after this AD is published.

FAA's Justification and Determination of the Effective Date

There are currently no domestic operators of these products. Accordingly, notice and opportunity for prior public comment are unnecessary, pursuant to 5 U.S.C. 553(b)(3)(B). In addition, for the forgoing reason(s), the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days.

Regulatory Flexibility Act (RFA)

The requirements of the RFA do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

Currently, there are no affected U.S.-registered airplanes. If an affected airplane is imported and placed on the U.S. Register in the future, the FAA provides the following cost estimates to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product
2 work-hours × $85 per hour = $170	$0	$170

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 ACTION

Action	Labor cost	Parts cost	Cost per product
Seat rail cover replacement	1 work-hour × $85 per hour = $85	Up to $160	Up to $245 (per rail cover).
Seat replacement	3 work-hours × $85 per hour = $255	Up to $21,600	Up to $21,855 (per seat).

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, and

(2) Will not affect intrastate aviation in Alaska.

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:

2022–10–08 Airbus SAS: Amendment 39–22046; Docket No. FAA–2022–0518; Project Identifier MCAI–2021–00822–T.

(a) Effective Date

This airworthiness directive (AD) is effective June 7, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus SAS Model A320–214, –251N, and –271N airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2021–0166, dated July 13, 2021 (EASA AD 2021–0166).

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/Furnishings.

(e) Unsafe Condition

This AD was prompted by reports that damaged seat rail covers were detected in the forward and aft seat fixation area of some airplanes during initial delivery. The FAA is issuing this AD to address deformation or compression of the seat rail covers caused by improper transportation, handling or installation on the airplane. This condition, if not addressed, could lead to seat track detachment, possibly resulting in injury to passengers.

(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 AD 2021–0166.

(h) Exceptions to EASA AD 2021–0166

(1) Where EASA AD 2021–0166 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2021–0166 does not apply to this AD.

(3) Where paragraph (2) of EASA AD 2021–0166 specifies actions if ''discrepancies are detected,'' for this AD a discrepancy is an out-of-tolerance distance between the forward and aft attachment screws or a damaged (deformed or compressed) seat rail cover.

(4) Where paragraph (3) of EASA AD 2021–0166 allows deferral of certain actions ''in accordance with the applicable instructions and limitations of Master Minimum Equipment List (MMEL) item 25–20–01A,'' for this AD use ''in accordance with the applicable instructions and limitations of FAA MMEL item 25–21–01 or equivalent instructions and limitations in the operator's existing FAA-approved minimum equipment list (MEL).''

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2021–0166 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, 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 Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: *9-AVS-AIR-730-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, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (j)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Related Information

For more information about this AD, contact Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3229; email *vladimir.ulyanov@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2021–0166, dated July 13, 2021.

(ii) [Reserved]

(3) For EASA AD 2021–0166, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://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 that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on May 6, 2022.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–10867 Filed 5–20–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0155; Airspace Docket No. 20–ASO–4]

RIN 2120–AA66

Establishment of Class E Airspace; Wiggins, MS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace at Dean Griffin Memorial Airport, Wiggins, MS. Controlled airspace is necessary to accommodate new standard instrument approach procedures developed at Dean Griffin Memorial Airport, for the safety and management of instrument flight ruled (IFR) operations.

DATES: Effective 0901 UTC, September 8, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Rebecca Shelby, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5857.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes the Class E airspace extending upward from 700 feet above the surface at Dean Griffin Memorial Airport, Wiggins, MS, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (85 FR 14427; March 12, 2020) for Docket No. FAA–2020–0155 to propose established Class E airspace extending upward from 700 feet above the surface at Dean Griffin Memorial Airport, Wiggins, MS. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 by establishing the Class E airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Dean Griffin Memorial Airport, Wiggins, MS, excluding that airspace within Desoto 1 and Desoto 2 MOAs, when active. This action will enhance safety and the management of IFR operations at the airport.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO MS E5 Wiggins, MS [Establish]

Dean Griffin Memorial Airport, MS
(Lat. 30°54′35″ N, long. 089°09′41″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Dean Griffin Memorial Airport excluding that airspace within Desoto 1 and Desoto 2 MOAs, when active.

Issued in Fort Worth, Texas, on May 16, 2022.

Martin Skinner,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–10940 Filed 5–20–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2520

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4065

RIN 1210–AB97

Annual Information Return/Reports

AGENCY: Internal Revenue Service, Treasury; Employee Benefits Security Administration, Labor; Pension Benefit Guaranty Corporation.

ACTION: Final forms revisions.

SUMMARY: This document contains final forms and instructions revisions for the Form 5500 Annual Return/Report of Employee Benefit Plan and Form 5500–SF Short Form Annual Return/Report of Small Employee Benefit Plan, effective for plan years beginning on or after January 1, 2022. The changes to the forms and instructions in this document primarily implement annual reporting changes for defined benefit plans included in that proposal. A limited number of instruction changes focus on reporting for multiple-employer pension plans (including pooled employer plans). The remaining changes are technical changes that are part of the annual rollover of the Form 5500 and Form 5500–SF forms and instructions.

DATES: The final forms and instructions revisions in this document are effective for plan years beginning on or after January 1, 2022.

FOR FURTHER INFORMATION CONTACT: Janet Song, Florence Novellino, or Colleen Brisport Sequeda, Office of Regulations and Interpretations, Employee Benefits Security Administration, U.S. Department of Labor (DOL), (202) 693–8500 for questions related to reporting requirements under Title I of ERISA. For information related to the IRS reporting requirements under the Internal Revenue Code, contact Cathy Greenwood, Employee Plans Program Management Office, Tax Exempt and Government Entities, (470) 639–2503. For information related to PBGC reporting and changes in this document, including proposed changes to the actuarial schedules, contact Karen Levin, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, (202) 229–3559.

Customer service information: Individuals interested in obtaining general information from the DOL concerning Title I of ERISA may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the DOL's website (*www.dol.gov/agencies/ebsa*).

SUPPLEMENTARY INFORMATION:

I. Background

Titles I and IV of the Employee Retirement Income Security Act of 1974 (ERISA) and the Internal Revenue Code (Code), generally require pension and other employee benefit plans to file annual returns/reports concerning, among other things, the financial condition and operations of the plans.[1] Filing a Form 5500 Annual Return/Report of Employee Benefit Plan (Form 5500) or, if eligible, a Form 5500–SF Short Form Annual Return/Report of Small Employee Benefit Plan (Form 5500–SF), together with any required schedules and attachments (together ''the Form 5500 Annual Return/Report''),[2] in accordance with related instructions, generally satisfies these annual reporting requirements. ERISA section 103 broadly sets out annual financial reporting requirements for employee benefit plans under Title I of ERISA. The Form 5500 Annual Return/Report, and related instructions and regulations, are also promulgated under the DOL's general regulatory authority in ERISA sections 109 and 505.

The Form 5500 Annual Return/Report serves as the principal source of information and data available to the Department of Labor (DOL or the Department), the Internal Revenue Service (IRS), and the Pension Benefit Guaranty Corporation (PBGC) (collectively the ''Agencies'') concerning the operations, funding, and investments of approximately 844,000 pension and welfare benefit plans that file.[3] ERISA plans cover roughly 158 million workers, retirees, and dependents of private sector pension and welfare plans[4] with estimated assets of $12.9 trillion.[5] Accordingly, the Form 5500 Annual Return/Report is essential to each Agency's enforcement, research, and policy formulation programs, as well as for the regulated community, which makes increasing use of the information as more capabilities develop to interact with the data electronically. The data is also an important source of information for use by other Federal agencies, Congress, and the private sector in assessing employee benefits, tax, and economic trends and policies. The Form 5500 Annual Return/Report also serves as a primary means by which the operations of plans can be monitored by participating employers in multiple-employer plans and other group arrangements, by plan participants and beneficiaries, and by the general public.

On September 15, 2021, the Agencies published a notice of proposed forms revisions (NPFR) to amend the Form 5500 Annual Return/Report primarily to implement annual reporting changes related to legislative provisions in the Setting Every Community Up for Retirement Enhancement Act of 2019 (SECURE Act) focused on multiple-employer pension plans (MEPs) and defined contribution reporting groups (DCGs). The NPFR also set forth additional proposed changes intended to improve reporting on multiemployer and single-employer defined benefit pension plans, updated reporting on Form 5500 Annual Return/Report to

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[1] Sections 101 and 104 of Title I and section 4065 of Title IV of ERISA and sections 6057(b), 6058(a), and 6059(a) of the Code, and related regulations, impose annual reporting and filing obligations on pension and welfare benefit plans, as well as on certain other entities. Plan administrators, employers, and others generally satisfy these annual reporting obligations by filing the Form 5500 or Form 5500–SF.

[2] References to the ''Form 5500 Annual Return/Report'' may include, depending on the context, the Form 5500, the Form 5500–SF, and the Form 5500–EZ, Annual Return of One Participant (Owners/Partners and Their Spouses) Retirement Plan or a Foreign Plan (Form 5500–EZ). The Form 5500–EZ is a return that is required to satisfy section 6058(a) of the Code only. Form 5500–EZ filers are not subject to Title I of ERISA.

[3] Estimates are based on 2019 Form 5500 filings. DOL notes that single employer welfare plans with under 100 participants that are unfunded or insured (generally don't hold assets in trust) are exempt from filing a Form 5500 under 29 CFR 2520.104–29. Therefore, while DOL estimates there are 2.0 million health plans and 662,000 non-health welfare plans, respectively, only 69,000 and 91,000 of these plans filed a 2019 Form 5500.

[4] Source: DOL/EBSA calculations using the Auxiliary Data for the March 2020 Annual Social and Economic Supplement to the Current Population Survey.

[5] EBSA based these estimates on the 2019 Form 5500 Annual Return/Report filings, reported SIMPLE assets from the Investment Company Institute (ICI) Report: The U.S. Retirement Market, First Quarter 2021, and the Federal Reserve Board's Financial Accounts of the United States Z.1 December 9, 2021.

make the financial information collected on the Form 5500 Annual Return/Report more useful and usable, enhanced the reporting of certain tax qualification and other compliance information by retirement plans, and transferred to the DOL Form M–1 (Report for Multiple Employer Welfare Arrangements (MEWAs) and Certain Entities Claiming Exception (ECEs)) (Form M–1) participating employer information for multiple-employer welfare arrangements that are required to file the Form M–1.[6] 86 FR 51488 (Sept. 15, 2021). The DOL simultaneously published a proposed rulemaking (NPRM) required to implement the proposed forms revisions. 86 FR 51284 (Sept. 15, 2021). The NPFR and the NPRM are collectively referred to as the September 2021 proposal.

The Agencies received 114 comments on the September 2021 proposal. The comments, which were all posted on the Department's website, generally focused on the proposed changes for the 2022 plan year forms and on future rulemakings. In December 2021, the Department published a final forms revisions rulemaking (2021 Final Forms Revisions) that set forth a narrow set of changes to the instructions for the Form 5500 and Form 5500–SF, effective for plan years beginning on or after January 1, 2021. 86 FR 73976 (Dec. 29, 2021). Those instruction changes generally implemented annual reporting changes for MEPs, including pooled employer plans (PEPs).[7] The Department noted in that publication that other changes to the Form 5500 Annual Return/Report would be the subject of one or more separate and later final notices to address other elements of the September 2021 proposal.

This document sets forth a limited number of annual reporting changes that would apply beginning with the 2022 plan year Form 5500 Annual Return/Report. These changes focus mainly on finalizing the improvements in annual reporting for defined benefit pension plans that were included in the September 2021 proposal, but also include some further annual reporting changes for MEPs.[8] Specifically, the annual reporting changes for 2022 being adopted in this document are revisions to Schedules MB, SB, and R and their respective instructions to improve reporting by defined benefit plans subject to Title IV of ERISA and additions to the plan characteristics codes reportable on line 8 of Form 5500 and line 9 of Form 5500–SF that require defined contribution MEPs (including PEPs) to be identified as such. No changes to the DOL's implementing regulations are required for these forms and instructions changes.

In this document, the Agencies are not adopting final annual reporting changes based on other proposals included in the September 2021 proposal because of the need to coordinate the careful consideration of public comments and other regulatory processes for adopting final changes to the Form 5500 Annual Return/Report with a separate contractual development schedule for integrating forms and instructions changes into the wholly-electronic EFAST2 filing system that receives and displays Form 5500 Annual Return/Report filings.

ERISA section 103 broadly sets out annual reporting requirements for employee benefit plans. The Form 5500 Annual Return/Report and the DOL's implementing regulations are promulgated through notice and comment rulemaking under general ERISA regulatory authority and specific ERISA provisions authorizing limited exemptions to these requirements and simplified reporting and disclosure for welfare plans under ERISA section 104(a)(3), simplified annual reports under ERISA section 104(a)(2)(A) for pension plans that cover fewer than 100 participants, and alternative methods of compliance for all pension plans under ERISA section 110. The Form 5500 Annual Return/Report filings are also information collections for the Agencies, subject to a separate clearance process under the Paperwork Reduction Act (PRA). EFAST2, on the other hand, is operated by a private sector government contractor on behalf of the Agencies. Each year the EFAST2 system is rolled over for the coming year's annual return/report filings; for example, the system must be updated to reflect changes from the 2021 plan year return/report filings to the 2022 plan year return/report filings. That rollover process is governed by a contractual development schedule that sets deadlines designed to ensure that forms and instructions changes are smoothly integrated into the EFAST2 system and the products developed by private software developers to provide filing services to employee benefit plans. Integration of the regulatory and EFAST2 processes is less complicated in years that do not involve material changes to the forms or instructions. These processes, however, are considerably more challenging when the Agencies propose substantial changes to the forms and instructions.

As noted above, the Agencies received 114 public comments on the September 2021 proposal. The comments were from a wide range of stakeholders. Some commenters were generally supportive of the proposed changes while others objected to some aspects of the proposal. Objections include those based on an alleged lack of legal authority or conflicts with legislative intent, challenges to the value of some of the proposed information collections, and concerns about administrative costs and burdens of some of the proposed annual reporting requirements that would purportedly create disincentives for employers to establish or continue to offer employee benefit plans to their employees. Some public commenters also suggested alternative approaches for some of the proposed annual reporting changes, and a range of commenters argued for delayed applicability dates for some proposed changes if they were adopted as final revisions to the forms and instructions.

The Agencies are still evaluating public comments on elements of the September 2021 proposal not included in these final forms revisions, including DCG reporting and related audit issues,[9]

[6] The SECURE Act was enacted on December 20, 2019, as Division O of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94).

[7] Specifically, the 2021 Final Forms Revisions adopted revisions to the instructions for the 2021 Form 5500 Annual Return/Report that: (1) Note that a pooled employer plan operated by a pooled plan provider that meets the definition under ERISA section 3(43) is a multiple-employer plan that files a single Form 5500 Annual Return/Report; (2) require defined contribution multiple-employer pension plans, including pooled employer plans, to report aggregate account balance information by employer in addition to existing ERISA section 103(g) reporting requirements on participating employer information; and (3) require ''pooled employer plans'' to indicate whether they are in compliance with the Form PR registration requirements and provide the AckID number for their latest Form PR filing.

[8] A Form 5500 Annual Return/Report for the 2022 plan year generally is not required to be filed until seven months after the end of the 2022 plan year, *e.g.,* July 31, 2023, for calendar year plans, and a 2½-month extension is available by filing IRS Form 5558, Application for Extension of Time to File Certain Employee Plan Returns, on or before the normal due date.

[9] The SECURE Act directed DOL and Treasury to develop a consolidated reporting option for certain groups of defined contribution or individual account plans. Section 202 of the SECURE Act provides that the Secretaries, shall, in cooperation, modify annual return/report so that all members of a group of defined contribution or individual account plans described in section 202(c) may file a single aggregated annual return/report satisfying the requirements of both section 6058 of the Code and section 104 of ERISA. The SECURE Act further provides that, in developing the consolidated return/report, the Secretaries may require any information regarding each plan in the group as such Secretaries determine is necessary or appropriate for the enforcement and administration of the Code and ERISA. The SECURE Act also requires that the consolidated return/report include such information as will enable participants in any

Schedule MEP and related reporting requirements regarding MEPs, financial statement improvements to the Schedule H and Schedules of Assets, changes in participant counting methodology for Independent Qualified Public Accountant (IQPA) purposes, changes regarding reporting on participating employers for MEWAs that file the Form M–1, and additional questions on pension plan compliance with certain Code requirements. These were areas in which a number of commenters suggested a delay in implementation, substantial revisions, or re-proposals. The Agencies agree that sufficient lead time for programming and systems changes, as well as time to develop contracts and other communications among plans and service providers is needed to properly implement these significant changes to annual reporting requirements. The Agencies also believe that, in light of the public comments on these aspects of the September 2021 proposal, employee benefit plan stakeholders are best served by the Agencies taking additional time to consider the range of public comments on these proposals and develop final rules that are cost-effective and improve the annual report data in a way that is protective of the retirement security interests of participants and beneficiaries. Accordingly, rather than rush consideration of issues and decision-making on these important annual reporting issues, the Agencies have decided that any changes to the Form 5500 Annual Return/Report in connection with the above listed elements of the September 2021 proposal will be addressed either in a further final forms revisions notice based on the September 2021 proposal, or re-proposed with modifications in a separate proposal that would focus on a broader range of improvements to the annual reporting requirements. As the Department noted in the September 2021 proposal, the Department added an additional regulatory project to its semi-annual agenda as part of a separate project with the IRS and PBGC to: (i) Modernize the financial and other annual reporting requirements on the Form 5500 Annual Return/Report; (ii) continue an ongoing effort to make investment and other information on the Form 5500 Annual Return/Report more data mineable; and (iii) consider potential changes to group health plan annual reporting requirements, among other improvements that would enhance the Agencies' ability to collect employee benefit plan data in a way that best meets the needs of compliance projects, programs, and activities. *See www.reginfo.gov* for more information. In the Agencies' view, this approach is the best way to allow for appropriate consideration of relevant public comments and facilitate a smooth and efficient process for integrating any new schedules or other annual reporting changes into the EFAST2 annual rollover process for Form 5500 Annual Return/Report filings.

Discussed below are final forms revisions on specific elements of the September 2021 proposal with respect to which the Agencies completed review of the public comments and reached conclusions on final forms and instructions changes in time to coordinate those changes into the EFAST2 development cycle for the 2022 plan year Form 5500 Annual Return/Report.[10]

II. 2022 Form 5500 Annual Return/Report Changes

A. Schedules MB, SB, and R—Modifications and Additions to Information Reported

As described more fully below, the Agencies are adding new questions and revising existing questions to the Form 5500 Annual Return/Report Schedule MB (Multiemployer Defined Benefit Plan and Certain Money Purchase Plan Actuarial Information), Schedule SB (Single-Employer Defined Benefit Plan Actuarial Information), and Schedule R (Retirement Plan Information), and modifying the contribution and benefit attachment requirements to enable the Agencies to more easily access defined benefit pension plans' information and project more precisely insurance programs' liabilities. For both single-employer and multiemployer defined benefit pension plans, the Agencies are providing plans with the option to provide certain required attachments in a spreadsheet file (CSV format).

1. Schedule MB Modifications

In summary, and as described in more detail below, the changes to Schedule MB and its instructions include the following: (1) Modify Schedule MB, line 3 instructions to require that additional information be included in the currently required attachment that shows the date and amount of each withdrawal liability amount paid to the plan (*i.e.,* a breakdown between lump sum amounts and amounts that are part of a schedule of periodic payments); (2) modify Schedule MB by clarifying the line 4f instructions and Schedule MB language concerning when or if plans in critical status or critical and declining status are projected to either emerge or become insolvent; (3) modify Schedule MB by adding a new requirement in a new line 6f to report information about the interest assumption used to determine the present value of vested benefits for withdrawal liability determinations; (4) modify Schedule MB for the questions related to the line 6 ''expense load'' to better align with the various ways multiemployer plans incorporate expense loads into their calculations; (5) modify Schedule MB, line 8 by requiring additional information about benefits and contributions for plans with 1,000 or more total participants at the beginning of the plan year; and (6) modify Schedule MB by changing the benefit information required to be included in the ''age/service'' scatter attachment (required for PBGC-insured multiemployer plans with active participants).

a. Line 3—Contributions Made to the Plan for the Plan Year

Currently, line 3 of Schedule MB requires that if any of the employer contributions reported in line 3 include amounts owed for withdrawal liability, an attachment must be provided listing the total withdrawal liability amounts and the dates such amounts were contributed. In the NPFR, the Agencies proposed to modify the instructions to line 3 to require that the total withdrawal liability amounts reported on the attachment be broken down between periodic withdrawal liability amounts and lump sum withdrawal liability amounts. The Agencies received several comments on proposed changes to the withdrawal liability attachment. Two commenters expressed opposite views about whether the additional information should be reported. One expressed support because the additional detail will result in more transparency. The other expressed concern because, in the commenter's opinion, that additional level of details could be misinterpreted by bankers and creditors. Because the only additional detail being added to the attachment relates to type of payment (*i.e.,* whether a payment is part of a series of periodic payments or a lump sum), the Agencies do not share that concern and are therefore requiring the breakdown, as proposed. Two commenters asked the Agencies to clarify when a withdrawal liability

plan using a consolidated return/report to identify the consolidated return/report filed with respect to their plan.

[10] Consistent with the Agencies' annual updates to the Form 5500 Annual Return/Report, the final versions of the 2022 plan year forms and instructions may include minor technical edits or corrections that do not require notice and comment under the PRA, or the APA, or review under any relevant Executive Order.

payment should be considered a periodic payment and when it should be considered a lump sum payment in situations where it is not clear which payment type applies (*e.g.,* where an employer making annual periodic payments settles the remaining obligation with a lump sum payment or makes a lump sum payment to cover delinquent periodic payments). The Agencies agree that clarification for such situations would be helpful and are revising the instructions to line 3 accordingly. One commenter noted that information about withdrawal liability payments is not maintained by a plan's actuary and requested that, rather than expanding the information that is reported on the Schedule MB attachment, all of the detailed information about withdrawal liability payments (*i.e.,* date, amount and type of payment) be reported as an attachment to a part of the Form 5500 Annual Return/Report that someone other than the actuary (*e.g.,* the plan sponsor or auditor) is responsible for completing (*e.g.,* Schedule R). The Agencies acknowledge that the plan's actuary does not have direct access to information about withdrawal liability payments but the same is true of the other information that is reported on Schedule MB (*e.g.,* date and amount of contributions) and, to date, this does not appear to have posed a problem. The Agencies continue to believe that the withdrawal liability information should be provided on an attachment to Schedule MB because Schedule MB is where information about contributions to the plan, including withdrawal liability payments, is reported. Accordingly, no changes are being made in response to this comment.

b. Line 4f—Rehabilitation Plan Projected To Emerge From Critical or Critical and Declining Status

Currently, line 4f of Schedule MB requires completion by a plan that is in critical or critical and declining status. The year the plan is projected to emerge from critical status or become insolvent is reported on Schedule MB, and an illustration of year-by-year cash flow projections is provided in a required attachment to line 4f. The Agencies' review of filers' previous responses to line 4f suggested that the instructions on how to fill out this line correctly might have been unclear to filers. In the NPFR, the Agencies proposed to modify the instructions to line 4f and to clarify the time period for the year-by-year cash flow projection and the basis for the projections. Two commenters wrote that the instructions needed further clarification, especially with respect to how the instructions describe the first and last year to be included in the projection. One of those commenters questioned whether the required projection period would necessitate doing additional projections (as opposed to reporting projections that had to be done to determine the year of emergence/insolvency). In response, the Agencies are clarifying in the final forms revisions both the time period and basis for projection in line 4f. The Agencies believe the revised instructions will make clear that the projections to be reported in the attachments are projections that have already been done.

c. Line 6—Checklist for Actuarial Assumptions

Currently, line 6 of Schedule MB is where filers provide information about the actuarial assumptions used to determine plan liabilities. The Agencies proposed in the NPFR to add a new item to line 6 (line 6f) regarding the interest rate used to determine the present value of vested benefits for withdrawal liability determinations. With respect to plans that do not use a single interest rate for this purpose, the proposed instructions required the reporting of the single equivalent interest rate that produces the same present value of vested benefits. Two commenters expressed concerns about the extra work it would take to determine the single equivalent interest rate noted above. The same commenters also requested clarification as to which withdrawal liability calculations should be considered when determining the equivalent single interest rate that produced the same result (*i.e.,* is it based on when the withdrawal liability amount is assessed or when the employer withdrew). In response, the Agencies are revising this question and instructions in these final forms revisions. As revised, the instructions provide that the filer will check a box in a new line, 6f(1), to report whether the interest assumption for this purpose is a single interest rate, ERISA section 4044 interest rates, or something else (*i.e.,* ''Other''). If the ''single rate'' box is checked, the single interest rate is reported in a new line, 6f(2). If the ''Other'' box is checked, the filer must provide an attachment describing the interest rate assumption. Lastly, if this question doesn't apply (*i.e.,* if no employers withdrew and were assessed withdrawal liability during the plan year), the filer will check an ''N/A'' box. One of the commenters asked whether the definition of ''withdrawal'' is limited to complete withdrawals (*i.e.,* whether amounts assessed with respect to partial withdrawals are included when determining the single rate that produced the same result). That commenter noted that in Schedule R the definition of withdrawal is limited to complete withdrawals, but that it is not clear that that this definition carries over to Schedule MB. In response, PBGC has clarified the instructions accordingly.

In addition, the Agencies proposed to modify the questions related to the line 6 ''expense load'' to better align with the various ways multiemployer plans incorporate expense loads into their calculations. Filers would be required to indicate if an expense load is included in normal cost and, if so, whether it is determined as a percentage of normal cost, a dollar amount that varies from year to year, or something else. In addition, the Agencies proposed moving the expense load item from line 6e to a new line 6i and the salary scale item from 6f to 6e and revising the instructions accordingly so that the expense load assumptions that may differ between pre-retirement and post-retirement are grouped together. No revisions are being made to these proposed changes.

d. Line 8—Miscellaneous Information

Currently, line 8 of Schedule MB requires filers to report miscellaneous information about demographics, benefits, and contributions. The Agencies proposed in the NPFR to modify line 8 by requiring additional information about demographics, benefits, and contributions, as described below. After considering the public comments, the Agencies have decided to adopt the changes to line 8 described below. As is currently required under line 8, the additional requirements would apply only to PBGC-insured multiemployer plans with 500 or more total participants as of the beginning of the plan year.

• *Benefit Projections*—Currently, plans are required to attach a projection of benefits expected to be paid in each of the next ten years (see line 8b(1)).[11] The Agencies proposed in the NPFR to modify the format of the attachment to show the benefit projection broken down into three categories based on the participant's or beneficiary's status on

[11] The current instructions provide that the line 8b(1) attachment is required for plans with 500 or more participants as of the valuation date, not as of the beginning of the plan year. The Agencies proposed changing that to ''the beginning of the plan year'' because the only participant count reported on Schedule MB is the count at the beginning of the plan year (*i.e.,* line 2b(3)(c), column 1) and because doing so is consistent with another Schedule MB requirement, See instructions for line 8b(2).

the valuation date (*i.e.,* active, terminated vested, or in pay status). In addition, the projection period was extended from 10 to 50 years. Three commenters stated that the line 8b(1) proposal would be costly and burdensome. These commenters also stated that the projection would unlikely produce meaningful, reliable, and useful information because future benefit accruals are not reflected. The Agencies are not persuaded that this change to line 8 would be unduly costly or burdensome. Rather, as noted in the NPFR, based on the Agencies' experience with the valuation software generally in use by affected DB pension plans, the incremental cost of expanding a projection from 10 to 50 years is nominal. In addition, the Agencies paired these line 8 changes with a provision that allows filers to attach a spreadsheet file (CSV format) instead of a PDF file. The ability to use generally available spreadsheet software to produce the required data will allow the Agencies to more easily access defined benefit plans' information and to project more precisely insurance programs' liabilities. However, after considering the comments received, the Agencies decided to reduce the number of plans required to provide the benefit projection attachment (from plans with 500 or more participants to plans with 1,000 or more participants).[12] Also, although a projection may provide more meaningful results if additional accruals were reflected and/or if the projection were done stochastically, the Agencies did not add such a requirement or requirements as part of these final forms revisions because of the potentially more significant compliance costs involved. The Agencies believe that by increasing the projection period from 10 to 50 years, this will provide valuable information and enable the Agencies to better estimate anticipated future benefit payments from pension plans.

• *Contribution Projections*—The Agencies also proposed in the NPFR to add a new requirement that plans provide, as an attachment, a 10-year projection of employer contributions and withdrawal liability payments. A new line, line 8b(3), would be added to Schedule MB where the filer would report whether the projection is required. As is the case with the benefit projection attachments, the instructions would provide the required format for the attachment. In addition, although the Agencies did not receive any substantive comments concerning this new requirement, to be consistent with the modification to line 8b(1) noted above, the final forms revisions provides that this 10-year projection of employer contributions and withdrawal liability payments is required only for plans with 1,000 or more participants as of the beginning of the plan year.

• *Average age/benefit*—The Agencies additionally proposed in the NPFR to require plans to report the average age and average monthly benefit separately for (1) terminated vested participants and (2) retired participants and beneficiaries receiving payments. Under the proposal, this information would be provided directly on Schedule MB, in new line 8b(4). Two commenters provided comments on the new line 8b(4) requirement. Although one supported the proposal, the other commented that the additional data was both unnecessary and costly. In an effort to minimize the burden on plans, the Agencies have decided not to move forward with this part of the proposal. Accordingly, this final forms revision does not include a new line 8b(4).

• *Age/service scatter*—The Agencies proposed in the NPFR a change to the existing ''age/service'' attachment for line 8b(2), which is required for PBGC-insured multiemployer plans with active participants, regardless of the number of participants. Currently, the scatter shows, for each ''attained age'' and ''years of credited service'' grouping of active participants, the number of active participants, and, if the total number of active participants at the beginning of the plan year is 1,000 or more, (1) for plans that use compensation to determine benefits, the average compensation, and (2) for cash balance plans, the average cash balance account (see line 8b(2)). These latter two requirements do not apply for any age/service grouping of fewer than 20 participants. Because there are few, if any, multiemployer cash balance plans, the Agencies proposed modifying the additional reporting requirement for multiemployer plans with 1,000 or more active participants by replacing the required information related to cash balance plans with a requirement to report average accrued monthly benefits as of the valuation date for each grouping. Two commenters provided comments on the proposed change to the age/service scatter. One suggested that the Schedule MB instructions be modified to specify that plans that do not use compensation to determine benefits should enter ''N/A'' in each age/service grouping. The Agencies do not believe such modification is needed because the existing instructions for line 8b(2) state that only plans ''using compensation to determine benefits'' need to provide average compensation data. There is no need to enter ''N/A'' because it is implied. The other commenter asked whether the cash balance information will also be removed from the Schedule SB (for single-employer plans). The Agencies believe that it was clear from the NPFR that no changes were proposed with respect to the age/service scatter on Schedule SB (for single-employer plans).

2. Modifications to Schedule SB

In the NPFR, the Agencies proposed adding two new reporting requirements for PBGC-insured single-employer plans with 500 or more total participants to better align requirements for single-employer defined benefit plans with the more detailed requirements for PBGC-insured multiemployer plans. The new reporting requirements proposed in the NPFR were:

• A 50-year benefit payment projection broken down into three categories based on the participant's or beneficiary's status on the valuation date (*i.e.,* active, terminated vested, in pay status), and

• The average age and average monthly benefit separately for (1) terminated vested participants and (2) retired participants and beneficiaries receiving payments (similar to the information required to be reported in line 8b(4) of Schedule MB).

For the most part, the Agencies proposed that these two new reporting requirements would be similar to the Schedule MB requirements for multiemployer plans (lines 8b(1) and 8b(4), respectively). However, because the only participant count information for single-employer plans on Schedule SB is as of the valuation date, to determine whether a plan has 500 or more participants (and is thus required to provide information for these two new reporting requirements) the Agencies proposed that participants be counted as of the valuation date instead of as of the beginning of the plan year (the ''count'' date for multiemployer plans). To facilitate these changes, the Agencies proposed rearranging Schedule SB line 26. Currently, line 26 relates only to the ''age/service'' scatter of active participant data required to be attached to Schedule SB for single-employer plans covered by Title IV of ERISA with active participants. The Agencies proposed changing line 26 into a three-part question (26a, 26b, and 26c). Current line 26 would become new line 26a. The benefit projection question would become new line 26b, and the

[12] In addition, the Agencies added the 50-year benefit projection attachment to Schedule SB (for single-employer plans).

average age/benefit question would become new line 26c.

The Agencies received several comments about the benefit projection attachment. One commenter supported the change. Two commenters expressed concern that the benefit projection attachment would impose substantial additional costs and burdens on plans without any apparent benefit. As discussed above in the Agencies' responses to comments received on Schedule MB and in the NPFR, it is the Agencies' understanding that these projections are done as part of the valuation, so the only additional work would be to capture those projected amounts in an accessible or downloadable file. Accordingly, we are not convinced that the additional burden is significant. However, after considering the comments received, the Agencies have decided to reduce the number of plans required to provide the benefit projection attachment from plans with 500 or more participants to plans with 1,000 or more participants. In addition, and consistent with the Schedule MB change from the proposal with respect to multiemployer plans, the Agencies are not moving forward with the proposal to require reporting average age and benefit information for retirees and terminated vested participants (*i.e.,* there will not be a new line 26c(2)).

One commenter expressed concern about the application of line 26b to MEPs because they believe attaching a benefit projection would impose substantial additional costs and burden without any apparent benefit. The same commenter requested that, at a minimum, cooperative and small employer charity (CSEC) pension plans (almost all of which are MEPs) be exempt from this requirement. The Agencies see no compelling reason to treat PBGC-insured MEPs differently from other single-employer plans with respect to this requirement. However, it should be noted that it was never the intent to have CSEC plans provide this information. The current instructions state that CSEC plans are not required to complete Part VI—Miscellaneous Items (the section which includes line 26). As noted above, the proposal called for breaking down line 26 into new lines 26a, 26b, and 26c. Since all three of those lines are part of line 26 (and in Part VI), the proposal exempted CSEC plans from the proposed new reporting requirements.

The Agencies received one comment on line 26c(2) to clarify what should be shown as the average benefit for terminated vested participants in cash balance plans. As noted above, the Agencies have decided not to move forward with that part of the proposal (*i.e.,* line 26c(2) will not be added to the Schedule SB). Accordingly, the question asked by the commenter is moot.

Finally, the Agencies proposed modifying Part IX of Schedule SB, and its instructions, so that it relates to elective amortization funding relief provided under the American Rescue Plan (ARP) Act of 2021 instead of elective funding relief provided under the Pension Relief Act of 2010 (PRA 2010). The NPFR explained that the PRA 2010 information is no longer needed because ARP reduces to zero all shortfall amortization bases, including amortization bases established pursuant to the PRA 2010 elective funding relief. As modified, plan sponsors of single-employer defined benefit plans that elect to have the ARP extended amortization rule apply before the 2022 plan year would be required to report the first plan year to which the extended amortization rule applies. The proposal would require such a plan to check a box to indicate the first plan year for which the plan elected to have ARP amortization funding relief. One commenter opposed the change as unnecessary because Schedule SB attachments would indicate when an election was made. The Agencies agree that they could obtain this information from attachments, but information reported on attachments cannot be accessed electronically. In addition, because this is only a check box for which the answer will not change from year-to-year, there is virtually no burden associated with it. Accordingly, the Agencies are adopting this requirement as part of the final forms revisions.

3. Modification to Schedule R Reporting Requirement

Currently, Schedule R's Part V, line 13 requirement requires multiemployer defined benefit pension plans subject to minimum funding standards to report identifying information about any participating employer whose contributions to the plan account for more than five percent of the total contributions for the year. The NPFR proposed to change this requirement to require plans to report identifying information about any participating employer that either (1) contributed more than five percent of the plan's total contributions or (2) was one of the top ten highest contributors. The Agencies received no comments on this proposal and have incorporated this modification in the final forms revisions.

4. Change in Format for Certain Schedule MB and SB Attachments

EFAST2 filers currently file Form 5500 Annual Return/Report attachments as PDF and plain text (TXT) files. A PDF file is required only if the attachment must be signed. TXT attachments are rarely provided. Many attachments include a lot of numbers (*e.g.,* benefit projections, age/service scatters) that are reported in tables. These numbers have to be extracted out of PDF tables and entered into databases or spreadsheets before the Agencies can use the information for various projects, studies, etc. This is costly and inefficient. In the NPFR, the Agencies proposed to modify the instructions to allow and suggest (but not require) that certain attachments be provided in a spreadsheet file (such as CSV format), rather than PDF or TXT formats. The Agencies did not receive any comments on this proposed modification of the instructions and have incorporated this change in the final forms revisions.

Thus, the instructions for the Schedules MB and SB are being modified to permit (but not require) certain attachments to Schedule MB and SB to be provided in a spreadsheet file (CSV format) rather than PDF or TXT formats. The following chart lists the Schedule MB and Schedule SB attachments that are affected by the formatting change:

Attachment	Schedule MB	Schedule SB
Schedule of Projection of Expected Benefit Payments	Line 8b(1)	Line 26b.
Schedule of Active Participant Data (*i.e.,* Age/service scatter)	Line 8b(2)	Line 26a.
Withdrawal Liability Amounts	Line 3	N/A.
Schedule of Projection of Employer Contributions and Withdrawal Liability	Line 8b(3)	N/A.

B. Reporting Changes for Multiple-Employer Plans

The final forms revisions include a limited number of changes to the instructions for the Form 5500 Annual Return/Report that are intended to clarify and improve annual reporting for ERISA-covered defined contribution MEPs, including those that meet the definition of ''pooled employer plan.'' New plan characteristics codes are being added to the Form 5500 and Form 5500–SF instructions for filers to use to identify different types of defined contribution MEPs on Form 5500 and Form 5500–SF, Part II, lines 8 and 9, respectively. The Form 5500 and Form 5500–SF instructions are also being updated to clarify which entities should report as plan sponsors on line 2a and as plan administrators on line 3a, with respect to certain types of defined contribution MEPs. For 2022 filings, these revisions include other minor amplifying and clarifying changes to instructions for 2022 forms.

With respect to the new plan characteristics codes, the final forms revisions add new defined contribution MEP characteristics codes for the List of Plan Characteristics Codes for Form 5500 and Form 5500–SF, Part II, lines 8 and 9, respectively. The addition of identifying codes will help the Agencies, participants and beneficiaries, and the public identify and distinguish between different types of defined contribution MEPs, including new plan types like PEPs and existing plan types like association retirement plans and professional employer organization MEPs. The new defined contribution pension feature codes are:

- For both Form 5500 and Form 5500–SF—Code 2U—Multiple-employer pension plan sponsored by a bona fide group or association of employers that is an Association Retirement Plan that meets all the conditions under 29 CFR 2510.3–55(b).
- For both Form 5500 and Form 5500–SF—Code 2V—Multiple-employer pension plan that is a Professional Employer Organization Plan (PEO Plan) that meets all the conditions under 29 CFR 2510.3–55(c).
- For Form 5500 Only—Code 2W—Multiple-employer pension plan that is a pooled employer plan that meets the definition under ERISA section 3(43).[13]
- For both Form 5500 and Form 5500–SF—Code 2X—Multiple-employer defined contribution pension plan that does not fall under characteristics code 2U, 2V or 2W (Form 5500) or, for Form 5500–SF, is eligible to file the Form 5500–SF and does not fall under characteristics code 2U or 2V (Form 5500–SF).

Thus, for both Form 5500 and Form 5500–SF, a filer would enter Code 2U for a defined contribution MEP that is an Association Retirement Plan under applicable conditions in 29 CFR 2510.3–55(b). For both Form 5500 and Form 5500–SF, a filer would enter Code 2V for a defined contribution MEP that is a PEO Plan under applicable conditions in 29 CFR 29 CFR 2510.3–55(c). For the Form 5500, a filer would enter Code 2W for a defined contribution MEP that is a pooled employer plan as defined in ERISA section 3(43). All other defined contribution MEPs would enter Code 2X on their Form 5500 and Form 5500–SF filing as applicable. Note that Code 2W is being added to the Form 5500 instructions but was intentionally skipped in the Form 5500–SF instructions because PEPs are not eligible to file the Form 5500–SF and, therefore, Code 2W is not an eligible code for Form 5500–SF filers.

One of the several commenters expressing broad support for the part of the Agencies' proposal dealing specifically with MEP reporting provided a number of more specific comments. First, the commenter observed that while the pooling of employers and capital in the provision of retirement benefits has the potential to improve access to workplace retirement plans in the United States, multiple-employer plans raise novel governance and oversight challenges. The commenter specifically noted that the lack of an identifier for particular kinds of multiple-employer plans hampers comparisons across plan types, especially those relating to fees. That commenter also pointed out that the Agencies' September 2021 proposal would have filers specifically identify different types of MEPs: Association retirement plans within the meaning of 29 CFR 2510.3–55(b); PEO Plans within the meaning of 29 CFR 2510.3–55(c); PEPs within the meaning of ERISA Section 3(43); and other MEPs covering the employees of two or more employers that are not single or multiemployer plans for annual reporting purposes. In that regard, the commenter cited as a key benefit of the proposal an ability to systematically track and evaluate the new plan types that have been established in recent years. As noted above, however, there were a range of other commenters who objected to parts of proposed Schedule MEP or otherwise raised concerns with the proposal's new requirements for MEP reporting. These commenters generally focused their concerns on Parts II and III of the proposed Schedule MEP, and their comments largely related to requesting delay, removal, and reconsideration, rather than opposing providing identifying information proposed on Part I.

Although finalizing proposed Schedule MEP would provide more public information and provide more information in a more usable data capturable form and serve the interests of users of Form 5500 Annual Return/Report data, including the DOL, IRS, PBGC, other Federal agencies, Congress, and the private sector that use the Form 5500 Annual Return/Report as an important source of information and data in assessing employee benefit, tax, and economic trends and policies,[14] as discussed above, the Agencies have concluded that more time should be spent considering issues and alternatives presented by the public comments before deciding whether and, if so, how to finalize the proposed Schedule MEP as a vehicle for annual reporting of information on MEPs. The Agencies believe, nonetheless, that MEPs, especially defined contribution MEPs such as PEPs and PEOs, can present added complexity and related challenges to the Agencies when performing oversight and enforcement functions, and that participants and beneficiaries of such plans should be able to easily find and identify Form 5500 Annual Return/Report information for MEPs providing them with employee benefits, including those that may be sponsored by PEOs. The Agencies also believe that the information proposed for Part I of Schedule MEP is important for tracking and evaluating new MEP types, and for providing needed transparency for participants and beneficiaries of MEPs, and that such disclosures should be made for existing MEPs and newly established type of plans like PEPs. The Agencies also

[13] 29 U.S.C. 1002(43). The term pooled employer plan does not include a multiemployer plan as defined in ERISA section 3(37) and also does not include a plan established before the date the SECURE Act was enacted unless the plan administrator elects to have the plan treated as a pooled employer plan and the plan meets the ERISA requirements applicable to a pooled employer plan established on or after such date. It also does not include a plan maintained by employers that have a common interest other than having adopted the plan.

[14] Section 1 of ERISA states the ''Congressional findings and declaration of policy.'' Of relevance to our consideration of these alternatives, section (b) states, in relevant part: ''It is hereby declared to be the policy of this chapter to protect interstate commerce and the interests of participants in employee benefit plans and their beneficiaries, by requiring the disclosure and reporting to participants and beneficiaries of financial and other information with respect thereto . . . .'' 29 U.S.C. 1001(b).

concluded that much of the information proposed for Part I of the proposed Schedule MEP could be added with very limited changes to the forms or instructions. Accordingly, in light of the importance of MEP identifying information, the limited changes to the instructions involved for EFAST2 development purposes, and the relatively small burden of the additional information collection, the Agencies decided to make the above-described changes to the Form 5500 Annual Return/Report so that better and more useable identifying information on MEPs is collected beginning with the 2022 plan year forms. These changes also will help supplement the MEP reporting changes adopted beginning with the 2021 plan year forms.[15]

In addition to adding plan characteristics codes that identify MEP types, to address commenter concerns regarding how PEO plans should file, the instructions also contain clarifying additions to Part II of Form 5500 and Form 5500–SF that collect plan sponsor and plan administrator information. First, for Form 5500, the instructions for line 2a are revised so that the instructions for identifying the ''plan sponsor'' include instructions specifically for PEPs and PEO plans.[16] The instructions for Form 5500, line 3a are similarly revised so that the term ''plan administrator'' includes the above two additional types of plans, and references to the above definitions.[17] For Form 5500–SF, a parallel corresponding change has been made to instructions on identifying the ''plan sponsor'' and ''plan administrator'' for lines 2a and 3a, respectively, for PEO MEPs. Since PEPs are not permitted to file Form 5500–SF, no corresponding change to the instructions is made for PEPs. Other minor clarifying and conforming edits are made to instructions for lines 2a and 3a of both forms.

III. Regulatory Impact Analysis

The following is a discussion of the examination of the effects of this rule as required by Executive Order 12866,[18] Executive Order 13563,[19] the Paperwork Reduction Act of 1995,[20] the Regulatory Flexibility Act,[21] section 202 of the Unfunded Mandates Reform Act of 1995,[22] Executive Order 13132,[23] and the Congressional Review Act.[24] For the Department of Labor, the annual report form is a creature of rulemaking under ERISA sections 104 and 110. As such, form and instruction changes can involve both rulemaking under the Administrative Procedure Act and other rulemaking standards as well as approval under the Paperwork Reduction Act of changes to the form and instructions as an information collection. This tri-agency document is intended to constitute the regulatory impact analysis and Paperwork Reduction Act statement for DOL and a Paperwork Reduction Act statement for IRS and PBGC.[25]

A. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Under Executive Order 12866, ''significant'' regulatory actions are subject to review by the Office of Management and Budget (OMB).[26] Section 3(f) of the Executive Order defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A full regulatory impact analysis must be prepared for major rules with economically significant effects (for example, $100 million or more in any 1 year), and the Office of Management and Budget (OMB) reviews ''significant'' regulatory actions. It has been determined that this rule is not economically significant within the meaning of section 3(f)(1) of the Executive Order. Pursuant to the terms of the Executive Order, OMB has determined, however, that this action is ''significant'' within the meaning of section 3(f)(4) of the Executive Order. Therefore, the Agencies have provided an assessment of the potential costs, benefits, and transfers associated with the final forms revisions. In accordance with the provisions of Executive Order 12866, the final forms revisions were reviewed by OMB. Pursuant to the Congressional Review Act, OMB has designated the final forms revisions as not a ''major rule,'' as defined by 5 U.S.C. 804(2).

1. Introduction and Need for Regulation

The Form 5500 Annual Return/Report is the principal source of information and data available to the Agencies concerning the operations, funding, and investments of pension and welfare benefit plans covered by ERISA and the Code. Accordingly, the Form 5500 Annual Return/Report is essential to each Agency's enforcement, research, and policy formulation programs and is a source of information and data for use by other Federal agencies, Congress, and the private sector in assessing employee benefit, tax, and economic trends and policies. The Form 5500 Annual Return/Report also serves as the primary means by which the operations of plans can be monitored by plan participants and beneficiaries and the general public.

As discussed earlier in this document, these final forms revisions are making limited changes that would apply

[15] See footnote 7, supra, for a description of those changes.

[16] ERISA Section 3(16)(B) provides that the term ''plan sponsor'' means—(i) the employer in the case of an employee benefit plan established or maintained by a single employer, (ii) the employee organization in the case of an employee benefit plan established or maintained by an employee organization, or (ii) in the case of a plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, the association, committee, joint board of trustees, or similar group of representatives of the parties who establish or maintain the plan.

[17] ERISA Section 3(16)(A) provides that the term ''plan administrator'' means—(i) the person specifically so designated by the terms of the instrument under which the plan is operated; (ii) if an administrator is not so designated, the plan sponsor; or (iii) in the case of a plan for which an administrator is not designated and a plan sponsor cannot be identified, such other person as the Secretary may be regulation prescribe.

[18] Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993).

[19] Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 18, 2011).

[20] 44 U.S.C. 3506(c)(2)(A) (1995).

[21] 5 U.S.C. 601 *et seq.* (1980).

[22] 2 U.S.C. 1501 *et seq.* (1995).

[23] Federalism, 64 FR. 153 (Aug. 4, 1999).

[24] 5 U.S.C. 804(2) (1996).

[25] The regulatory impact analysis in various places refers to ''Agencies'' because the underlying decisions regarding the form and instructions generally are collective decisions of the DOL, IRS, and PBGC, but they should not be read as indications that the IRS and PBGC changes are subject to rulemaking processes, including Executive Orders 12866 and 13563.

[26] Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993).

beginning with the 2022 Form 5500 Annual Report/Return with most changes focused on defined benefit plans and some improvements to MEP reporting. The annual reporting changes are revisions to Schedules MB, SB, and R, and to the respective instructions, that are designed to improve reporting by defined benefit plans subject to Title IV of ERISA, and to the Form 5500 and Form 5500–SF instructions that further implement section 101 of the SECURE Act in ways that expand and improve transparency of MEP reporting, including for pooled employer plans.

Defined Benefit Pension Plan/ERISA Title IV Additions: The Form 5500 collects information from defined benefit pension plans in Schedules MB, SB, and R. The PBGC has determined that it needs more detail in these schedules to accurately project defined benefit pension plan and PBGC insurance program liabilities. The PBGC's changes to the information required to be reported by PBGC-insured defined benefit plans would remedy the deficiencies of the current Form 5500 filings and better protect participants. In 2019 PBGC estimated there were 23,694 single employer defined benefit plans and 1,375 multiemployer defined benefit plans that are covered by the PBGC and would be impacted by these changes.[27]

MEP Reporting Improvements Additions: The final forms revisions include new plan characteristics codes to identify pooled employer plans, association retirement plans, and PEO plans, along with a residual category code for all other defined contribution MEPs. These changes are designed to continue SECURE Act section 101 implementation by clarifying and further improving previous MEP reporting changes.

2. Affected Entities

The Agencies use historical filings of the Form 5500 to estimate affected entities. As discussed below, there have been several changes by statute and regulation that have created new types of MEPs. This analysis uses as its base the 2019 Form 5500 filings then estimates potential changes to the number of filers due to SECURE Act amendments creating pooled employer plans. As a result, there is uncertainty regarding the Agencies' ability to measure costs and benefits that may result from the final forms revisions. The Agencies nonetheless are presenting below an overview of potentially affected entities and an approach to evaluating the possible impact of the final forms revisions.

Defined Contribution Pension Plans: In 2019, there were 686,809 defined contribution plans with 109.1 million total participants and 85.5 million active participants. Plans with fewer than 100 total participants (small plans) account for 87.4 percent of plans.[28]

Defined Benefit Pension Plans: In 2019, there were 46,870 defined benefit plans with 32.8 million total participants and 12.6 million active participants. There were 45,302 single-employer defined benefit plans and 1,366 multiemployer defined benefit plans.[29]

Multiple-Employer Pension Plans (MEP): A MEP, for Form 5500 reporting purposes, generally is a retirement plan maintained by two or more employers that are not members of the same controlled group or affiliated service group under Code section 414(b), (c), or (m), and which is not a multiemployer plan.[30] In 2019, there were 4,741 MEPs filing a Form 5500, 202 of which were defined benefit pension plans and 4,538 were defined contribution pension plans. There were 7.5 million participants reported as covered by these plans.[31]

Association Retirement Plan: An association retirement plan is a defined contribution MEP sponsored by a bona fide group or association of employers that meets the conditions in 29 CFR 2510.3–55(b). The Agencies do not have information on how many reporting MEPs are association retirement plans or otherwise to estimate the number of association retirement plans (a sub-class of MEPs) that currently exist. These final regulations add a new code to identify association retirement plans.

Professional Employer Organizations (PEOs) Plan: A PEO MEP is a defined contribution MEP sponsored by a bona fide PEO that meets the conditions under 29 CFR 2510.3–55(c). According to the National Association of Professional Employer Organizations, there are 487 PEOs in the United States.[32] The Agencies do not have information on how many PEOs currently meet the conditions under 29 CFR 2510.3–55(c) to sponsor defined contribution MEPs for their clients, but instead assume a substantial percentage of PEOs do sponsor MEPs, including defined contribution MEPs. These final regulations add a new code to identify PEO MEPs.

Pooled Employer Plans: The SECURE Act amended section 3(2) of ERISA and added section 3(43) to ERISA to authorize a new type of ERISA-covered defined contribution MEP referred to as a ''pooled employer plan'' sponsored by a ''pooled plan provider.'' In its 2020 final rule on Registration Requirements for Pooled Plan Providers, the Agencies noted the uncertainty surrounding the number of pooled employer plans that could be created based on the final rule, the number of employers that would participate in such plans, and the number of participants and beneficiaries that would be covered by them.[33] Approximately 71 pooled plan providers have filed with the DOL an initial Form PR Pooled Plan Provider Registration (Form PR) and reported to service at least one pooled employer plan.[34] With these records the Agencies have estimated there will be, on average, approximately 2.85 pooled employer plans per registered pooled plan provider. Therefore, the Agencies estimate a total 202 pooled employer plans will file the Form 5500 in 2022 for their 2021 reporting year.[35] The final forms revisions add a new code to identify pooled employer plans.

[27] Due to differing methodologies between Agencies such as weightings factors for delinquent filers and how plans currently receiving financial assistance are counted, the EBSA and PBGC estimates for the ME universe differ slightly. For purposes of this analysis EBSA is using their estimate of 1,366. PGBC 2019 Pension Insurance Data Tables. *https://www.pbgc.gov/sites/default/files/2019_pension_data_tables.pdf.*

[28] Employee Benefits Security Administration. ''Private Pension Plan Bulletin, Abstract of 2019 Form 5500 Annual Report.'' (2021). The 2019 Form 5500 data set is the most recent available because Form 5500 filings for the 2019 reporting year generally are not required to be filed for calendar year plans until July through October of 2020, and the deadline for fiscal year plans may extend well into 2021. The User Guide for the 2019 Form 5500 Private Pension Plan Research File includes a discussion of the creation of the annual data set and timing of data extraction. *See www.dol.gov/sites/dolgov/files/EBSA/researchers/data/retirement/pension-user-guide-2019.pdf* (Accessed February 9, 2022).

[29] *Id.*

[30] *See, e.g.,* 2020 Form 5500 instructions at 14.

[31] Employee Benefits Security Administration. ''Private Pension Plan Bulletin, Abstract of 2018 Form 5500 Annual Reports.'' (June 2020).

[32] National Association of Professional Employee Organizations, *Industry Statistics* (Accessed 6/28/2021), *https://www.napeo.org/what-is-a-peo/about-the-peo-industry/industry-statistics.* NAPEO had previously reported 904 PEOs but revised its methodology. An explanation of the revision is included on the NAPEO website. *See* The PEO Industry Footprint 2021, Laurie Bassi and Dan McMurrer, McBassi & Company at page 4 (May 2021) (available at *www.napeo.org/docs/default-source/white-papers/2021-white-paper-final.pdf?sfvrsn=6dde35d4_2.*)

[33] 85 FR 72934, 72949 (Nov. 16, 2016).

[34] Department of Labor. Form PR. *https://www.dol.gov/agencies/ebsa/employers-and-advisers/plan-administration-and-compliance/reporting-and-filing/form-pr.*

[35] The estimated total number of pooled employer plans is calculated as follows: 2.85 pooled employer plans (average per provider) * 71 registered pooled plan providers = 202 pooled employer plans in total (rounded).

The Agencies do not have comprehensive data on how many employers are participating in pooled employer plans or the number of participants covered by the plans until the pooled employer plans file their first Forms 5500 in 2022 for their 2021 reporting year. While pooled plan providers are required to update the Form PR to advise the DOL and the IRS about the establishment and offering of new pooled employer plans, the Form PR does not collect information on the number of employers participating in their pooled employer plans or the number of employees covered by each plan. The Agencies attempted to review available public information on pooled employer plans by looking at information included in the filed Forms PR, and by examining news articles and statements on the pooled plan provider's websites. That review indicated that that there are a variety of approaches in how pooled employer plans are offered, and a variation in the number of employers that have joined a pooled employer plan.

Although the Agencies do not know for certain how many plans would decide to offer benefits through a pooled employer plan, the Agencies believe the current average number of participating employers in a MEP is indicative of the average number of employers that would eventually be in any particular pooled employer plan that may be established in the future. The Agencies estimates that MEPs, on average, have nine employers participating in a MEP with fewer than 100 participants and two employers with 100 or more participants. The Agencies use these averages to inform the estimate of the average number of participating plans in a pooled employer plan. The final estimate does take into account one pooled plan provider registrant that has already listed 2,000 participating employers. It is estimated that a total of 3,369 small employers (*i.e.,* under 100 plan participants) and 842 large employers would seek to provide benefits as participating employers in pooled employer plans.[36] The Agencies assume this would result in a direct decrease of defined contribution Form 5500–SF filers and a decrease of defined contribution Form 5500 filers, and a total reduction of filers from 843,662 to 839,728 filers. Such a reduction in filers would be partially offset by an increase in pooled employer plan filings. In the proposed rule, the Agencies requested comments regarding the number of employers that have already joined a pooled employer plan; however, no comments were received that helped the Agencies revise the estimates of the number of filers.

3. Benefits

Defined Benefit Plan/Title IV Questions for the 2022 Form 5500s: The changes to the Form 5500 Schedules MB, SB, and R would help remedy data and information inadequacies, increasing plans' transparency, enable Agencies to project more precisely defined benefit pension plans' and insurance programs' liabilities, and help the PBGC more effectively conduct research and better protect plan participants and beneficiaries.

Schedule MB collects actuarial information on multiemployer defined benefit plans and certain money purchase plans. Based on reviewing previously filed Schedules MB responses to line 4f, it appears to the Agencies that the instructions may be unclear as to how to fill out line 4f of Schedule MB correctly. Clarification of the line 4f instructions and line language is intended to provide more consistent and correct responses. Revisions to line 6 and clarification of the expense load percentage calculation is intended to allow the Agencies to easily identify the expense load and more accurately project plan liabilities. The changes to line 6 will provide greater transparency in the actuarial status and the actuarial assumptions of the plans. The expansion of line 8b to require additional projected benefit payment and employer contribution information will allow the Agencies to collect more information to more precisely project defined benefit pension plans' and insurance programs' liabilities.

Schedule SB collects actuarial information on single-employer defined benefit plans. The expansion of line 26 to require additional projected benefit payment information and the change to Part IX will allow the Agencies to collect more information to more precisely project defined benefit pension plans' and insurance programs' liabilities. It also aligns the filing requirements for single-employer defined benefit plans with the more detailed requirements for PBGC-insured multiemployer plans resulting from the modification of line 8 on the schedule MB.

Schedule R collects information on retirement plans. Previously, multiemployer defined benefit pension plans were required to report identifying information for each employer that contributed more than five percent of total contributions to the plan during the plan year. The final forms revisions, instead, requires plans to report identifying information on any employer who (1) contributed more than five percent of the plan's total contributions or (2) was one of the top ten highest contributors. This will provide greater transparency as related to concentrations of potential risk within participating employers.

The final forms revisions also make changes in format for certain attachments. EFAST2 filers currently file some Form 5500 attachments as PDF and plain text files. Due to the nature of the attachments, they often include many numbers that are difficult to extract from these file types. There is consideration being given to steps that could be taken to allow more integration of common spreadsheet files (such as CSV formats). As this is not being considered as a requirement at this point, plans would not incur an additional cost if such functionality were made available. The Agencies expect this option may simplify the process for preparing and filing attachments.

Multiple-Employer Pension Plan Reporting Improvements: The final forms revisions add new plan characteristics codes to identify pooled employer plans, association retirement plans, and PEO plans, along with a residual category for all other defined contribution MEPs. This information would help protect plan participants and beneficiaries by allowing for improved analysis for oversight and research purposes by the government, the regulated community, and other interested stakeholders.

Benefits of Changes for Pooled Employer Plans. The SECURE Act established a new type of ERISA-covered defined contribution pension plan, the pooled employer plan, that is established and maintained by a pooled plan provider that meets the conditions of the statute. By creating the pooled employer plan structure, the SECURE Act permitted multiple unrelated

[36] For the calculation of the total number of participating employers in pooled employer plans, it is first assumed that 80 percent of all the employers who would participate in a pooled employer plan are currently providing benefits through small plans, and that the remaining 20 percent through large plans. This distribution would apply to the registrant that has already exceptionally listed 2000 employers (which would then be divided in 1600 small participating plans and 400 large participating plans) and to the other 201 pooled employer plans assumed to be created. It is also assumed that each one of these other 201 pooled plan providers would be servicing in total 11 employers. Therefore, the total number of small participating plans in a pooled employer plan is calculated as: 1,600 + (201*11*0.8) = 3,369 (rounded). Similarly, the total number of large participating plans is calculated as 400 + (201*11*0.2) =842 (rounded).

employers to participate without the need for any common interest among the employers (other than having adopted the plan). As discussed above, pooled employer plans need to provide ERISA section 103(g) participating employer information, as well as certain basic information regarding the pooled plan provider. Potentially increased reporting costs for those employers choosing to offer retirement benefits to their employees through participating in a pooled employer plan would be offset by other cost reductions or business benefits relative to not having to administer an individual plan as further discussed below.

By participating in a pooled employer plan, employers could minimize their fiduciary responsibilities for ongoing administration and operation of the plan. Employers could benefit from reduced risk and liability because the pooled plan provider would bear most of the administrative and fiduciary responsibility for operating the pooled employer plan, including hiring and monitoring the 3(38) investment manager. Similarly, because the pooled plan provider handles the administrative tasks such as participant communications, plan recordkeeping, submitting the Form 5500 and complying with plan audits, this could increase the operating efficiency for participating employers. Also, as they are expected to be professional plan providers, it is anticipated that a pooled plan provider, relative to a small employer, would ensure that more accurate and complete data is reported to the Agencies on the Form 5500. Further, as discussed in the regulatory impact analysis to the regulation establishing the Form PR, pooled employer plans generally would benefit from scale advantages, including the ability to obtain lower fees for investment options.[37] The marginal costs for pooled employer plans would diminish and pooled plan providers would spread fixed costs over a larger pool of member employers and employee participants, creating direct economic efficiencies. Szapiro's research finds that the per-employer cost of a large MEP can be lower than the cost of a small single employer plan.[38] Specifically, the study finds that a MEP with $125 million and 80 participating companies cost 78 basis points, whereas 80 single-employer plan each with $1.5 million in assets would have an estimated cost of 111 basis points per plan. Thus, compared to single-employer plans, MEPs can be a more cost-efficient option for small employers. The increased economic efficiency may result in small businesses being able to compete more easily with larger companies in recruiting and retaining workers due to a competitive employee benefit package. Finally, pooled employer plans may enable participants to achieve better retirement outcomes. VanDerhei's research finds that the adoption of a MEP in which the members do not need to share a common interest, other than participating in the same plan, with a 25 percent opt-out rate among employees, results in an overall 1.4 percent reduction in the retirement savings deficit, compared to when a MEP is not adopted.[39] The study also finds a 3.1 percent reduction in the retirement savings deficit for individuals working for employers with fewer than 100 employees and 3.3 percent reduction in the retirement savings deficit for individuals working for employers with 100 to 500 employees.

4. Costs

The Agencies anticipate that the costs for plans to satisfy their annual reporting obligations would on average stay the same for most plans and increase slightly for some under the final forms revisions relative to the current regime.[40] The Agencies estimate that the final forms revisions would impose an additional annual burden of $5.0 million with most costs falling on 25,069 defined benefit plan filers.

Defined Benefit Plan/Title IV Questions for the 2022 Form 5500s: The final forms revisions include changes related to reporting requirements for defined benefit pensions subject to filing Schedules MB, SB, and R. The Agencies believe the changes and additional questions reflect information plans should know and expect that reporting this information would result in a de minimis increase in burden.

Based on the changes that will be effective beginning with the 2022 Schedules SB, MB and R, and the relevant comments for each, the Agencies believes that the implementation of the changes by plans will be the only measurable change and the aggregate change is de minimis. The opinion is founded on the idea that the changes can be described by one or more of the following; (1) The change replaces an existing data element for a new element or set of elements that are assumed to be at hand for plans, (2) changes to reporting thresholds based on plan size reduce the number of plans required to respond and this change offsets any potential additional burden incurred by plans still required to report[41] and (3) the changes are benign and meant to clarify or simplify reporting. Therefore, the Agencies include 2 hours for plan administrators to prepare for the reporting changes in plan year 2022 and assume there to be no ongoing additional burden from the changes in subsequent years. This results in a one-time cost of $5.0 million for the 25,069 defined benefit plan filers.

Multiple-Employer Pension Plan (MEP) Reporting Improvements: New to the 2022 plan year forms are four new plan characteristics codes to identify different types of defined contribution MEPs: (a) Pooled employer plans, (b) association retirement plans, and (c) PEO plans, along with a residual category (d) for all other defined contribution MEPs. Plans already report characteristics codes and the inclusion of these additional codes for these recently added plan types does not increase the estimated plan reporting burden for these plans.

5. Uncertainty

The SECURE Act created pooled employer plans. Due to these final rules designed to implement the SECURE Act, as well as the DOL's final rules with respect to association retirement plans and PEO-sponsored plans, the Agencies assume that these types of entities will file a Form 5500 and report the number of participating employers, numbers of covered participants, and amount of assets in the future. However, until they

[37] 85 FR at 72949–72950.

[38] Szapiro, Aron, ''Pooled Employer Plans: Paperwork or Panacea.'' Accessible at *https://www.morningstar.com/lp/paperwork_or_panacea.*

[39] VanDerhei, Jack. ''How Much More Secure Does the SECURE Act Make American Workers: Evidence from EBRI's Retirement Security Projection Mode.'' *EBRI Issue Brief.* No 501 (2020). VanDerhei refers to MEPs in which the members do not need to share a common interest as ''Open MEPs.'' (Available at *https://www.ebri.org/docs/default-source/ebri-issue-brief/ebri_ib_501_secure-20feb20.pdf?sfvrsn=db6f3d2f_4.* (Accessed July 21, 2021.))

[40] The Agencies believe that the annual cost burden on filers would be higher still in the absence of the regulations enabling use of the Form 5500 Annual Return/Report in lieu of the statutory requirements. Without the Form 5500 Annual Return/Report, filers would not have the benefits of any regulatory exceptions, simplified reporting, or alternative methods of compliance, and standardized and electronic filing methods.

[41] Using data from the 2019 PBGC Data Tables table S–31 and M–6, EBSA calculates that the change in size threshold will half the number of PBGC insured Single-employer (SE) plans required to provide information (where applicable) from 19.2 percent (4,511 plans) to 10 percent (2,343 plans) of the plan universe (23,477 plans) in plan year 2020. The PBGC insured multiemployer universe reporting falls as well, from 79.7 percent (1,091 plans) to 62.1 percent (850 plans) of the plan universe (1,369 plans). *https://www.pbgc.gov/sites/default/files/2019-pension-data-tables.xlsx.*

file and there is a way to identify them, the Agencies face significant uncertainty about the number of each type of entity and whether they are providing coverage in a different manner than was already provided by employers to their employees through single employer plans or already existing MEPs (including association retirement plans and PEOs) or whether with the availability of additional commercial arrangements and plans, more employers will establish plans for their employees.

The Agencies requested information during the proposed rule stage that would help improve its estimates of the numbers of affected entities, employers and the burdens they would experience, but did not receive comments that would help improve its estimates.

6. Alternatives

As discussed earlier in the preamble, the Agencies considered alternative approaches for some of the information required to be reported in order to reduce possible burden, including:

In the NPFR, line 8b(3) of Schedule MB and line 26b of Schedule SB were proposed to be applicable to plans with 500 or more participants. After receiving comments on the proposed changes, the Agencies decided to revise this requirement for these lines and also for line 8b(1) of Schedule MB so the requirement would only be applicable to plans with 1,000 or more participants, hence reducing the number of plans required to provide attachments. In the NPFR, line 8b(4) of Schedule MB and line 26(c) of Schedule SB were proposed to require plans to provide the average age and average benefit for terminated vested participants and participants in pay-status. After receiving comments on the proposed changes, the Agencies decided to not include these provisions in the final rule.

The Agencies also considered finalizing the Schedule MEP but as discussed above, the Agencies decided not to finalize the Schedule MEP in the final forms revisions because of the need to carefully consider the public comments, allow sufficient lead time for programming and systems changes, as well as time to develop contracts and other communications among the plans and their service providers, done in conjunction with a separate contractual development schedule for integrating form and instruction changes into the EFAST2 wholly-electronic filing system that receives and displays Forms 5500 series annual returns/reports.

B. Paperwork Reduction Act Statement

In accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)), the Agencies solicited comments concerning the information collection request (ICR) included in the revision of the Form 5500 Annual Return/Report. At the same time, the Agencies also submitted an information collection request (ICR) to the Office of Management and Budget (OMB), in accordance with 44 U.S.C. 3507(d).

The Agencies did not receive comments that specifically addressed the paperwork burden analysis of the information collection requirement contained in the proposed rule.

In connection with publication of the final forms revision, the Agencies are submitting an ICR to OMB requesting a revision of the collection of information under OMB Control Number 1210–0110 reflecting the instruction changes being finalized in this document. The Agencies will notify the public when OMB approves the ICR.

A copy of the ICR may be obtained by contacting the PRA addressee shown below or at *www.RegInfo.gov*. PRA ADDRESSEE: Address requests for copies of the ICRs to James Butikofer, Office of Research and Analysis, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5655, Washington, DC 20210 or email: *ebsa.opr@dol.gov*. ICRs submitted to OMB also are available at *http://www.RegInfo.gov*.

The burden analysis is based on data from the 2019 Form 5500 filings (the latest year for which complete data are available). The burden analysis includes the burden of the current information collection and adjusts it for changes made by the final forms revisions.

Burden estimates take into account the change in plan counts due to the creation of pooled employer plans, with an increase in MEPs and a small decrease in single employer plans, reflecting some single employer plans moving to pooled employer plans. The Agencies estimated that there are 4,538 defined contribution MEPs and that 202 PEPs will be formed. The burden also includes the additional burden from the changes to the 2022 Form 5500 and related schedules.

The Agencies' burden estimation methodology excludes certain activities from the calculation of ''burden.'' If the activity is performed for any reason other than compliance with the applicable Federal tax administration system or the Title I annual reporting requirements, it was not counted as part of the paperwork burden. For example, most businesses or financial entities maintain, in the ordinary course of business, detailed accounts of assets and liabilities, and income and expenses for the purposes of operating the business or entity. These recordkeeping activities were not included in the calculation of burden because prudent business or financial entities normally have that information available for reasons other than Federal tax or Title I annual reporting. Only time for gathering and processing information associated with the tax return/annual reporting systems, and learning about the law, was included. In addition, an activity is counted as a burden only once if performed for both tax and Title I purposes. The Agencies also have designed the instruction package for the Form 5500 Annual Return/Report so that filers generally will be able to complete the Form 5500 Annual Return/Report by reading the instructions without needing to refer to the statutes or regulations. The Agencies, therefore, have considered in their PRA calculations the burden of reading the instructions and find there is no recordkeeping burden attributable to the Form 5500 Annual Return/Report.

Note that to reflect OMB's preference that burden incurred by service providers be reported as hour burden instead of cost burden, burden that has historically been included as cost burden has been included here as hour burden.

A summary of paperwork burden estimates follows. As noted above, these estimates include the burden of the overall Form 5500 information collection and makes adjustments for the final instructions revisions included in this document.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Annual Information Return/Report of Employee Benefit Plan.

Type of Review: Revision of existing collection.

Affected Public: Individuals or households; Private Sector—Business or other for-profit; Not-for-profit institutions.

OMB Number: 1210–0110.

Total Respondents: 839,728.

Total Responses: 839,728.

Estimated Total Burden Hours: 3,029,299.

Estimated Total Annualized Costs: $0.

Agency: Department of Treasury—IRS.

Title: Annual Information Return/Report of Employee Benefit Plan.

Type of Review: Revision of existing collection.

Affected Public: Individuals or households; Private Sector—Business or other for-profit; Not-for-profit institutions.

OMB Number: 1545–1610.

Total Respondents: 984,354.

Total Responses: 984,354.

Estimated Total Burden Hours: 1,970,038.

Estimated Total Annualized Costs: $0.

Agency: PBGC.

Title: Annual Information Return/Report of Employee Benefit Plan.

Type of Review: Revision of existing collection.

Affected Public: Individuals or households; Private Sector—Business or other for-profit; Not-for-profit institutions.

OMB Number: 1212–0057.

Total Respondents: 25,069.

Total Responses: 25,069.

Estimated Total Burden Hours: 17,743.

Estimated Total Annualized Costs: $0.

Paperwork and Respondent Burden: Estimated time needed to complete the forms listed below reflects the combined requirements of the IRS, the DOL, and the PBGC. The times will vary depending on individual circumstances. The estimated average times are:

TABLE 1—AVERAGE ESTIMATED TIME PER SCHEDULE, PER FILER TYPE

	Pension plans		
	Large	Small, filing Form 5500	Small, filing 5500–SF
Form 5500	1 hr, 50 min	1 hr, 19 min.	
Sch A	2 hr, 52 min	2 hr, 52 min.	
Sch MB	8 hr, 53 min	8 hr, 14 min	8 hr, 14 min.
Sch SB	6 hr, 38 min	6 hr, 49 min	6 hr, 49 min.
Sch C	2 hr, 49 min.		
Sch D	1 hr, 39 min	20 min.	
Sch G	14 hr, 14 min.		
Sch H	7 hr, 38 min.		
Sch I		2 hr, 6 min.	
Sch R	1 hr, 41 min.	1 hr, 7 min.	
Form 5500–SF			2 hr, 35 min.

	Direct filing entities				
	Master trusts	CCTs	PSAs	103–12 IEs	GIAs
Form 5500	1 hr, 50 min	1 hr, 29 min	1 hr, 24 min	1 hr, 33 min	1 hr, 22 min.
Sch A	2 hr, 54 min	2 hr, 48 min	2 hr, 46 min	2 hr, 52 min	2 hr, 53 min.
Sch C	3 hr, 1 min	1 hr, 1 min	29 min	1 hr, 22 min	51 min.
Sch D	1 hr, 30 min	47 min	34 min	49 min	41 min
Sch G	12 hr, 32 min			5 hr, 42 min.	
Sch H	8 hr, 7 min	7 hr, 36 min	7 hr, 33 min	8 hr, 17 min	7 hr, 38 min.

	Welfare plans that include health benefits	
	Large	Small, unfunded, combination unfunded/fully insured, or funded with a trust 5500–SF
Form 5500	1 hr, 45 min	1 hr, 14 min.
Sch A	3 hr, 40 min	2 hr, 43 min.
Sch C	3 hr, 38 min.	
Sch D	1 hr, 52 min	20 min
Sch G	11 hr, 0 min.	
Sch H	8 hr, 36 min.	
Sch I		1 hr, 56 min.
Form 5500–SF		2 hr, 35 min.

	Welfare plans that do not include health benefits		
	Large	Small, filing Form 5500	Small, filing Form 5500–SF
Form 5500	1 hr, 45 min	1 hr, 14 min.	
Sch A	3 hr, 40 min	2 hr, 43 min.	
Sch C	3 hr, 38 min.		
Sch D	1 hr, 52 min	20 min.	
Sch G	11 hr, 0 min.		
Sch H	8 hr, 36 min.		
Sch I		1 hr, 56 min.	
Form 5500–SF		2 hr, 35 min.	

The aggregate hour burden for the Form 5500 Annual Return/Report (including schedules and short form) is estimated to be 5 million hours annually shared between the DOL, IRS, and the PBGC. The hour burden reflects filing activities carried out directly by filers.

Presented below is a chart showing the total hour and cost burden of the revised Form 5500 Annual Return/Report, including the changes due to the current and past revisions. The chart displays the total hour burden separately allocated across the DOL, the IRS, and the PBGC.

TABLE 2—HOUR BURDEN DISTRIBUTION PER AGENCY

	Hour burden		
	DOL	IRS	PBGC
Pension Large Plans	893,879	409,717	2,513
Pension Small Plans	929,498	1,063,423	12,649
Welfare Large Plans	1,065,506	17,906	.....
Welfare Small Plans	64,616	22,140	.....
DFEs	70,103	34,404	75
EZ Filers	.....	374,340	.....
January 2013 Revision	630	.....	.....
2014 CSEC Revision	2,728	.....	.....
2021/2022 Revisions	2,339	48,108	2,507
Total Agency Burden	3,029,299	1,970,038	17,743

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)[42] imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act and are likely to have a significant economic impact on a substantial number of small entities.[43] Unless the head of an agency certifies that a final rule is not likely to have a significant economic impact on a substantial number of small entities, section 604 of the RFA requires the agency to present a final regulatory flexibility analysis of the final rule.[44] The Department prepared an Initial Regulatory Flexibility Analysis at the proposed rule stage. However, the final forms revisions are focused only on a subset of the requirements proposed. As discussed in the cost section above, most changes have negligible or no added burden. The Defined Benefit Plan/Title IV Revisions have added costs in the first year as plans make changes to what information is being reported. In 2019 there were 23,694 single employer defined benefit plans and 1,375 multiemployer defined benefit plans that are covered by the PBGC and would be impacted by these changes. These plans are a non-substantial fraction (3.7 percent) of the 686,809 pension plans filing in 2019. The Department certifies that the final forms revisions will not have a significant impact on a substantial number of small entities. Therefore, the Department has not prepared a Final Regulatory Flexibility Analysis.

[42] 5 U.S.C. 601 *et seq.* (1980).

[43] 5 U.S.C. 551 *et seq.* (1946).

[44] 5 U.S.C. 604 (1980).

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation with the base year 1995) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector.[45] For purposes of the Unfunded Mandates Reform Act, as well as Executive Order 12875, the final forms revisions does not include any Federal mandate that the Agencies expect would result in such expenditures by State, local, or tribal governments, or the private sector.[46]

E. Federalism Statement

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have ''substantial direct effects'' on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government.[47] Federal agencies promulgating regulations that have federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the final rule.

In the Agencies' view, the final forms revisions would not have federalism implications because they would not have direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among various levels of government. Section 514 of ERISA provides, with certain exceptions specifically enumerated, that the provisions of Titles I and IV of ERISA supersede any and all laws of the States as they relate to any employee benefit plan covered under ERISA. The requirements implemented in these rules do not alter the fundamental provisions of the statute with respect to employee benefit plans, and as such would have no implications for the States or the relationship or distribution of power between the national government and the States.

[45] 2 U.S.C. 1501 *et seq.* (1995).

[46] Enhancing the Intergovernmental Partnership, 58 FR 58093 (Oct. 28, 1993).

[47] Federalism, *supra* note 6.

IV. Appendices

The Agencies have included Appendices A and B to provide more detailed illustrations and explanations of the changes, which will be implemented for the 2022 Form 5500 series, expected to be available for filing on January 1, 2023:[48] Appendix A contains a detailed description of final changes to the 2022 Form 5500, Schedules MB, SB and R. Appendix B contains a detailed description of final changes to the 2022 Form 5500 and Form 5500–SF to implement Section 101 of the SECURE Act.[49]

[48] Consistent with prior year practice, ''information-only'' copies of the forms, schedules, and instructions may be published earlier than January 1, 2023.

[49] This approach of showing proposed changes will reduce costs associated with publication of the proposed form changes in the **Federal Register** and provide greater flexibility for the related EFAST2 development processes. The Agencies intend to publish mock-ups of the forms on the DOL's website as part of the EFAST2 third party software

developer certification process and in furtherance of public education efforts about the changes to be implemented.

Consistent with the Agencies annual updates to the forms, the final versions may include minor technical corrections that do not require further notice and comment under the PRA, the APA, or any relevant Executive Order.

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APPENDIX A - CHANGES TO 2022 SCHEDULE MB, SCHEDULE SB AND SCHEDULE R, AND THEIR INSTRUCTIONS

1. Changes to 2022 Schedule MB and Instructions to Improve PBGC Reporting.

- **Instructions to 2022 Schedule MB.** Line 3 of the 2022 Schedule MB instructions is modified to read as follows:

Line 3. Contributions Made to Plan. Show all employer and employee contributions for the plan year. Include employer contributions made not later than 2½ months (or the later date allowed under Code section 431(c)(8) and ERISA section 304(c)(8)) after the end of the plan year. Show only contributions actually made to the plan by the date this Schedule MB is signed.

Add the amounts in both columns (b) and (c) and enter both results on the total line. All contributions must be credited toward a particular plan year.

If any of the contributions reported in line 3 include amounts owed for withdrawal liability, report in line 3(d) the total withdrawal liability amounts included in line 3(b).

Attach a list showing the date and amount of each withdrawal liability amount included, broken down between periodic amounts and lump sum amounts. For this purpose, include a withdrawal liability payment as a lump sum only if the entire liability is paid in one lump sum or if the payment from an employer that paid its assessed withdrawal liability in periodic installments (e.g., monthly or quarterly) in prior years settled the remaining liability via one lump sum payment during the plan year. Use the format shown below and label this attachment ***"Schedule MB, line 3(d) – Withdrawal Liability Amounts."*** The attachment may be provided in a spreadsheet file (CSV format).

Schedule MB line 3(d) – Withdrawal Liability Amounts			
Payment Date	**Periodic Amounts**	**Lump Sum Amounts**	**Total Amounts**

- **2022 Schedule MB.** Line 4f of Schedule MB is modified to read as follows:

***

f If the plan is in critical status or critical and declining status, and is: • Projected to emerge from critical status within 30 years, enter the plan year in which it is projected to emerge; • Projected to become insolvent within 30 years, enter the plan year in which insolvency is expected and check here …….. ☐ • Neither projected to emerge from critical status nor become insolvent within 30 years, enter "9999."	**4f**	

***

- **Instructions to 2022 Schedule MB.** Instructions for line 4f of the 2022 Schedule MB are modified to read as follows:

Line 4f. If Code C (Critical Status) or Code D (Critical and Declining Status) was entered on line 4b you must complete line 4f as follows:

If the projections underlying the actuarial certification for the plan year indicate that the plan is:

- Projected to emerge from critical status within 30 years, enter the plan year in which the plan is projected to emerge from critical status.
- Projected to become insolvent within 30 years, check the box provided and enter the plan year in which the insolvency is expected. In addition, attach an illustration showing year-by-year cash flow projections for the period beginning with the plan year and ending with the year the plan is projected to become insolvent (or, if earlier, the 19th year after the plan year) and a

summary of the assumptions underlying the projections. Label this attachment "***Schedule MB, line 4f – Cash Flow Projections.***"

- Neither projected to emerge from critical status nor become insolvent within 30 years, enter "9999." In addition, attach an illustration showing year-by-year cash flow projections for the 20-year period beginning with the plan year and a summary of the assumptions underlying the projections. Label this attachment "***Schedule MB, line 4f – Cash Flow Projections.***"

- **2022 Schedule MB.** Lines 6e and 6f are modified and line 6i is added to the 2022 Schedule MB, to read as follows:

***

6 Checklist of actuarial assumptions					
a Interest rate for 'RPA 94 current liability				**6a**	
		Pre-retirement		Post-retirement	
b Rates specified in insurance or annuity contracts		☐ Yes ☐ No ☐ N/A		☐ Yes ☐ No ☐ N/A	
c Mortality table code for valuation purposes:					
(1) Males	**6c(1)**				
(2) Females	**6c(2)**				
d Valuation liability interest rate	**6d**	%		%	
e Salary scale	**6e**	%	☐ N/A		
f Withdrawal liability interest rate					
(1) Type of interest rate	**6f(1)**	☐ Single rate ☐ ERISA 4044 ☐ Other ☐ N/A			
(2) If "Single rate" is checked in (1), enter applicable single rate				**6f(2)**	%
g Estimated investment return on actuarial value of assets for year ending on the valuation date				**6g**	%
h Estimated investment return on market value of assets for year ending on the valuation date				**6h**	%
i Expense load included in normal cost reported in line 9b				**6i**	☐ N/A
(1) If the expense load is described as a percentage of normal cost, enter the assumed percentage				**6i(1)**	%
(2) If the expense load is a dollar amount that varies from year to year, enter dollar amount included in line 9b				**6i(2)**	
(3) If neither (1) nor (2) describes the expense load, check the box				**6i(3)**	☐

***

- **Instructions to 2022 Schedule MB.** Instructions for the salary scale assumption (line 6f on the 2021 Schedule MB) are renumbered to be line 6e. Instructions for the withdrawal liability interest rate assumption, a new item to be reported on line 6f, are added as shown below.

Instructions for the expense load assumption (line 6f for the 2021 Schedule MB) are renumbered to be line 6i and modified as shown below.

Lines 6f(1) and 6(f)(2). Withdrawal Liability Interest Rate. In line 6f(1), check the box that describes the type of interest rate assumption used to determine the present value of vested benefits for withdrawal liability determinations for employers withdrawing during the plan year. If the present value of vested benefits noted above was not determined by the time the Form 5500 is filed, check "N/A". In addition:

- If "Single rate" is checked, enter the single rate in line 6f(2).
- If "Other" is checked, attach a description of the interest rate used for this purpose and label this attachment "***Schedule MB, line 6f(1) – Description of Withdrawal Liability Interest Rate".***

Line 6i. Expense Load Included in Normal Cost. If the normal cost reported in line 9b does not include a load for administrative or investment expenses, check the "N/A" box. Otherwise, provide information in lines 6i(1), 6i(2), or 6i(3), whichever is applicable, about the expense load included in the normal cost. If the expense load is described as a percentage of normal cost, the reported percentage in line 6i(1) should be the expense load as a percent of the unloaded normal cost. For example, if the expense load is 5% of the normal cost, the unloaded normal cost is $100,000 and the reported normal cost is $105,000, enter 5%, not 4.8% (i.e., $5,000/$105,000). Enter rates to the nearest .1 percent.

- **2022 Schedule MB.** The title for line 8b is modified and a new line 8b(3) is added to the 2022 Schedule MB to read as follows:

***

8 Miscellaneous information		
a If a waiver of a funding deficiency has been approved for this plan year, enter the date (MM-DD-YYYY) of the ruling letter granting the approval	**8a**	
b Demographic, benefit, and contribution information		
(1) Is the plan required to provide a projection of expected benefit payments? (see instructions) If "Yes," attach a schedule	☐ Yes ☐ No	
(2) Is the plan required to provide a Schedule of Active Participant Data? (see instructions) If "Yes," attach a schedule	☐ Yes ☐ No	
(3) Is the plan required to provide a projection of employer contributions and withdrawal liability payments? (see instructions) If "Yes," attach a schedule	☐ Yes ☐ No	

***

- **Instructions to 2022 Schedule MB**. Instructions for lines 8b(1) and 8b(2) are modified and instructions for line 8b(3) are added to the 2022 Schedule MB, to read as follows:

Line 8b(1). Schedule of Projection of Expected Benefit Payments. Check "Yes" only if this is a multiemployer plan covered by Title IV of ERISA that has 1,000 or more total participants as of the beginning of the plan year (i.e., reported on line 2b(3)(c), column (1)).

If line 8b(1) is "Yes," in an attachment, provide a projection of benefits expected to be paid separately for active participants, terminated vested participants, and retired participants and beneficiaries receiving payments, and for the entire plan (not to include expected expenses) in each of the next fifty years starting with the plan year and based on the participant's status as of the valuation date. For purposes of this projection, assume (1) no additional accruals, (2) experience (e.g., termination, mortality, and retirement) is in line with valuation assumptions, (3) no new entrants, and (4) benefits are paid in the form assumed for valuation purposes.

Use the format shown below and label the schedule "***Schedule MB, line 8b(1) – Schedule of Projection of Expected Benefit Payments.***" The attachment may be provided in a spreadsheet file (CSV format).

Schedule MB, line 8(b)(1) - Schedule of Projection of Expected Benefit Payments				
Plan Year	**Active Participants**	**Terminated Vested Participants**	**Retired Participants and Beneficiaries Receiving Payments**	**Total**
Current Plan Year				
Current Plan Year + 1				
Etc.				
Current plan year + 49				

Line 8b(2). Schedule of Active Participant Data. Check "Yes" only if this is a multiemployer plan covered by Title IV of ERISA that has active participants.

If line 8b(2) is "Yes," attach a schedule of the active plan participant data used in the valuation for this plan year. Use the format shown below and label the attachment *"**Schedule MB, line 8b(2) – Schedule of Active Participant Data.**"* The attachment may be provided in a spreadsheet file (CSV format).

Schedule MB, line 8b(2) – Schedule of Active Participant Data													
	YEARS OF CREDITED SERVICE												
	Under 1			1 to 4			5 to 9				40 & up		
Attained Age	No.	Average		No.	Average		No.	Average		.	No.	Average	
		Comp.	Accrued Mon. Ben.		Comp.	Accrued Mon. Ben.		Comp.	Accrued Mon. Ben.			Comp.	Accrued Mon. Ben.
Under 25 25 to 29 30 to 34 35 to 39 40 to 44 45 to 49 50 to 54 55 to 59 60 to 64 65 to 69 70 & up													

Expand this schedule by adding columns after the "5 to 9" column and before the "40 & up" column for active participants with total years of credited service in the following ranges: 10 to 14; 15 to 19; 20 to 24; 25 to 29; 30 to 34; and 35 to 39. For each column, enter the number of active participants with the specified number of years of credited service divided according to

age group. For participants with partial years of credited service, truncate the total number of years of credited service. Years of credited service are the years credited under the plan's benefit formula.

Plans reporting 1,000 or more active participants on line 2b(3)(c), column (1), and using compensation to determine benefits must also provide average compensation data. For each grouping, enter the average compensation of the active participants in that group. For this purpose, compensation is the compensation taken into account for each participant under the plan's benefit formula, limited to the amount defined under section 401(a)(17) of the Code. Do not enter the average compensation in any grouping that contains fewer than 20 participants.

Plans reporting 1,000 or more active participants on line 2b(3)(c), column (1), must also provide average accrued monthly benefits, as of the valuation date, that are payable at normal retirement age. For each grouping, enter the average accrued monthly benefit that is payable at normal retirement age for the active participants in that group. Do not enter the average accrued monthly benefit in any grouping that contains fewer than 20 participants.

General Rule. In general, data to be shown in each age/service bin includes:

1. the number of active participants in the age/service bin,
2. the average compensation of the active participants in the age/service bin, and
3. the average accrued monthly benefit of the active participants in the age/service bin, using $0 for anyone who has no accrued monthly benefit.

In general, information should be determined as of the valuation date. Average accrued monthly benefits may be determined as of either:

1. the valuation date or

2. the day immediately preceding the valuation date.

Line 8b(3). Schedule of Projection of Employer Contributions and Withdrawal Liability Payments. Check "Yes" only if this is a multiemployer plan covered by Title IV of ERISA that has 1,000 or more total participants as of the beginning of the plan year (i.e., reported on line 2b(3)(c), column (1)). If line 8b(3) is "Yes," in an attachment, separately provide a projection of employer contributions and withdrawal liability payments expected to be received for the entire plan in each of the next ten years starting with the plan year. For purposes of this projection, use the assumption used to determine the plan's status under line 4b. Use the format shown below and label the schedule "***Schedule MB, line 8b(3) – Schedule of Projection of Employer Contributions and Withdrawal Liability Payments.***" The attachment may be provided in a spreadsheet file (CSV format).

Schedule MB, line 8b(3) – Schedule of Projection of Employer Contributions and Withdrawal Liability Payments			
Plan Year	**Employer Contributions**	**Withdrawal Liability Payments**	**Total**
Current Plan Year			
Current Plan Year + 1			
Etc.			
Current plan year + 9			

2. Changes to 2022 Schedule SB and Instructions to Improve PBGC Reporting.

- **2022 Schedule SB.** Line 26 is modified in Part VI of the 2022 Schedule SB to read as follows:

26 Demographic and benefit information	
a Is the plan required to provide a Schedule of Active Participants? If "Yes," see instructions regarding required attachment.	☐ Yes ☐ No
b Is the plan required to provide a projection of expected benefit payments? If "Yes," see instructions regarding required attachment	☐ Yes ☐ No

- **Instructions to 2022 Schedule SB.** The first two paragraphs of the instructions for line 26 (now line 26a) are modified to reference line 26a instead of line 26 as shown below. The remaining paragraphs of the instructions for line 26 (now line 26a) are not modified. In addition, instructions for line 26b are added as follows:

Line 26a. Schedule of Active Participant Data. Check "Yes" only if (a) the plan is covered by Title IV of ERISA and (b) the plan has active participants.

If line 26a is "Yes," attach a schedule of the active plan participant data used in the valuation for this plan year. Use the format shown and label the schedule ***"Schedule SB, line 26a – Schedule of Active Participant Data."*** The attachment may be provided in a spreadsheet file (CSV format).

Line 26b. Schedule of Projection of Expected Benefit Payments. Check "Yes" only if this plan is covered by Title IV of ERISA and has 1,000 or more total participants as of the valuation date.

If line 26b is "Yes," in an attachment, provide a projection of benefits expected to be paid separately for active participants, terminated vested participants, and retired participants and beneficiaries receiving payments, and for the entire plan (not to include expected expenses) in each of the next fifty years starting with the plan year and based on the participant's status as of the valuation date. For purposes of this projection, assume (1) no additional accruals, (2) experience (e.g., termination, mortality, and retirement) is in line with valuation assumptions, (3) no new entrants, and (4) benefits are paid in the form assumed for valuation purposes.

Use the format shown below and label this attachment *"**Schedule SB, line 26b – Schedule of Projection of Expected Benefit Payments.**"* The attachment may be provided in a spreadsheet file (CSV format).

	Schedule SB, line 26b – Schedule of Projection of Expected Benefit Payments			
Plan Year	**Active Participants**	**Terminated Vested Participants**	**Retired Participants and Beneficiaries Receiving Payments**	**Total**
Current Plan Year				
Current Plan Year + 1				
Etc.				
Current plan year + 49				

- **2022 Schedule SB**. The title for Part IX of the 2022 Schedule SB and line 41 are replaced with the following:

Part IX	Pension Funding Relief under the American Rescue Plan Act of 2021 (See instructions)
41 If an election was made to use the extended amortization rule for a plan year beginning on or before December 31, 2021, check the box to indicate the first plan year for which the rule applies. ☐ 2019 ☐ 2020 ☐ 2021	

- **Instructions to 2022 Schedule SB**. The instructions for Part IX are replaced with the following:

Part IX – Pension Funding Relief under the American Rescue Plan Act of 2021

Line 41. If an election was made under Code section 403(c)(8) or ERISA section 303(c)(8) to apply the extended amortization rule for a plan year beginning on or before December 31, 2021, check the box to indicate the first plan year for which the rule applies (i.e., the box for the 2019, 2020, or 2021 plan year).

3. Changes to 2022 Schedule R Instructions to Improve PBGC Reporting.

- **Instructions to 2022 Schedule R.** Line 13 is modified in the instructions for Part V of the 2022 Schedule R to read as follows:

Line 13. This line should be completed only by multiemployer defined benefit pension plans that are subject to the minimum funding standards (see Code section 412 and Part 3 of Title I of ERISA). Enter the information on lines 13a through 13e for any employer that, for the plan year, (1) contributed more than five (5) percent of the plan's total contributions or (2) was one of the top-ten highest contributors. List employers in descending order according to the dollar amount of their contributions to the plan. Complete as many entries as are necessary to list all employers required to be reported.

APPENDIX B - CHANGES TO FORM 5500 AND FORM 5500-SF INSTRUCTIONS

1. Changes to 2022 Form 5500 Instructions.

- **Instructions to 2022 Form 5500, Section 4, What to File, Quick Reference Chart of Form 5500, Schedules, and Attachments.** Footnote 2 for Small Pension Plan and Small Welfare Plan is modified to add a new clarifying text at the end to read as follows:

[2] Pension plans and welfare plans with fewer than 100 participants at the beginning of the plan year that are not exempt from filing an annual return/report may be eligible to file the Form 5500-SF, a simplified report. In addition to the limitation on the number of participants, a Form 5500-SF may only be filed for a plan that is exempt from the requirement that the plan's books and records be audited by an independent qualified public accountant (but not by reason of enhanced bonding), has 100 percent of its assets invested in certain secure investments with a readily determinable fair market value, holds no employer securities, is not a multiemployer plan, is not required to file a Form M-1 (*Report for Multiple Employer Welfare Arrangements (MEWAs) and Certain Entities Claiming Exception (ECEs)*) for the plan year, and is not a pooled employer plan. See the Form 5500-SF Instructions, *Who May File Form 5500-SF*.

- **Instructions to 2022 Form 5500, Section 5, Part II, line 2a.** The instruction following paragraph 1 that includes the definition for the term "plan sponsor," is modified to add new fourth and fifth bulleted list text that read as follows:

  - The pooled plan provider that operates the plan, in the case of a pooled employer plan that meets the definition under ERISA section 3(43); or
  - The professional employer organization (PEO), in the case of a PEO multiple-employer plan that meets the conditions under 29 CFR 2510.3-55(c).

- **Instructions to Form 5500, Section 5, Part II, line 2a, "Note" Paragraph.** The first sentence of the accompanying Note to line 2a, definition for the term "plan sponsor," is modified to read as follows:

> **Note.** In the case of a multiple-employer plan, file only one annual return/report for the plan. If an association, pooled plan provider, PEO or other entity is not the sponsor, enter the name of a participating employer as sponsor. ***

- **Instructions to 2022 Form 5500, Section 5, Part II, line 3a.** The instruction following paragraph 1 that includes the definition for the term "plan administrator" is modified to add new second and third bulleted list text to read as follows:

  - The pooled plan provider that operates the plan, in the case of a pooled employer plan that meets the definition under ERISA section 3(43);
  - The professional employer organization (PEO), in the case of a PEO multiple-employer plan that meets the conditions under 29 CFR 2510.3-55(c);

- **Instructions to 2022 Form 5500, Section 5, Part II, line 3, New Caution paragraph.** The following CAUTION paragraph in a caution box graphic is added after the Note section.

> CAUTION *In the case of a pooled employer plan, information for the pooled employer plan and the pooled plan provider operating the plan reported on the Form 5500 must match the information reported on the Form PR. Failure to report the same information could result in correspondence from the Department of Labor or the Internal Revenue Service.*

- **Instructions to 2022 Form 5500, Section 5, List of Plan Characteristics Codes for line 8a, Pension Benefits Provided Under the Plan.** The "Defined Contribution Pension Features" codes are modified to add, to the two-character plan characteristics codes from the List of Plan Characteristics Codes that describe the characteristics of the plan being reported, four new multiple-employer defined contribution pension features codes that, when applicable, must be reported on Part II, line 8a of the Form 5500, as follows:

LIST OF PLAN CHARACTERISTICS CODES FOR LINES 8a AND 8b

***

CODE	Defined Contribution Pension Features

***

2U	Multiple-employer pension plan sponsored by a bona fide group or association of employers that is an Association Retirement Plan that meets all the conditions under 29 CFR 2510.3-55(b).
2V	Multiple-employer pension plan that is a Professional Employer Organization Plan (PEO Plan) that meets all the conditions under 29 CFR 2510.3-55(c).
2W	Multiple-employer pension plan that is a pooled employer plan that meets the definition under ERISA section 3(43).
2X	Multiple-employer defined contribution pension plan that does not fall under characteristics code 2U, 2V or 2W.

***

2. Changes to 2022 Form 5500-SF Instructions.

- **Instructions to 2022 Form 5500-SF, Specific Line-by-Line Instructions, Part I – Annual Report Identification Information.** The CAUTION note that appears after the "Multiple-Employer Plan Participating Employer Information" data element box is modified to

*Multiemployer plans and pooled employer plans cannot use the Form 5500-SF to satisfy their annual reporting obligations. They must file the Form 5500. For these purposes, a plan is a pooled employer plan if it is a multiple-employer pension plan that meets the definition under ERISA section 3(43), and ****

add a reference to "pooled employer plans" in the first sentence and revise the third sentence to add a clause referring to such plans, so those sentences read or begin as follows:

- **Instructions to 2022 Form 5500-SF, Specific Line-by-Line Instructions, Part II, line 2a.** The instruction for paragraph 1 is modified to strike existing text in paragraph 1, and in its place add a definition of the term "plan sponsor" to read as follows:

1. Enter the plan sponsor's name. If the plan covers only the employees of one employer, enter the employer's name.

The term ''plan sponsor'' means:

- The employer, for an employee benefit plan that a single employer established or maintains;
- The employee organization, in the case of a plan of an employee organization;
- The association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan, if the plan is established or maintained jointly by one or more employers and one or more employee organizations, or by two or more employers; or
- The professional employer organization (PEO), in the case of a PEO multiple-employer plan that meets the conditions under 29 CFR 2510.3-55(c).

***

- **Instructions to 2022 Form 5500-SF, Specific Line-by-Line Instructions, Part II, Basic Plan Information, line 3a.** Modify the instruction sentence that appears after the

numbered paragraph list and begins with *"Plan administrator for this purpose means*," to insert a new third bulleted list item to read as follows:

- The professional employer organization (PEO), in the case of a PEO multiple-employer plan that meets the conditions under 29 CFR 2510.3-55(c); or

- **Instructions to 2022 Form 5500-SF, Part IV, Specific Line-by-Line Instructions, line 9, Benefits Provided Under the Plan.** The "Defined Contribution Pension Features" codes are modified to add, to the two-character plan characteristics codes from the List of Plan Characteristics Codes that describe the characteristics of the plan being reported, three new multiple-employer defined contribution pension plan feature codes that, when applicable, must be reported on Part IV, line 9a of the Form 5500-SF as follows:

LIST OF PLAN CHARACTERISTICS CODES FOR LINES 9a AND 9b

***

CODE	Defined Contribution Pension Features

***

2U	Multiple-employer pension plan sponsored by a bona fide group or association of employers that is an Association Retirement Plan that meets all the conditions under 29 CFR 2510.3-55(b).
2V	Multiple-employer pension plan that is a Professional Employer Organization Plan (PEO Plan) that meets all the conditions under 29 CFR 2510.3-55(c).
2X	Multiple-employer defined contribution pension plan that does not fall under characteristics codes 2U or 2V and is not a pooled employer plan as defined in ERISA section 3(43).

***

Statutory Authority

Accordingly, pursuant to the authority in sections 101, 103, 104, 109, 110 and 4065 of ERISA and sections 6058 and 6059 of the Code, the Form 5500 Annual Return/Report and the instructions thereto are proposed to be amended as set forth herein.

Signed at Washington, DC, this 9th day of May, 2022.

Ali Khawar,

Acting Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

Eric Slack,

Director, Employee Plans, Tax Exempt and Government Entities Division, Internal Revenue Service.

Gordon Hartogensis,

Director, Pension Benefit Guaranty Corporation.

[FR Doc. 2022–10658 Filed 5–20–22; 8:45 am]

BILLING CODE 4510–29–C

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Docket No. TTB–2018–0008; T.D. TTB–179; Ref: Notice No. 177]

RIN: 1513–AC40

Establishment of the West Sonoma Coast Viticultural Area

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) establishes the approximately 141,846-acre ''West Sonoma Coast'' viticultural area in Sonoma County, California. The viticultural area lies entirely within the established Sonoma Coast and North Coast viticultural areas and contains the established Fort Ross–Seaview viticultural area. TTB designates viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase.

DATES: This final rule is effective June 22, 2022.

FOR FURTHER INFORMATION CONTACT: Karen A. Thornton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; phone 202–453–1039, ext. 175.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background on Viticultural Areas
A. TTB Authority
B. Definition
C. Requirements
II. West Sonoma Coast Petition
A. General Characteristics
B. Notice of Proposed Rulemaking
III. Discussion of Comments Received and TTB Responses
A. Comments on Establishment of Proposed West Sonoma Coast AVA
B. Comments on Inclusion of Fort Ross–Seaview AVA
IV. TTB Determination
V. Boundary Description
VI. Maps
VII. Impact on Current Wine Labels
VIII. Regulatory Analysis and Notices
A. Regulatory Flexibility Act
B. Executive Order 12866
IX. Drafting Information

I. Background on Viticultural Areas

A. TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated the functions and duties in the administration and enforcement of these provisions to the TTB Administrator through Treasury Order 120–01.

Part 4 of the TTB regulations (27 CFR part 4) authorizes TTB to establish definitive viticultural areas and regulate the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) sets forth standards for the preparation and submission to TTB of petitions for the establishment or modification of American viticultural areas (AVAs) and lists the approved AVAs.

B. Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region having distinguishing features as described in part 9 of the regulations and, once approved, a name and a delineated boundary codified in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to the wine's geographic origin. The establishment of AVAs allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of an AVA is neither an approval nor an endorsement by TTB of the wine produced in that area.

C. Requirements

Section 4.25(e)(2) of the TTB regulations (27 CFR 4.25(e)(2)) outlines the procedure for proposing an AVA and allows any interested party to petition TTB to establish a grape-growing region as an AVA. Section 9.12 of the TTB regulations (27 CFR 9.12) prescribes standards for petitions to establish or modify AVAs. Petitions to establish an AVA must include the following:

- Evidence that the area within the proposed AVA boundary is nationally or locally known by the AVA name specified in the petition;
- An explanation of the basis for defining the boundary of the proposed AVA;
- A narrative description of the features of the proposed AVA affecting viticulture, such as climate, geology, soils, physical features, and elevation, that make the proposed AVA distinctive and distinguish it from adjacent areas outside the proposed AVA;
- If the proposed AVA is to be established within, or overlapping, an existing AVA, an explanation that both identifies the attributes of the proposed AVA that are consistent with the existing AVA and explains how the proposed AVA is sufficiently distinct from the existing AVA and therefore appropriate for separate recognition;
- The appropriate United States Geological Survey (USGS) map(s) showing the location of the proposed AVA, with the boundary of the proposed AVA clearly drawn thereon; and
- A detailed narrative description of the proposed AVA boundary based on USGS map markings.

II. West Sonoma Coast Petition

A. General Characteristics

TTB received a petition from Patrick Shabram, on behalf of the West Sonoma Coast Vintners, proposing the establishment of the ''West Sonoma Coast'' AVA. The proposed West Sonoma Coast AVA is located in Sonoma County, California, and is entirely within the established Sonoma Coast AVA (27 CFR 9.116) and North

Coast AVA (27 CFR 9.30) and entirely contains the smaller established Fort Ross–Seaview AVA (27 CFR 9.221). The proposed West Sonoma Coast AVA contains 141,846 acres and has approximately 47 commercial vineyards covering approximately 1,028 acres distributed throughout the proposed AVA.

According to the petition, the distinguishing features of the proposed West Sonoma Coast AVA include its topography, geology, and climate. The topography of the proposed West Sonoma Coast AVA is characterized by the steep, rugged mountains and ridgelines that form the Coastal Ranges. The summits of these coastal mountains can exceed 1,000 feet. The high elevations of the Coastal Ranges provide areas for vineyards that are above the fog layer. The ridgelines also create areas at lower elevations that are sheltered from the heaviest marine fogs, where viticulture may take place successfully within the fog line. By contrast, the region to the east of the proposed AVA, within the Russian River Valley AVA (27 CFR 9.66), is generally lower and the slopes are less steep, particularly in the Santa Rosa Plain. To the south, within the Petaluma Gap AVA (27 CFR 9.261), the topography is characterized by gentle, rolling hills with lower elevations.

Much of the proposed West Sonoma Coast AVA is underlain with sedimentary rocks of the Franciscan Complex. The Franciscan Complex is not easily eroded, which contributes to the high elevations and steep slopes within the proposed AVA. Soils derived from the Franciscan Complex are typically thin and have a high sand content, which promotes good drainage in vineyards. To the east and south of the proposed AVA, the Franciscan Complex is present, but the Wilson Grove Formation is the dominant geological feature. To the east of the proposed AVA, alluvial soils are also more common.

Lastly, the proposed West Sonoma Coast AVA has a climate that is more influenced by marine winds and fog than the more inland regions of Sonoma County. Much of the proposed AVA is located within the Marine zone climate classification, and gradually transitions to the Coastal Cool zone.[1] Within the proposed AVA, daytime temperatures are generally cooler and nighttime temperatures are generally warmer than in the more inland regions. Growing degree day (GDD)[2] accumulations within the proposed AVA are typically lower than within the region to the east. Wind speeds within the proposed AVA are lower than within the region to the south, where lower elevations allow the coastal winds to enter relatively unhindered. According to the petition, higher wind speeds can slow photosynthesis, thereby slowing fruit development and maturation. The petition also states that the climate of the proposed AVA is suitable for growing cooler climate varietals of grapes such as Pinot Noir and Chardonnay.

TTB notes that the petition did not provide information on the features of the region to the north of the proposed AVA, within Mendocino County. However, the petition states that the proposed name ''West Sonoma Coast'' is not used to describe any region outside of Sonoma County. Therefore, even if the region to the north has features similar to those of the proposed AVA, the proposed AVA could not extend into Mendocino County because § 9.12(a)(1) of the TTB regulations requires the proposed name to apply to the entire region included in the proposed AVA.

B. Notice of Proposed Rulemaking

TTB published Notice No. 177 in the **Federal Register** on December 6, 2018 (83 FR 62750), proposing to establish the West Sonoma Coast AVA. In that document, TTB summarized the evidence from the petition regarding the name, boundary, and distinguishing features for the proposed AVA. The proposal also compared the distinguishing features of the proposed AVA to the surrounding areas, including the established Sonoma Coast, North Coast and Fort Ross–Seaview AVAs. For a detailed description of the evidence relating to the name, boundary, and distinguishing features of the proposed AVA, and for a detailed comparison of the distinguishing features of the proposed AVA to the surrounding areas, see Notice No. 177.

In Notice No. 177, TTB solicited comments on the accuracy of the name, boundary, and other required information submitted in support of the petition. In addition, given the proposed West Sonoma Coast AVA's location within the Sonoma Coast and North Coast AVAs, TTB solicited comments on whether the evidence submitted in the petition regarding the distinguishing features of the proposed AVA sufficiently differentiates it from the two larger established AVAs. TTB requested comments on whether the geographic features of the proposed AVA are so distinguishable from the Sonoma Coast and North Coast AVAs that the proposed West Sonoma Coast AVA should no longer be part of the established AVAs. Finally, TTB requested comments on whether the evidence included in the petition regarding the distinguishing features of the proposed AVA sufficiently differentiates it from the smaller established Fort Ross–Seaview AVA, and if the geographic features of the proposed AVA are so distinguishable that the Fort Ross–Seaview AVA should not be a part of the proposed West Sonoma Coast AVA.

The comment period for Notice No. 177 was originally scheduled to close on February 4, 2019. However, TTB received two comments requesting an extension of the comment period and subsequently published Notice No. 177A on February 12, 2019 (84 FR 3353), which reopened the comment period until April 15, 2019.

III. Discussion of Comments Received and TTB Responses

In response to Notice No. 177, TTB received a total of 72 comments. However, one comment was a duplicate of a previously submitted comment, and one comment was replaced by a later comment from the same submitter before the original comment was posted. Therefore, a total of 70 comments were posted for public viewing within *Regulations.gov* docket number TTB–2018–0008 (see *https://www.regulations.gov*). Commenters included local vineyard and winery owners and employees, wine writers and educators, sommeliers, and consumers.

Of the 70 comments that TTB posted to the docket, 67 express either support for or opposition to the proposed West Sonoma Coast AVA, while two comments request an extension of the comment period (comments 27 and 28), and one comment withdraws but does not replace a previously submitted and posted comment (comment 1, withdrawn by comment 42). Of the 67 comments that express a specific opinion on the proposal, 49 support the proposed AVA, 1 comment supports the proposed AVA and requests an

[1] See Vossen, Paul, *Sonoma County Climatic Zones,* University of California Cooperative Extension Service, Sonoma County, 1986. (This publication notes the findings of University of California Extension Farm Advisors Robert Sisson and Paul Vossen regarding the climate zones of Sonoma County, California.).

[2] See Albert J. Winkler, *General Viticulture* (Berkeley: University of California Press, 2nd ed.1974), pages 61–64. In the Winkler climate classification system, annual heat accumulation during the growing season, measured in annual growing degree days (GDDs), defines climatic regions. One GDD accumulates for each degree Fahrenheit that a day's mean temperature is above 50 degrees, the minimum temperature required for grapevine growth.

expansion of the boundary to include the commenter's vineyard (comment 55), 1 comment supports the establishment of the proposed AVA but opposes the choice of name (comment 62), and 14 oppose the establishment of the proposed West Sonoma Coast AVA. Additionally, the petitioner submitted two comments in defense of his analysis of the proposed AVA (comments 54 and 67), including one (comment 54) which withdrew and replaced his previously submitted and posted comment (comment 36).

A. Comments on Establishment of Proposed West Sonoma Coast AVA

1. Proposed AVA Name

i. Opposing Comments

TTB received two comments that oppose the proposed ''West Sonoma Coast'' name. One of these comments (comment 62) opposes the proposed name, although the commenter does support the establishment of an AVA limited to the extreme coastal regions of the established Sonoma Coast AVA. The commenter, who is a self-identified grape grower and winemaker in the established Sonoma Coast AVA, believes that the name ''West Sonoma Coast'' begs the question where is the ''East Sonoma Coast?'' The commenter is also concerned that the proposed name ''will risk creating an inland or east version of the Sonoma Coast, which could be read by some as being less than'' the proposed West Sonoma Coast AVA. The commenter supports the establishment of the AVA if it were proposed with another name; however, he did not suggest an alternative name for the proposed AVA.

The second comment opposing the proposed ''West Sonoma Coast'' name was submitted jointly by Lester Schwartz, owner of Fort Ross Vineyards, and Daniel Schoenfeld, owner of Wild Hog Vineyard (comment 51). Both vineyards are within the proposed AVA and also within the Fort Ross–Seaview AVA. The commenters assert that the name evidence provided by the petitioner does not meet the requirements of § 9.12(a)(1)(i) and (ii) of the TTB regulations. The commenters provide two articles which they believe demonstrate that the proposed AVA is not locally or nationally known as ''West Sonoma Coast.'' The first article quotes the director of sales and marketing of Peay Vineyards, saying that the West Sonoma Coast Vintners' first petition to establish an AVA was rejected by TTB ''because there was no historical reference to a West Sonoma Coast,'' and that the ''proposed moniker seems nonsensical at first blush'' because there is no ''East Sonoma Coast.'' [3] The second article is titled ''California's Edgiest, Riskiest Wine Region Is About to Get a New Name: Five wines to know from West Sonoma Coast, as it'll soon be known.'' [4] The commenters assert that the phrases ''get a new name'' and ''as it'll soon be known'' in the title of the article suggests that the region of the proposed AVA is not currently known by the name ''West Sonoma Coast.''

The commenters provided examples of different names currently used to describe the region of the proposed AVA, including materials from the West Sonoma Coast Vintners' West of the West Wine Festival and Vintners Farm Camp. These materials use the terms ''True Coast,'' ''True Sonoma Coast,'' ''Far Sonoma Coast,'' ''Sonoma Coast Mountains,'' and ''Sonoma Coast Highlands,'' among others when referring to the region of the proposed AVA. Another article included in the comment refers to the region of the proposed AVA as ''Gold Coast'' and ''California's cote d'or.'' [5] The commenters further claim that the name ''West Sonoma Coast'' does not apply to the entire region, as portions of the proposed AVA are known by other names such as ''Annapolis,'' ''Freestone,'' ''Occidental,'' and ''Fort Ross.'' The commenters assert that the use of these other names to describe the region of the proposed AVA shows that the proposed name is not locally or nationally recognized, nor does it apply to the entire proposed AVA.

Comment 51 also questions the petition's use of the West Sonoma County Union High School District as evidence to support the proposed AVA name. The commenters claim that the petition incorrectly portrays the school district as the only school district serving the proposed AVA when in fact there are multiple school districts. The commenters included a map of the school districts serving the proposed AVA and surrounding regions and note that the northern portion of the proposed AVA is not within the school district, and 60 percent of the school district is located outside the proposed AVA.[6]

Finally, the commenters claim that the name evidence provided by the petitioner is not independent of the petitioner, as required by TTB regulations. The commenters assert that the proposed name is a ''recent fiction of the petitioner's own making.'' As evidence, the commenters point to a statement from page 5 of the proposed West Sonoma Coast AVA petition that says that the name ''offers the best descriptive delineator given the limitations of being able to use the most appropriate identifier'' for the proposed AVA.

ii. Supporting Comments

Only one comment expressly supports the use of the proposed name ''West Sonoma Coast.'' The petitioner, Patrick Shabram, submitted a comment (comment 67) which included additional name evidence and was submitted in response to comment 51. The petitioner submitted an article entitled ''Way Out on the West Sonoma Coast,'' which describes places to visit in the towns of Annapolis, Occidental, Freestone, and Sebastopol.[7] Another item submitted was a wine list from the Lazy Bear Restaurant [8] in San Francisco that uses the ''West Sonoma Coast'' moniker to describe several wines from the region of the proposed AVA. For example, the Alma Fria Doña Margarita Vineyard 2014 pinot noir is listed as ''Freestone, West Sonoma Coast, California,'' and the 2014 Alma Fria Holterman Vineyard pinot noir is designated ''Annapolis, 2014, West Sonoma Coast, California.''

iii. TTB Response

After careful review of the comments and the name evidence provided in the petition, TTB has determined that there is sufficient evidence to support the proposed West Sonoma Coast AVA name. The petition provided ample evidence that the term ''West Sonoma'' is used to describe the entire western portion of Sonoma County, where the proposed AVA is located. TTB notes that the use of a directional term such as ''West'' in an AVA name does not require that there be a separate region known by the opposite direction. TTB has approved several such AVAs, including the North Yuba (27 CFR 9.106), North Fork of Long Island (27 CFR 9.113), and West Elks (27 CFR 9.172) AVAs.

TTB believes that the West Sonoma County Union High School District name is an acceptable piece of evidence to demonstrate that the proposed AVA

[3] McIntyre, Dave. ''Why American wine labels aren't as specific as they could be,'' Washington Post (December 31, 2016).

[4] McCoy, Elin. ''California's Edgiest Riskiest Wine Region Is About to Get a New Name: Five wines to know from West Sonoma Coast, as it'll soon be known,'' Bloomberg Wine (August 31, 2018).

[5] Boone, Virginia. ''Wines Way Out West.'' Press Democrat (July 21, 2014).

[6] See Exhibit A–10 to comment 51 in docket TTB–2018–0008 at *https://www.regulations.gov.*

[7] Boone, Virginie. ''Way Out on the West Sonoma Coast,'' Wine Enthusiast Magazine (June 13, 2016).

[8] *http://www.lazybearsf.com/site/wp-content/uploads/2019/01/20190129-Beverage-Menu.pdf,* pages 35, 67, and 70.

is in a region known as ''West Sonoma'' or ''West Sonoma Coast.'' The petition claimed that ''much of the proposed AVA is within'' the school district. The school district map included in comment 51 does not disprove this claim. TTB notes that the school district name was not the only piece of name evidence for the proposed AVA. The petition also included magazine and newspaper articles, an excerpt from a book, and a real estate listing that all referred to the region of the proposed AVA as ''West Sonoma Coast'' or ''West Sonoma.'' [9]

TTB does not agree with the assertion in comment 51 that the Washington Post and Bloomberg Wine articles demonstrate that the proposed name does not currently apply to the region. While the Washington Post article notes the proposed ''West Sonoma Coast'' name ''seems nonsensical'' and that there is a lack of historical evidence for this name, TTB does not believe these statements demonstrate the region is not known as the ''West Sonoma Coast.'' Under TTB regulations, a petitioner does not need to submit historical name evidence in support of a proposed AVA name, but only needs to submit evidence that the proposed AVA name is ''currently and directly associated'' with the area ''in which viticulture exists'' (see § 9.12(a)(1)). TTB finds that the petitioner for this rulemaking meets this requirement, and has determined that both the proposed West Sonoma Coast AVA petition and comment 67, which was submitted by the petitioner, included multiple examples of the name ''West Sonoma Coast'' or ''West Sonoma'' being used currently to describe the region of the proposed AVA.

Also, TTB does not believe the Bloomberg Wine article's statement that the region of the proposed AVA will ''soon be known'' by a ''new name'' is evidence that the region is not known by the West Sonoma Coast name. TTB finds this statement is referring to the fact that a new AVA with the name ''West Sonoma Coast'' may soon be established. TTB finds the article refers to the region of the proposed AVA in the present tense as ''West Sonoma Coast,'' noting, ''The dramatic, 51-mile-long sliver of land next to the ocean is known as the West Sonoma Coast * * *.''

TTB also disagrees with the claim in comment 51 that, because the region of the proposed AVA is known by many different names, it cannot be designated as ''West Sonoma Coast.'' TTB regulations do not preclude the region of a proposed AVA from being known by more than one name. In fact, the towns of Annapolis, Freestone, and Occidental are already within the established Sonoma Coast and North Coast AVAs, and the existence of these communities did not affect the ability of TTB to recognize the names ''Sonoma Coast'' and ''North Coast'' for those AVAs. Additionally, none of the comments provided evidence that any of the other names used to describe the region would be a more appropriate choice. Therefore, TTB has determined that the petition provided sufficient evidence to support the proposed name ''West Sonoma Coast.''

Additionally, TTB believes that the proposed West Sonoma Coast AVA petition provided sufficient evidence to demonstrate that the towns of Annapolis, Freestone, and Occidental are considered part of a larger region known as West Sonoma Coast. For example, Exhibit J to the petition included an article entitled ''West Sonoma Coast Wines are on the Rise'' [10] which mentions Summa Vineyards in Occidental, while another article about the ''west (sic) Sonoma Coast'' mentions that Peay Vineyards ''makes three estate pinots from their vineyard in Annapolis.'' [11] Furthermore, in comment 67, the petitioner provided additional name evidence linking the proposed ''West Sonoma Coast'' name to the towns of Annapolis, Occidental, and Freestone.

Finally, TTB disagrees with the assertion in comment 51 that the petition did not include name evidence that is independent of the petitioner, as required by § 9.12(a)(1)(ii). The name evidence included in the petition shows that the name has been recognized and used by others to describe the region of the proposed AVA. For example, the real estate ad for ''West Sonoma Coast Ranch Land'' that was included in the petition provides evidence that the name ''West Sonoma Coast'' is currently used by people outside the wine industry. TTB acknowledges that many of the articles cited as name evidence in the petition are references to the wine industry. However, they include articles from newspapers and journals not exclusively dedicated to wine, such as the Wall Street Journal and Forbes, suggesting that the name has been accepted and used by people outside the wine industry.

2. General Distinguishing Features

i. Opposing Comments

Nine of the comments opposing the establishment of the proposed West Sonoma Coast AVA raise objection to the proposal based on a lack of distinguishing features. These opposing comments generally claim that the features of the proposed AVA are too diverse to be combined into a larger, generalized AVA, but do not provide evidence to support these claims.

One of the comments (comment 52) asserts that the distinguishing features data in the petition did not meet TTB's regulatory requirements because the petition did not compare the proposed AVA to all of the seven AVAs that overlap or are adjacent to the proposed AVA, including the Northern Sonoma (27 CFR 9.70), Petaluma Gap, Russian River Valley, Green Valley of Russian River Valley (27 CFR 9.57), Fort Ross–Seaview, Sonoma Coast, and North Coast AVAs. The comment states that the comparisons that were included in the petition are not sufficiently supported by facts, but the comment did not provide any evidence to refute the data in the petition.

Comment 51 also asserts that the petition failed to meet the requirements of § 9.12(a)(2) of the TTB regulations because it does not explain with specificity how the commonalities and similarities within the proposed AVA are different from those in the adjacent areas outside the proposed AVA. The comment states that the petition does not provide comparisons to the neighboring Northern Sonoma, Green Valley of the Russian River Valley, and Petaluma Gap AVAs, and that the petition's comparison to the North Coast AVA is insufficient. The comment also claims that the proposed West Sonoma AVA consists of four regions with ''too diverse a range of geographic and climatic features to be considered a unitary AVA.'' These four regions are identified as the Fort Ross–Seaview AVA and the Annapolis, Freestone, and Occidental regions. The comment asserts that an attempt to establish a Freestone–Occidental AVA in 2008, as well as TTB's rejection of a request to include the Annapolis region in the Fort Ross–Seaview AVA in 2011, illustrate that the two regions are too different to be included in a single AVA.

ii. Supporting Comments

Five of the supporting comments express general agreement that the features of the proposed West Sonoma

[9] The name evidence is included in Exhibit J to the petition in Docket TTB–2018–0008 at *www.regulations.gov.*

[10] McInerney, Jay. ''West Sonoma Coast Wines are on the Rise,'' The Wall Street Journal (July 18, 2013).

[11] Brown, Elaine Chukan. ''Sonoma's Far Coast: A haven for pinot noir,'' Wines and Spirits (August 31, 2015).

Coast AVA are distinctive from those of the surrounding regions. These five comments did not focus on a particular feature, nor did they provide any additional evidence.

iii. TTB Response

After careful review of the comments and the petition, TTB has determined that the information in the petition sufficiently demonstrates that the features of the proposed West Sonoma Coast AVA generally distinguish it from the surrounding regions, including neighboring and overlapping established AVAs. The TTB regulations at § 9.12(a)(2) require an AVA petition to explain how a proposed AVA's distinguishing features are ''different in the adjacent areas outside that boundary.'' The AVAs adjacent to the eastern boundaries of the proposed West Sonoma Coast AVA are the Russian River Valley AVA and the Sonoma Coast AVA, which entirely overlaps both the proposed AVA as well as the Green Valley of Russian River AVA and most of the Russian River Valley AVA. The Petaluma Gap AVA is adjacent to the southern boundary of the proposed West Sonoma Coast AVA and is also partially located within the Sonoma Coast AVA. The Green Valley of Russian River Valley AVA is entirely within the Russian River Valley AVA, and the Northern Sonoma AVA completely encompasses both the Green Valley of Russian River Valley AVA and the Russian River Valley AVA.

TTB disagrees with the assertion in comments 51 and 52 that the petition does not include comparisons of the proposed West Sonoma Coast AVA's distinguishing features to those of the surrounding AVAs. In its discussion of topography, the petition compares the proposed AVA to the established Russian River Valley, Green Valley of Russian River Valley, and Petaluma Gap AVAs. The climate section of the petition includes GDD, average monthly maximum temperature, and monthly low temperature data from the town of Windsor, which is within the Sonoma Coast, Russian River Valley, and Northern Sonoma AVAs. The average monthly maximum and minimum temperature graphs also include data from the city of Santa Rosa, which is partially within the Sonoma Coast, Northern Sonoma, and Russian River Valley AVAs. Wind speed data is provided from Windsor, Santa Rosa, and the town of Valley Ford, which is within both the Petaluma Gap AVA and the Sonoma Coast AVA. Finally, the geology section of the petition contains a discussion of the geology of the Russian River Valley and Petaluma Gap AVAs. Therefore, TTB has determined that the proposed West Sonoma Coast AVA petition meets the regulatory requirements to provide comparison data from the ''adjacent areas outside the boundary.'' TTB notes that its regulations do not require that each of the features of the proposed AVA must be distinguishable from all of the surrounding regions. In other words, the feature that distinguishes a proposed AVA from the regions to the east and west does not have to be the same feature that distinguishes the proposed AVA from the north and south.

TTB also finds that the petition provided a sufficient comparison of the proposed West Sonoma Coast AVA to the larger North Coast AVA that encompasses it. As noted in T.D. ATF–145, which established the North Coast AVA, the primary distinguishing features of the North Coast AVA are a climate that is ''influenced by intrusions of cooler, damper coastal marine air and fog, by temperatures that are cooler than the Central Valley, and by greater rainfall than surrounding areas.'' [12] The proposed West Sonoma Coast AVA petition notes that, like the North Coast AVA, the proposed AVA is influenced by maritime air. Although the petition does not provide any additional specific comparisons to the North Coast AVA, the petition does describe how the proposed AVA differs from the Sonoma Coast, Russian River Valley, and Petaluma Gap AVAs, all of which are also located in the North Coast AVA. Therefore, TTB finds that the petition sufficiently demonstrated that the proposed AVA shares a marine-influenced climate with the North Coast AVA, but is also a distinct microclimate within the larger AVA. Also, due to its smaller size, the proposed AVA experiences a much smaller range of climatic variations within its proposed boundaries than the diverse, multicounty North Coast AVA.

TTB does not believe that the information included in comment 51 demonstrates that the characteristics of the proposed West Sonoma Coast AVA are too diverse to be considered ''a unitary AVA.'' The comment includes an elevation map (Exhibit A–2) and an elevation statistics table (Exhibit A–3), both of which do show a variety of elevations within the proposed AVA. However, neither the map nor the table provide sufficient evidence to refute the petition's claims that the proposed AVA's elevations are generally higher than elevations in the surrounding regions, particularly in the Petaluma Gap AVA and the Santa Rosa Plain region of the Russian River Valley AVA. For example, Exhibit A–3 notes elevations of acreage outside the proposed AVA that exist at less than 400 feet. However, this exhibit also shows that within the four regions comprising the proposed AVA, no region has an average vineyard elevation of below 500 feet. Additionally, the petition shows the proposed AVA contains the mountainous terrain of the Coastal Ranges, which contain summits which exceed 1000 feet, a contrast to the Santa Rosa Plain to the east of the proposed AVA, which contains slopes of less than 5 percent.

Comment 51 includes a letter from meteorologist Roland Clark that also claims, ''While the petition seeks to simply distinguish the western half [of the established Sonoma Coast AVA] from the eastern half, it does not address the differences that have been proven to exist between Annapolis, Fort Ross–Seaview AVA, Occidental and Freestone,'' which are all communities within the proposed West Sonoma Coast AVA.[13] TTB regulations allow for an AVA to contain regions with differences in distinguishing features. However, § 9.12(a)(3) of the TTB regulations requires that the regions within an AVA must still share ''common or similar features.'' TTB believes the various regions of the proposed AVA share climatic features, topography, and geology that are more similar to each other than to the regions outside the proposed AVA. TTB also notes that the entire proposed AVA is already located within the established Sonoma Coast and North Coast AVAs, further indicating that the various regions within the proposed AVA share at least some similar features.

TTB does not agree with the assertion in comment 51 that the exclusion of the Annapolis region from the Fort Ross–Seaview AVA indicates that the two regions are too dissimilar to now be included in a single AVA. Although the Annapolis region does not share enough of the characteristics of the Fort Ross–Seaview AVA, particularly the name evidence, to be included with that AVA, the two regions share enough similarities to be included in a larger, overlapping AVA, such as the proposed West Sonoma Coast AVA. As noted previously, both the Annapolis region and the Fort Ross–Seaview AVA are already located within the Sonoma Coast and North Coast AVAs, indicating that TTB found them to share at least some broad characteristics of the two larger AVAs.

[12] See 48 FR 42973, 42976, September 21, 1983.

[13] See Exhibit B–1 of comment 51 in docket TTB–2018–0008 at *https://www.regulations.gov.*

Last, in contrast to the assertion in comment 51, TTB does not believe that submission of a petition to establish a Freestone–Occidental AVA in 2008 indicates that the Freestone–Occidental region is too distinct from the Fort Ross–Seaview AVA and the Annapolis region to be included with those regions in a larger AVA such as the proposed West Sonoma Coast AVA. The submission of a petition to establish an AVA within another AVA does not mean that the smaller region cannot have features that are distinct enough to warrant recognition as an AVA and still share some of the broader characteristics of the encompassing AVA. For example, the Fort Ross–Seaview AVA is currently within the larger, established North Coast and Sonoma Coast AVAs, along with the Freestone–Occidental and Annapolis regions. Even though the Fort Ross–Seaview AVA is distinguishable from the Freestone–Occidental and Annapolis regions, they all still share marine-influenced climates characteristic of the two larger coastal AVAs. Therefore, TTB believes that the submission of a petition to recognize the Freestone–Occidental region as an AVA does not, by itself, serve as evidence that the region is too distinct to be included in a larger AVA with the Annapolis region and Fort Ross–Seaview AVA.

3. Climate

i. Opposing Comments

Six comments, comments 41, 43, 47, 49, 50, and 51, oppose including the Fort Ross–Seaview AVA within the proposed West Sonoma Coast AVA. These commenters allege the climate of the Fort Ross–Seaview AVA is distinct from other regions to be included in the proposed West Sonoma Coast AVA. However, comment 51 was the only opposing comment that addressed the petition's climate evidence and provided data to support its claims. The comment states that the petition is incorrect in asserting that the proposed AVA is largely within the Marine climate zone, as developed by Robert Sisson and Paul Vossen.[14] The comment states that the vineyards in the Annapolis region of the proposed AVA are within the Coastal Cool zone, not the Marine zone, and that although some vineyards within the Occidental and Freestone regions are within the Marine zone, others are in the Costal Cool zone. The comment claims that the Sisson model of climate zones is ''unsupportive of [the petitioner's] thesis for distinguishing the proposed AVA,'' because the model claims that the Marine zone is too cold for grape growing.

Comment 51 also disagrees with the petition's description of fog intrusion within the proposed West Sonoma Coast AVA and the surrounding regions, particularly the petition's claim that ridgelines form pockets protected from the heaviest marine fog in the Freestone, Annapolis, and Occidental regions of the proposed AVA. The comment states that the Annapolis region has low-elevation gaps that allow for the penetration of fog, and that there are no high coastal ridges to form protected areas around Freestone. As evidence, the comment includes a statement from the winemaker of Peay Vineyards.[15] In the statement, the winemaker says that her Annapolis-area vineyard is below the inversion layer, and cool ocean fog persists throughout the day. Comment 51 also includes a Sonoma County fog map created from satellite imagery from August 24, 2018, that shows fog intruding into much of the county, including the region east of the proposed West Sonoma Coast AVA.[16] The fog, however, appears to intrude only partially into the portion of the proposed AVA that contains the Fort Ross–Seaview AVA.

Comment 51 also disputes the petition's claims that the proposed AVA generally has warmer nocturnal temperatures than the regions to the east. The comment includes a printout from a graph published by the West Sonoma Coast Vintners that shows the average diurnal temperature shift in the proposed AVA, the Green Valley of Russian River AVA, and the Russian River Valley AVA from veraison through harvest.[17] According to the comment, the graph shows that the Occidental region of the proposed AVA has substantially lower nocturnal temperatures than the Russian River Valley AVA.

Additionally, comment 51 included a letter dated February 20, 2019, from Ronald Clark, a retired naval meteorologist and president of Weather Mission, Inc.[18] The letter responds to additional maximum and minimum temperature data and temperature variation calculations submitted by the petitioner in comment 54. In the letter, Mr. Clark states his belief that diurnal temperature difference is not what ''makes the difference in plant growth.'' Instead, Mr. Clark suggests that GDDs, which take into consideration the total number of hours a day with temperatures above 50 degrees F, are more important in predicting plant growth, Mr. Clark concludes by stating that neither the climate data in comment 54 nor the climate data provided in the original petition provide sufficient evidence to establish the proposed West Sonoma Coast AVA.

Comment 51 disagrees with the petition's claim that wind speeds within the proposed West Sonoma Coast AVA are lower than within the regions to the south and east. As evidence, the comment provided a map of average annual wind speeds in the western portion of Sonoma County.[19] The map indicates that winds of up to 15.7 miles per hour occur within the proposed AVA and the region to the south, while wind speeds generally do not exceed 14.4 miles per hour in the region to the east.

Comment 51 further claims that the climate data in the petition is incomplete because it does not provide information on rainfall amounts, which the comment claims is required by § 9.12(a)(3)(1) of the TTB regulations. The comment includes a map showing the annual average precipitation amounts for the proposed AVA and surrounding regions from 1981 to 2010.[20] The comment asserts that the average annual precipitation amounts in the four regions of the proposed West Sonoma Coast AVA are too diverse to be included in a single AVA, and that the differences between the Fort Ross–Seaview AVA and the Annapolis, Occidental, and Freestone regions are particularly significant.

Last, comment 51 questions the methodology used by the petitioner to calculate the GDDs of the proposed West Sonoma Coast AVA and the surrounding regions. The comment included a second letter from Roland Clark, dated January 11, 2019.[21] The letter argues that even though the proposed West Sonoma Coast AVA petition ''seeks to distinguish the western half [of the established Sonoma Coast AVA] from the eastern, it still does not address differences which have been proven to exist between

[14] See Vossen, Paul, *Sonoma County Climatic Zones,* University of California Cooperative Extension Service, Sonoma County, 1986.

[15] The statement was taken from a comment submitted to TTB in 2010 in response to Notice No. 34, which proposed the Fort Ross–Seaview AVA. The comment was submitted by Patrick Shabram, the current petitioner. See 70 FR 11174, March 8, 2005.

[16] See Exhibit A–6 of comment 51 in docket TTB–2018–0008 at *https://www.regulations.gov.*

[17] See Exhibit D–8 of comment 51 in docket TTB–2018–0008 at *https://www.regulations.gov.*

[18] See Exhibit B–2 of comment 51 in docket TTB–2018–0008 at *https://www.regulations.gov.*

[19] See Exhibit A–4 of comment 51 in docket TTB–2018–0008 at *https://www.regulations.gov.*

[20] See Exhibit A–5 of comment 51 in docket TTB–2018–0008 at *https://www.regulations.gov.*

[21] See Exhibit B–1 of comment 51 in docket TTB–2018–0008 at *https://www.regulations.gov.*

Annapolis, Fort Ross–Seaview, Occidental and Freestone,'' which are all regions within the proposed AVA. Mr. Clark claims that the most basic method of calculating GDDs is ''to average the daily low and the daily high temperature, then subtract the determined base temperature and assign 0 for anything less than 0. So for each day, if the average temperature does not exceed the base temperature, no GDD accumulation is added * * *.'' According to the letter, a base temperature of 50 degrees Fahrenheit (F) is typically used when calculating GDDs for grapes, and a cap temperature may be applied, typically 85 degrees F.[22] Graph 1 on page 12 of the petition uses 70 degrees F as a base temperature and 90 degrees F as the cap. Mr. Clark claims he ran a ''simple average GDD model'' with 2017 and 2018 data from five locations in the proposed AVA and two locations within the Russian River Valley AVA. He then ran the same model on the same data using a base temperature of 50 degrees F and a cap of 85 degrees F. Both computations resulted in higher GDD accumulations for the Fort Ross–Seaview AVA than for any other the other locations. The results, he claims, cast doubt on the data in Graph 1 of the petition.

Mr. Clark's letter also questioned Table 3 on page 16 of the petition, noting that the methodology for calculating the information in Table 3 is not described and the data is incomplete. In particular, only one year of data is available from the Red Car Vineyard and KJ Seascape weather stations within the proposed AVA. The letter states that Tables 4 and 5 on pages 16 and 17 of the petition use a single location to represent the entirety of the proposed West Sonoma Coast AVA. Because the methodology of calculating the GDDs is not known and the data is incomplete, the letter concludes that the petition's conclusion of cooler temperatures existing within the proposed AVA than in the surrounding regions cannot be deemed accurate.

ii. Supporting Comments

Thirty-four comments specifically expressed support for the climate evidence in the petition. These commenters generally state that the proposed West Sonoma Coast AVA's climate is more affected by the marine breezes and fog than the regions farther inland, resulting in cooler daytime temperatures, warmer nighttime temperatures, and later harvest dates. Only 2 of these 32 comments provided objective data, rather than anecdotal evidence, to support their claims. Both of these comments were submitted by the petitioner (comments 54 and 67).

In his first comment (comment 54), the petitioner submitted data relating to the 2018 average maximum and minimum temperatures and average temperature variation for six locations within the proposed AVA, including the Annapolis, Freestone, and Occidental regions and the Fort Ross-Seaview AVA, and four locations in the neighboring Russian River Valley AVA. The data shows that in 2018, the locations within the proposed West Sonoma Coast AVA had lower average maximum temperatures and higher minimum temperatures than the locations in the Russian River Valley AVA. The average diurnal temperature variations for the proposed AVA locations were also smaller than the variations for the Russian River Valley AVA. This data supports the petitioner's original climate claims relating to maximum daytime and minimum nighttime temperatures within the proposed AVA and the surrounding regions.

In comment 67, the petitioner clarifies his characterization of the climatic zones created by Robert Sisson and Paul Vossen, which was questioned in comment 51. The petitioner states that the climatic zones are a ''brilliant'' creation, but that since their creation, ''the kind of weather data available, trial and error with different sites, population densities, and even the climate have all changed.'' He states that it is correct to claim that ''sections of the West Sonoma Coast AVA with active viticulture are within the Marine climate type,'' which was originally created to define regions too cold for successful viticulture. He agrees with comment 51 that portions of the proposed AVA are within the Coastal Cool zone, including much of the Fort Ross-Seaview AVA and portions of the Occidental and Freestone regions. He states that the proposed West Sonoma Coast AVA is based on ''the coolest parts of the [established] Sonoma Coast AVA, and that would include the cooler sections of the Coastal Cool climate type and the transitional Marine zone.'' He concludes by suggesting that it would be more accurate to say that vineyards in the Fort Ross-Seaview AVA and Annapolis region of the proposed AVA straddle the ''edge'' between the Coastal Cool and Marine zones, while vineyards ''near'' Occidental and Freestone are within the Marine zone.

In comment 67, the petitioner also addresses the issue of fog intrusion that was raised in comment 51. He states that the comment inaccurately interpreted the summary in Notice No. 34 of the statement from the winemaker at Peay Vineyards to mean that the Peay Vineyards near Annapolis are below the inversion layer, not above it. The petitioner states that within the proposed AVA, the regions below the fog are generally below 400 feet. Vineyards in the Annapolis region, including the Peay Vineyards, are planted at elevations between 550 and 800 feet, putting them within the fog and not below it. He states that this distinction is important because ''solar radiation has less fog to penetrate to reach vines'' within the fog layer, as opposed to vines planted below the fog. Sitting below the fog in the Annapolis region, the petitioner concludes, ''would likely mean grapes that do not consistently mature.''

The petitioner also responds to comment 51's criticism of the GDD data and methodology used in the petition. He states that the data from Red Car Estate Vineyard used in Graph 1 of the petition is not from a single year, as claimed in comment 51, but is from the years stated in the heading of the graph. He clarifies that Graph 1 of the petition was provided by the West Sonoma Coast Vintners, as noted in the petition, and that he did not describe the methodology used to calculate the GDDs in that graph because he ''could not definitively verify the methodology'' the association used. The petitioner says that he did receive some partial data sets to test the GDD calculations, but he was unable to do a complete test because the totals for Annapolis, Occidental, and Freestone were in aggregate. He also states that according to the background data, he deduced that GDD was calculated using April 1 to October 31 heat accumulations for temperatures above 50 degrees F, with no cap temperature. The petitioner states that this method is commonly used in the wine industry and is the basis for A.J. Winkler's and M.A. Amerine's wine regions, often referred to as the Winkler Index or Winkler Scale,[23] and is the method he used for the other GDD calculations in the petition.

Last, the petitioner addresses the completeness of his GDD data in the other tables and graphs in the petition, as questioned in comment 51. The petitioner acknowledges that he lacked complete data from every station and every year listed in Tables 2 and 3 of the petition, but that he clearly stated as

[22] On days when the actual maximum temperature exceeds the cap temperature, the cap temperature is used in place of the maximum temperature when calculating GDDs.

[23] Winkler, A.J., et al. *General Viticulture,* University of California Press, 1962, 1974.

such in his petition. He also noted that weather station data is becoming increasingly more available, ''but because data are available today doesn't mean that they were available at the time of the West Sonoma Coast study.'' He also says that he checked the Fort Ross-Seaview AVA, Graton, and Sebastopol weather stations used for the 2017 and 2018 GDD calculations in Exhibit B–1 of comment 51. The petitioner found that the data for those stations for the period during which the petition was written was unavailable or incomplete and, therefore, would have been of little use to him at the time he was developing the proposed West Sonoma Coast AVA petition.

The petitioner also states that he was not aware of the degree day modeling tool from Oregon State University mentioned in comment 51 and instead relied on growers to provide him with data or on data he gathered from the Western Region Climate Center, the California Data Exchange Center, and the California Irrigation Management Information System. He notes that, after learning of the degree day modeling tool, he attempted to test it by locating several stations just outside the proposed AVA. He particularly looked for data from 2010 to 2014, to be consistent with the years he had used in the petition. The petitioner claims that data from those years was also incomplete for the stations he found using the modeling tool. He also discovered that the modeling tool uses temperature observations and digital elevation models to interpolate high and low temperatures and precipitation. He asserts that when this method is used for single-year data sets, the results ''are in 4KM x 4KM pixels, which isn't very helpful when trying to assess climatic variations at the scale that assessment of viticulture is usually done at.'' Instead, the method is best used with thirty-year normals, and the petitioner states he seldom has 30 years of historical data to make meaningful use of the model. Therefore, he does not believe that using the Oregon State University modeling tool would have provided more accurate GDD data at the time he was developing the petition than the data he obtained from weather stations.

iii. TTB Response

After reviewing the petition and the comments, TTB has determined that the climate of the proposed West Sonoma Coast AVA distinguishes it from the surrounding regions. TTB agrees with the petition's statement that much of the proposed AVA is in the climate zone originally identified as ''Marine'' by Sisson and Vossen, which was characterized as being too cool for grape growing. TTB points to the climate zone map included in the petition as evidence that much of the proposed AVA is in the Marine zone.[24] TTB also notes that comment 51 acknowledges that some vineyards in the Freestone and Occidental regions are within the Marine zone. TTB lacks data that determines definitively the reason viticulture is now occurring in a zone originally defined as too cool for grape growing. However, TTB has determined that the petition's description of a large portion of the proposed West Sonoma Coast AVA being in the Marine zone is not inaccurate.

TTB finds that, although part of the proposed West Sonoma Coast AVA is within the Coastal Cool zone, the climate zone map in the petition shows the portion within the Coastal Cool zone is smaller than the portion of the regions east of the proposed AVA that are within the Coastal Cool zone. TTB also notes that the petition did not state that the proposed AVA contains only regions within the Marine zone; the petition describes the climate as '' 'Marine' to 'Coastal Cool' '' and notes that the proposed AVA ''contains the western edge of the Coastal Cool climate type.'' Therefore, TTB believes that the proposed AVA's climate can be distinguished from that of the region farther east, which lacks the Marine zone and is instead in the Coastal Cool, Coastal Cool transitioning to Coastal Warm, and Coastal Warm zones.

Based on the climate zone map in the petition, TTB does not agree with the assertion in comment 51 that a ''significant portion of the Russian River Valley AVA in the eastern portion of the Sonoma Coast AVA'' is within the Marine zone. Using the climate zone map, TTB believes that only the extreme southern portion of the Russian River Valley AVA, roughly the triangular region from Cunningham south to Roblar and east to U.S. Highway 101, would be in the Marine zone. TTB agrees that the fog map included as Exhibit A–6 to comment 51 shows marine fog extending east of the proposed West Sonoma Coast AVA into the Russian River Valley AVA, but the map only shows the fog as it occurred on a single day. Therefore, TTB cannot determine from the map alone that the petition was incorrect in stating that the region east of the proposed AVA is not typically subjected to the heaviest marine fog and air.

TTB does agree with comment 51 that the Petaluma Gap AVA, to the south of the proposed AVA, is also within the same Marine zone as much of the proposed West Sonoma Coast AVA. However, the petition did not use climate zones to distinguish the proposed AVA from the region to the south, and instead used topography, geology, and wind speed. Therefore, in spite of the climate zone similarity, TTB has determined that the petition provided suitable evidence for not including the Petaluma Gap AVA in the proposed AVA.

TTB also agrees with comment 51 that several tables in the proposed West Sonoma Coast AVA petition include incomplete or insufficient GDD data. For that reason, TTB did not consider the data in Tables 3 and 4 of the petition when determining if GDDs were a distinguishing feature of the proposed AVA. Additionally, the petition notes that the Laguna de Santa Rosa GDD data in Table 5 came from a station located in a bowl-like region that trapped cooler air and was thus not representative of the climate of the majority of the Russian River Valley AVA. For this reason, TTB did not consider the Laguna de Santa Rosa GDD data in that table. However, TTB did determine that Table 2 of the petition contains sufficient data to indicate lower GDD accumulations in the proposed AVA than are generally found in the region to the east. Table 2 includes four consecutive years of GDD data from a station in Occidental, located within the proposed AVA, and one from Windsor, within the Santa Rosa Plain[25] that covers much of the adjacent Russian River Valley AVA to the east of the proposed AVA. Each year, GDD accumulations within the proposed AVA were lower than those from the Windsor station.

TTB does not agree that the GDD calculations in Exhibit B–1 of comment 51 refute the petition's claims of lower GDD accumulations in the proposed West Sonoma Coast AVA. First, the comment's calculations used data from 2017 and 2018, which was not available at the time the petition was submitted. Second, the comment acknowledges that the summers of 2017 and 2018 were the two hottest summers on record in California, including the coastal regions, so it is possible that the resulting GDD accumulations are skewed and not indicative of typical weather patterns in Sonoma County. Additionally, the calculations in comment 51 used a growing season period of March 1 to October 31, compared to the petition's growing season of April 1 to October 1.

[24] See Exhibit H of the petition in docket TTB–2018–2008 at *https://www.regulations.gov.*

[25] *https://www.usgs.gov/centers/california-water-science-center/science/santa-rosa-plain.*

Finally, both of comment 51's GDD calculation methods used a cap temperature, whereas the petition's GDD method did not include a cap temperature. For these reasons, TTB does not find that the GDD calculations in comment 51 can be compared directly to the GDD calculations in the petition, nor do they disprove the petition's claims that GDD accumulations east of the proposed AVA are generally higher than within the proposed AVA.

TTB also disagrees that the graph created by the West Sonoma Coast Vintners and included in comment 51 as Exhibit D–8 disproves the petition's claim that nocturnal temperatures in the proposed West Sonoma Coast AVA are generally warmer than nocturnal temperatures in the regions to the east. The graph does show that nighttime temperatures in the Russian River Valley and Green Valley of Russian River AVA are warmer than two of the three proposed AVA locations at hours 20 through 24. However, the graph also shows that temperatures in the Russian River Valley and Green Valley of Russian River Valley AVAs continue to fall into the early morning hours, so that between hours 0 and 8, only one proposed AVA location has lower temperatures. Additionally, the graph does not include a period of record for the data, nor does it say where the weather stations were located within the Russian River Valley and Green Valley of Russian River Valley AVAs. As a result, TTB cannot determine the period of time the data represents, or if the data for each AVA comes from a single station or is an average of multiple stations' data. Therefore, TTB does not believe that the graph in comment 51 provides sufficient evidence to disprove the nocturnal temperature data in the petition.

TTB disagrees with the assertion in Exhibit B–2 of comment 51 that the proposed AVA should not be established because the climate data in comment 54 is insufficient. TTB agrees that the single year of average maximum and minimum temperatures included in comment 54 is insufficient by itself to demonstrate climate differences. However, the petition did include similar data collected from multiple consecutive years. As described in Notice No. 177, the temperature data suggested that the proposed AVA generally has lower maximum temperatures and higher minimum temperatures than the region to the east. The information included in Exhibit B–2 of comment 51 does not disprove the data included in the petition, nor does it disprove the average maximum temperature and average minimum temperature date included in comment 54.

TTB does agree that the single year of diurnal temperature variation data included in comment 54 is insufficient to demonstrate a difference between the proposed AVA and the surrounding regions. However, TTB notes that diurnal temperature variation data was not included in the original petition, nor was it considered to be a distinguishing feature of the proposed AVA in Notice No. 177. Instead, GDDs and average monthly maximum temperatures and average monthly low temperatures were discussed as distinguishing climatic features. TTB believes that the climate data in the petition, along with the topographic and geologic information, is sufficient to demonstrate that conditions within the proposed West Sonoma Coast differ from those of the surrounding regions.

With respect to the question of the petition's wind speed data, TTB finds the wind speed map in comment 51 (Exhibit A–4) does not refute the petition's claim of higher wind speeds to the south of the proposed West Sonoma Coast AVA, within the Petaluma Gap AVA. TTB agrees with comment 51 that the wind speed map does appear to show that wind speeds immediately to the east of the proposed AVA, within the western portions of the Russian River Valley and Green Valley of Russian River AVAs, are lower, whereas the data in the petition that indicates higher wind speeds is from a location farther east within the Russian River Valley AVA, in the town of Windsor. The comment's map indicates that wind speeds in the western parts of the Russian River Valley and Green Valley of Russian River Valley AVAs are generally less than 12 miles per hour. While wind speeds within those two AVAs may generally be lower than those generally found within the proposed AVA, the map also suggests that there are, in fact, regions east of the proposed AVA that do have higher wind speeds. In particular, the map shows wind speeds east of the Annapolis region of the proposed AVA reaching 15.7 miles per hour, compared to calmer speeds of between 0 and 14.3 miles per hour near Annapolis. However, the regions of higher wind east of Annapolis have similar speeds to the regions near the southern end of the Fort Ross-Seaview AVA and between the towns of Jenner and Carmel, which calls into question the petition's claim that winds east of the proposed West Sonoma Coast AVA are higher than within the proposed AVA. As a result, TTB has determined that wind speeds cannot definitively distinguish the proposed AVA from the region to the east. However, TTB continues to believe that wind speed does distinguish the proposed AVA from the region to the south, within the Petaluma Gap AVA.

Last, TTB disagrees with comment 51 that the petition is incomplete because it did not include precipitation data from within the proposed AVA and the surrounding regions. The TTB regulations in § 9.12(a)(3)(i) list precipitation as a climate feature that may be used to distinguish a proposed AVA. However, the TTB regulations do not require a petition to include all the types of climate information listed in § 9.12(a)(3)(i). Therefore, the proposed West Sonoma Coast AVA can meet the regulatory requirements without discussing precipitation—or without mentioning climate at all—as long as at least one of the features listed in § 9.12(a)(3) is used to distinguish it from the surrounding regions.

4. Topography and Elevation

i. Opposing Comments

Two comments specifically oppose the petition's characterization of the topography and elevation of the proposed West Sonoma Coast AVA and the surrounding regions. However, only comment 51 provides evidence to support its claims. Comment 51 first asserts that the four main regions of the proposed West Sonoma Coast AVA (the Fort Ross-Seaview AVA and the Annapolis, Freestone, and Occidental regions) are too diverse in topography and elevation to be included in a single, cohesive AVA. The comment claims the petition's characterization of the proposed AVA as a region of steep, rugged mountains and ridgelines is inaccurate. According to the comment, the region near Annapolis is rugged and steep, but the Freestone region is not mountainous and instead consists of low rolling hills and valleys. The comment asserts the Occidental region is a mixture of mountains, ridgelines, and rolling hills with low valleys. Comment 51 also states that, contrary to the petition's claims of lower elevations outside the proposed AVA, the adjacent areas have peaks exceeding 1,000 feet.

The comment also includes a map of vineyard locations and elevations within the proposed AVA and states that vineyards in the four regions of the proposed AVA are planted at varying elevations, which results in different growing conditions within the proposed AVA.[26] For example, the comment claims that all the vineyards except one

[26] See Exhibit A–2 of comment 51 in docket TTB–2018–0008 at *https://www.regulations.gov.*

within the Fort Ross-Seaview AVA are planted above 900 feet, which is above the fog line, while all vineyards in the Annapolis and Freestone regions are planted below 900 feet, which is within and below the fog line. Vineyards within the Occidental region, according to the comment, are planted both above and below the fog line.

ii. Supporting Comments

Twenty-one of the supporting comments address the topography and elevation of the proposed West Sonoma Coast AVA. All these comments note the area within the proposed AVA has high elevations and mountainous terrain, and some comments assert these two attributes contribute to unique growing conditions for viticulture within the proposed AVA. Comment 67, submitted by the petitioner, was the only supporting comment that provided substantive, non-anecdotal evidence.

In comment 67, the petitioner responds to claims in comment 51 about the accuracy of the topographic and elevation evidence in the petition. The petitioner first addresses the topography of the Freestone region of the proposed AVA, which he described in the petition as steep. He acknowledges that the terrain ''transitions to rolling hills south of Freestone, but the territory west of Freestone remains steep.'' As evidence, he included a slope map of the entire proposed AVA and the surrounding regions,[27] as well as a topographic profile of the region stretching westward from the most major road intersection in Freestone to the coast.[28]

With respect to the elevations within the proposed AVA, the petitioner disputes the claim in comment 51 that the Freestone region has elevations as low as 52 feet and lacks high coastal ridges. He notes that both Attachments A and B of his comment 67 demonstrate the presence of higher ridges in the regions west of Freestone. He states that elevations west of Freestone do not drop as low as 50 feet along Salmon Creek until the creek is less than 2½ miles from the Pacific Ocean. The petitioner believes the low region described in comment 51 likely refers to the land along Estero Americano, which is south of the proposed West Sonoma Coast AVA, within the Petaluma Gap AVA.

Last, comment 67 acknowledges that there are elevations over 1,000 feet within the Russian River AVA, as stated in comment 51. However, the petitioner states that the description of the elevations of the Russian River Valley AVA that he included in the proposed AVA petition referred to ''the terrain east of the proposed West Sonoma Coast AVA at its adjacent location south of the Russian River (*i.e.,* moving east from the common border onto the Santa Rosa Plain).'' He then asserts that the higher peaks within the Russian River Valley AVA ''are removed from the coastal ridges of the West Sonoma Coast'' and therefore are not relevant to the distinguishing characteristics of the entire proposed West Sonoma Coast AVA.

iii. TTB Response

After reviewing the information in the petition and the comments, TTB has determined that topography and elevation are distinguishing features of the proposed AVA. TTB agrees with comment 51 that there is a range of elevations and slope angles within the proposed West Sonoma Coast AVA. However, TTB does not agree with comment 51 that the topography is too diverse to be included in a unified AVA. As noted earlier, the proposed West Sonoma Coast AVA is located within two larger established AVAs: The Sonoma Coast AVA and the North Coast AVA. TTB recognizes that any AVA may have a degree of variation in its topography, but the AVA must still be distinguishable from the surrounding regions. The elevation map included in comment 51 shows that, while elevations below 400 feet do occur in the proposed AVA, most of the proposed AVA contains elevations between 400 and 2,297 feet. The Annapolis and Occidental regions, as well as the Fort Ross-Seaview AVA all contain elevations between 400 and 2,297 feet, while the region near Freestone also contains elevations between 400 and 900 feet.

TTB also agrees with comment 51 that certain peaks within the Sonoma Coast and Russian River AVAs east of the proposed West Sonoma Coast AVA do exceed 1,000 feet. However, TTB does not believe that the existence of certain peaks to the east of the proposed AVA that have elevations above 1,000 feet refutes the petition's claims that elevations outside the proposed AVA are generally lower and less steep. The Russian River Valley is still largely characterized by the Santa Rosa Plain, which the petition states has lower elevations and gentle slopes of 5 percent or less. The Santa Rosa Plain is also located within the portion of the Sonoma Coast AVA that does not include the proposed West Sonoma Coast AVA. To the south of the proposed AVA is the Petaluma Gap AVA (27 CFR 9.261), which is distinguished from surrounding areas by containing ''low, rolling hills not exceeding 600 feet,'' ''small valleys and fluvial terraces,'' and ''flat land along the Petaluma River * * *.'' (See T.D. TTB–149, December 7, 2017, 82 FR 57660).

5. Geology

i. Opposing Comments

Four comments oppose the AVA, asserting it contains geologies too diverse to be within one AVA. One of the opposing comments questions the petition's description of the geology of the proposed AVA and the surrounding regions. Comment 51 asserts that the proposed AVA is not comprised predominately of sedimentary rock of the Franciscan Complex, as claimed in the petition, but instead is comprised of a variety of geologic features. The comment included a letter from professional geologist Ryan Padgett,[29] along with a map of the geology of the proposed AVA and the surrounding regions[30] as evidence of the variety of geologic features within the proposed AVA. The comment states that the region near Annapolis where vineyards are planted is mainly Ohlson Ranch formation. Vineyards in the Fort Ross–Seaview AVA are planted mostly on what the comment describes as a ''mélange and greywacke sandstone and in a metabasalt unit of the Franciscan Formation with some localized plantings in Ohlson Ranch Formation * * *.'' Last, the comment states that vineyards in the Freestone and Occidental regions are predominately planted in the Wilson Grove formation. The comment asserts that this fact is contrary to the petition's claim that the Wilson Grove formation does not exist within the proposed West Sonoma Coast AVA.

ii. Supporting Comments

Nineteen supporting comments address the geology of the proposed AVA, generally noting that the proposed West Sonoma Coast AVA has a unique underlying geological structure. Some comments assert that the area within the proposed AVA has unique soil, and note this soil is comprised primarily of sedimentary material, rather than alluvium.

Comment 67, submitted by the petitioner, was the only comment that included substantive evidence to support its claims. Comment 67 first

[27] See Attachment B of comment 67 in docket TTB–2018–0008 at *https://www.regulations.gov.*

[28] See Attachment A of comment 67 in docket TTB–2018–0008 at *https://www.regulations.gov.*

[29] See Exhibit C of comment 51 in docket TTB–2018–0008 at *https://www.regulations.gov.*

[30] See Exhibit A–8 of comment 51 in docket TTB–2018–0008 at *https://www.regulations.gov.*

states that, contrary to the assertion in comment 51, the petition does not claim the Wilson Grove Formation is not found within the proposed AVA. Instead, the petition states that the Wilson Grove Formation is ''a much more common unit in the Petaluma Gap and southwestern Russian River Valley'' outside of the proposed AVA. The petitioner agrees with comment 51 that the Wilson Grove Formation is found in the southeastern portion of the proposed West Sonoma Coast AVA. However, the petitioner provides a geologic map [31] of the proposed AVA and surrounding regions to support his claim that, while the Wilson Grove Formation is present in portions of the proposed AVA, it is more common in the regions to the south and east of the proposed AVA.

iii. TTB Response

After reviewing the petition and the comments, TTB has determined that geology is a distinguishing feature of the proposed West Sonoma Coast AVA. TTB agrees with the petitioner's statement in comment 67 that the petition did not exclude the Wilson Grove formation entirely from the proposed AVA. The petition indicates that the formation is present in a portion of the proposed AVA, but the formation is much more common outside the proposed AVA, particularly in the Petaluma Gap and Green Valley of Russian River Valley AVAs and the southwestern region of the Russian River Valley AVA. TTB believes the geologic maps included in comments 51 and comment 67 support the petitioner's claims.

TTB also believes that the geologic maps in comments 51 and 67, along with the letter from the professional geologist included in comment 51, do not refute the petitioner's claims regarding the prevalence of the geologic unit known as the Franciscan Formation within the proposed West Sonoma Coast AVA. Therefore, TTB has determined that the petition correctly identifies the Franciscan Formation as comprising much of the proposed AVA.

Although comment 51 is correct that the vineyards in the Annapolis, Freestone, and Occidental regions of the proposed AVA are planted in geologic features other than the Franciscan Complex, those regions still contain large regions of Franciscan Complex. For example, the Annapolis region contains geologic units identified on the map in Exhibit A–8 of the comment as ''Sandstone–Maastrichtian (Franciscan Complex).'' The Freestone and Occidental regions contain units identified as ''Graywacke and mélange (Franciscan Complex).'' Furthermore, the geologic map indicates that vineyards in the Fort Ross–Seaview AVA are planted on the same unit of the Franciscan Formation found in the Annapolis region. Therefore, TTB believes the petition is correct when it states that the Franciscan Complex comprises much of the proposed AVA.

6. Proposed AVA Boundary

i. Opposing Comments

Two comments specifically object to the proposed West Sonoma Coast AVA on the basis of the proposed boundary. The two comments, comments 51 and 52, both express the belief that the proposed West Sonoma Coast AVA contains too many public and protected lands and beaches on which vineyards will never be planted. Comment 51 includes a map of the public and protected lands within the proposed AVA [32] and further states that lands unavailable for commercial viticulture should be removed from the proposed boundaries, per guidance given in TTB's AVA Manual for Petitioners.[33]

Comment 51 also claims that when TTB excluded the town of Fort Ross in the Fort Ross–Seaview AVA, the bureau set a precedent for omitting coastal regions from AVAs. According to the comment, TTB did not agree with the Fort Ross-Seaview AVA petition's proposal to include the town in the AVA because the town was located in a cold, low-elevation area near the coastline where viticulture is not viable.

Comment 51 also asserts that TTB should reject the proposed West Sonoma Coast AVA boundary because the written boundary description in the petition does not match the proposed boundaries drawn on the USGS maps or the boundary as published in Notice No. 177. The comment provided several examples of what it described as inaccuracies in the written boundary description, including incorrect distances between points and erroneous section numbers.[34]

Another issue raised in comment 51 is the placement of the northeastern boundary of the proposed West Sonoma Coast AVA. The northeastern boundary omits from the proposed AVA a mountainous region that comment 51 refers to as the ''Excluded Corridor.'' According to the comment, this region contains similar topography to the proposed AVA and was arbitrarily excluded.

Comment 51 further claims that the proposed West Sonoma Coast AVA boundary is arbitrarily drawn because it does not include all the regions previously promoted by the West Sonoma Coast Vintners as being in the ''West Sonoma Coast.'' The comment includes several West Sonoma Coast Vintners publications showing that portions of the Russian River Valley, Green Valley of Russian River Valley, and Petaluma Gap AVAs, as well as the region informally known as Sebastopol Hills, were at various times represented by the association as being part of the ''West Sonoma Coast.'' [35] The comment notes that as late as 2018, the association promoted the Sebastopol Hills region as part of the ''West Sonoma Coast AVA Marketing Region.'' [36] According to the comment, these various representations of the ''West Sonoma Coast'' demonstrate that the boundary proposed in the AVA petition is not based on solid name or distinguishing features evidence, as required by § 9.12(a)(2) of the TTB regulations.

ii. Supporting Comments

In response to Notice No. 177, TTB received thirteen comments that support the boundaries of the proposed West Sonoma Coast AVA. Nine of the comments generally express support for the proposed AVA as a way to create a smaller, more tightly defined AVA within the larger, more diverse Sonoma Coast AVA.

Four comments submitted in response to Notice No. 177 specifically express support for the proposed West Sonoma Coast AVA boundary as it was described in the proposed rule. One of these comments (comment 55) supports the proposed West Sonoma Coast AVA boundaries, in general, but also asks that they be expanded. Comment 55, submitted by Hans Vidkjer of Atlas Vineyard Management, requests that the proposed northeastern boundary be expanded slightly to include Walala Vineyard. Mr. Vidkjer claims that the vineyard, which contains 18 acres of Pinot Noir, is only 0.7 mile east of the proposed AVA boundary. The comment contains evidence that Mr. Vidkjer believes demonstrates that the Walala Vineyard has mean temperatures, nocturnal temperatures, elevations, slopes, and geology that are similar to

[31] See Attachment G of comment 67 in docket TTB–2018–0008 at *https://www.regulations.gov.*

[32] See Exhibit A–9 to comment 51 in docket TTB–2018–0008 at *https://www.regulations.gov.*

[33] *https://www.ttb.gov/wine/p51204_ava_manual.pdf.*

[34] See Exhibit A–1 to comment 51 in docket TTB–2018–0008 at *https://www.regulations.gov.*

[35] See Exhibits D–1 through D–7 of comment 51 in docket TTB–2018–0008 at *https://www.regulations.gov.*

[36] See Exhibit D–2 of comment 51 in docket TTB–2018–0008 at *https://www.regulations.gov.*

those of the proposed West Sonoma Coast AVA.

The other three comments specifically support using the coastline as the western boundary of the proposed AVA. Comment 53, submitted by the winegrower of Peay Vineyards, states that the coastline was used as the western boundary ''as a matter of simplicity.'' Comment 70, submitted by a self-identified local wine industry member, believes the coastal regions should remain in the proposed West Sonoma Coast AVA. The comment acknowledges that is it difficult to ripen grapes in the extreme coastal regions of the proposed AVA, but ''it is not impossible to achieve a level of ripeness that would enable a producer to produce a sparkling wine from this less-ripe fruit.'' Comment 67, submitted by the petitioner, also states that the coastline was used for simplicity. The comment goes on to say that removing all the public and protected lands from the proposed AVA would also have created an unnecessarily complicated boundary. The petitioner notes that TTB has established AVAs that include publicly-owned lands in order to avoid creating boundaries that are cumbersome to describe and difficult to administer. As evidence, he cites the Malibu Coast AVA (27 CFR 9.235), where 37 percent of the land within the AVA is administered by the Federal Government or the State of California.

Comment 67 also addresses comment 51's discussion of the discrepancies between the written boundary description and the boundary drawn on the USGS maps. The petitioner believes that the commenters may have relied upon copies of the USGS maps that were included as Exhibit A to the proposed West Sonoma Coast AVA petition. The petitioner notes, however, that he worked in consultation with TTB to make ''modest adjustments'' to the proposed boundaries to provide better clarity and simplification to the boundary description. These consultations took place in January of 2017, and as a result, the boundary description included in the proposed rule would not exactly match the original boundaries drawn on the USGS maps at the time the commenters may have viewed them. The petitioner states that any typographic errors appearing in the boundary description of the proposed rule may be corrected as needed, but they ''do not otherwise discredit the integrity of the proposed boundary.''

The petitioner also explains why the proposed AVA boundary does not include the region referred to in comment 51 as the ''Excluded Corridor.'' He claims that his field review of the region around Annapolis found a noticeable shift in vegetation approximately 8 miles inland from the coast. He explains that such a shift in vegetation signals a difference in climate and possibly soils. Therefore, even though the terrain of the Exclusion Corridor resembles that of the proposed West Sonoma Coast AVA, the change in vegetation strongly suggests the region does not share the same climate or underlying geology as the proposed AVA and should not be included.

In comment 67, the petitioner then addresses why the proposed West Sonoma Coast AVA boundary does not include certain regions that were previously described in various West Sonoma Coast Vintners publications as being within the ''West Sonoma Coast.'' The petitioner explains that when the West Sonoma Coast Vintners association was first formed, it was ''originally concerned with discerning the coolest regions of the west Sonoma Coast AVA from the greater Sonoma Coast AVA.'' The Green Valley of Russian River AVA, the Sebastopol Hills region, and a portion of the Petaluma Gap AVA were all considered to be cooler than the regions of the Sonoma Coast AVA that are farther inland and were included in the association's early maps of the ''West Sonoma Coast.'' Over time, and after consultation with AVA experts, the group determined that the extreme coastal mountains are unique from the milder topography of the Petaluma Gap and Green Valley of Russian River Valley AVAs, and also the Sebastopol Hills region. As a result, these regions ultimately were not included in the proposed West Sonoma Coast AVA boundary that was submitted to TTB.

iii. TTB Response

After careful review of the petition and comments, TTB has determined that the boundary as it was described in Notice No. 177, with the addition of the Walala Vineyard as requested in comment 55, is appropriate and shall be maintained.

TTB does not believe that the coastline and all public and protected lands need to be removed from the proposed West Sonoma Coast AVA. To do so would create an unnecessarily complex boundary that would be difficult to describe and to administer. Although TTB's AVA Manual for Petitioners does recommend removing public lands or lands otherwise unavailable for commercial viticulture, it does not require it. TTB typically does not request the removal of these lands unless they may be easily excluded without creating holes within the interior of the proposed AVA or an overly complex boundary description. Examples of established AVAs whose petitions specifically mention that the AVAs contain public lands include Upper Hiwassee Highlands (27 CFR 9.234) and Malibu Coast (27 CFR 9.235).

TTB does not agree with comment 51 that the exclusion of the town of Fort Ross from the established Fort Ross–Seaview AVA set a precedent for removing all coastal lands from AVAs. TTB has established many AVAs whose boundaries include a coastline, including the North Coast and Sonoma Coast AVAs, as well as the Martha's Vineyard (27 CFR 9.73), Long Island (27 CFR 9.170), Outer Coastal Plain (27 CFR 9.207), and Tip of the Mitt (27 CFR 9.257) AVAs. TTB notes that the town of Fort Ross was not included in the Fort Ross–Seaview AVA because one of the key features of the Fort Ross–Seaview AVA is elevations above 900 feet; the town of Fort Ross is located at lower elevations. Therefore, excluding a town with lower elevations from an AVA that is primarily characterized by elevations above 900 feet is appropriate, especially when removing the town from the AVA would not create a hole in the interior of the AVA. In addition, the exclusion of Fort Ross from the Fort Ross–Seaview AVA did not preclude TTB from including both the town and the AVA in the established Sonoma Coast and North Coast AVAs, which are larger, regional AVAs with broad characteristics that both the town and the AVA share.

TTB acknowledges that the proposed boundary description for the proposed West Sonoma Coast AVA that was included in Notice No. 177 is different from the description contained in the petition and originally shown on the USGS maps. TTB regularly works with petitioners to ensure that the boundary description meets TTB requirements and is described and defined as clearly as possible. When TTB accepts a petition as ''perfected,'' that simply means an initial review of the petition finds that it contains sufficient evidence to meet the regulatory requirements. However, TTB's acceptance of a ''perfected'' petition does not mean that TTB will not ask for additional information or edits to clarify the information or proposed boundary in the petition before publishing a proposed rule. TTB acknowledges that there are some minor typographic errors in the boundary description in Notice No. 177, particularly in paragraphs (c)(2), (14), (15), (21), and (24). These errors have been corrected in the boundary description at the end of this document.

With respect to the ''Excluded Corridor'' referred to in comment 51, TTB believes that the petition, along with the information provided by the petitioner in comment 67, provides a sufficient rationale for not including this region in the proposed West Sonoma Coast AVA. East of the proposed northeastern boundary, the climate is not affected by the heaviest marine influence and transitions entirely to the Coastal Cool zone and then to the Coastal Warm zone.

TTB does not agree with the assertion in comment 51 that the proposed AVA boundary is arbitrarily drawn and does not comply with the requirements of § 9.12(a)(2) of the TTB regulations. The petition included evidence that topography, climate, and geology are different outside the boundary of the proposed AVA. The petition also included evidence to demonstrate those regions of Sonoma County that are considered to be in the ''West Sonoma Coast,'' and the proposed boundary does not include regions that are not known by that name.

TTB does not believe that the West Sonoma Coast Vintners' changing definition of what defines the ''West Sonoma Coast'' demonstrates that the proposed West Sonoma Coast AVA boundaries are arbitrarily drawn. TTB agrees with the petitioner's assertion in comment 67 that the association refined over the years what it considered to be the key factors of the region—namely, mountainous terrain with heavy marine influence. Therefore, it is not inappropriate that the boundary that was proposed for a West Sonoma Coast AVA differs from what the association originally envisioned.

TTB also does not agree that the historical publications of the West Sonoma Coast Vintners are attempts by the association to mislead or deceive TTB or the public or to violate the requirements of § 4.39(a)(1) of the TTB regulations, as suggested in comment 51. The TTB regulations do not prohibit the region known by a proposed AVA name to be larger than the area included in the AVA. The regulations also do not prohibit an association from accepting members who are not within the boundaries of the AVA. However, TTB does note that wines produced primarily from grapes grown outside the AVA would not be allowed to be labeled with the AVA name or to be marketed as coming from within the AVA.

As previously mentioned, TTB is modifying the proposed West Sonoma Coast AVA boundary to include the Walala Vineyard, which is just east of the Annapolis region of the proposed AVA. Comment 55, which requests including Walala Vineyard in the proposed AVA, provided information on the climate, elevations, slope angle, and geology of the Walala Vineyard. The Walala Vineyard climate data was compared to the climate of the Goldrock Vineyard, located within both the proposed AVA and the Fort Ross–Seaview AVA, and to Windsor, which was the inland comparison location used in the proposed AVA petition. The data suggests that the mean growing season temperatures within the Walala Vineyard are very similar to those in the Goldrock Vineyard and cooler than those in Windsor. The data also suggests that minimum temperatures within the Walala Vineyard are higher than those in Windsor; minimum temperature data was not included for the Goldrock Vineyard. These climate findings are similar to those included in the proposed West Sonoma Coast AVA petition, which indicate cooler maximum and warmer minimum temperatures within the proposed AVA than are found in the inland regions to the east. Comment 55 also described the average elevation within the Walala Vineyard as 1,150 feet, which is within the range of elevations included in the proposed AVA and higher than the average elevation of the Santa Rosa Plain, within the Russian River Valley AVA. The comment also provided a map of slope angles that indicates the Walala Vineyard has slope angles similar to those in the Annapolis region of the proposed AVA, which is adjacent to the Walala Vineyard.[37] Finally, the comment included a geologic maps of the vineyard and the Annapolis region, which indicates that the vineyard is located on the Franciscan Formation [38] and has soils derived from weathered sedimentary rock,[39] similar to the proposed AVA.

In response to an inquiry from TTB, Mr. Shabram provided an email indicating that the board of directors of the West Sonoma Coast Vintners voted unanimously to expand the proposed AVA boundary to include Walala Vineyard. Because of the evidence included in comment 55, TTB is modifying the boundary of the proposed West Sonoma Coast AVA to include the Walala Vineyard.

[37] See Figure 10 to comment 55 in docket TTB–2018–0008 at *https://www.regulations.gov.*

[38] See Figure 11 of comment 55 in docket TTB–2018–0008 at *https://www.regulations.gov.*

[39] See Figure 13 of comment 55 in docket TTB–2018–0008 at *https://www.regulations.gov.*

7. FAA Act and TTB Regulations

i. Opposing Comments

Comment 51 asserts that establishing the proposed West Sonoma Coast AVA would be an ''arbitrary and capricious'' decision ''inconsistent with the purposes of the FAA Act and [TTB] Regulations'' and ''contrary to the public interest.'' The comment first notes that the Federal Alcohol Administration Act (FAA Act) ''prohibit[s] consumer deception and the use of misleading statements'' on wine labels. The comment then states that TTB regulations in § 4.39 prohibit wine labels from containing ''[a]ny statement that is false or untrue in any particular'' or creates a ''misleading impression.'' Furthermore, the comment claims that the petition contains ''a number of factual errors, unverified and incomplete or illegible documents, data, charts, and maps'' and cannot be considered ''true and correct.'' For these reasons, the comment claims that allowing wine to be labeled as ''West Sonoma Coast'' would mislead consumers by falsely attributing ''common quality, reputation, and characteristics'' to wine made from grapes grown in an AVA comprised of regions with ''dissimilar climates, geology, physical features and maximum and minimum elevations.''

ii. Supporting Comments

TTB did not receive any comments specifically addressing the comment's claims that establishing the proposed West Sonoma Coast AVA would be arbitrary and capricious, and inconsistent with the FAA Act or TTB regulations. However, TTB did receive 20 comments that express the belief that the proposed AVA would provide more information to consumers and help them distinguish coastal wines from wines made from grape grown farther inland. As discussed earlier in this document, TTB also received numerous comments supporting the petition's claim that the various regions within the proposed AVA contain similar distinguishing features that distinguish the proposed AVA from the larger established Sonoma Coast AVA.

iii. TTB Response

TTB has carefully reviewed the information in the petition and in the comments received in response to Notice No. 177, including the information in comment 51. TTB believes that the information in comment 51 and in other opposing comments does not conclusively demonstrate that all the information in the petition is false, misleading, or

erroneous. Based on information provided in comment 51, TTB has re-evaluated its determination that wind speeds distinguish the proposed AVA from the region to the east. However, as discussed earlier in this document, TTB still believes the petition provided sufficient information to meet the regulatory requirements for an AVA petition; namely, the petition provided name evidence, a delineated boundary, and evidence that the various regions within the AVA share similar features that are distinguishable from the surrounding regions and affect viticulture. Therefore, TTB does not believe that establishing the proposed West Sonoma Coast AVA would be an arbitrary and capricious decision inconsistent with the FAA Act or TTB regulations, nor does TTB believe that allowing wines to be labeled with ''West Sonoma Coast'' as an appellation of origin would mislead the public.

B. Comments on Inclusion of Fort Ross–Seaview AVA

Twenty-one comments specifically mentioned the proposal to include the Fort Ross–Seaview AVA within the proposed West Sonoma Coast AVA. Ten comments opposed the inclusion, while 11 comments supported it. Six of the supporting comments and three of the opposing comments were submitted by wine industry members who specifically indicated affiliations with wineries or vineyards within the Fort Ross–Seaview AVA.

Several of the comments simply expressed opposition or support with a general statement that the characteristics of the established AVA were either similar to or different from the proposed West Sonoma Coast AVA. However, other comments mentioned specific reasons for opposing or supporting the proposed AVA. Those specific reasons will be discussed in the following sections.

1. Reputation of Fort Ross–Seaview AVA.

i. Opposing Comments

Five comments express the belief that the reputation of the Fort Ross–Seaview AVA would be harmed if it were included in the proposed West Sonoma Coast AVA. Four of these comments were submitted by wine industry members who claim an affiliation with vineyards or wineries within the Fort Ross–Seaview AVA (comments 44, 48, and 51). The opposing comments generally claim that the characteristics of the Fort Ross–Seaview AVA would be ''watered down'' (comment 48) if it were included, and that ''the elements that make Fort Ross–Seaview so unique would be lost in this change'' (comment 41). The result would be ''quite confusing to consumers,'' (comment 44) who would no longer know what to expect from wines labeled with the Fort Ross–Seaview AVA. This consumer confusion could lead to ''incalculable damage'' for winemakers and grape growers within the AVA (comment 51).

ii. Supporting Comments

Six of the comments disagree with the idea that the Fort Ross–Seaview AVA would be diminished or devalued if it was included in the proposed West Sonoma Coast AVA. Four of these comments were submitted by wine industry members who claim an affiliation with vineyards or wineries within the Fort Ross–Seaview AVA (comments 31, 34, 63, and 66). Comment 31 believes that the Fort Ross–Seaview AVA and the proposed West Sonoma Coast AVA are ''harmonious and complementary,'' and that including the established AVA in the proposed AVA will help customers ''distinguish wines from the coast'' of Sonoma County. The commenter also notes that her vineyard, Hirsch Vineyards ''are strong proponents of the Fort Ross Seaview AVA, and helped foster its creation.'' The winemaker of Alma Fria Wines submitted two comments (comments 34 and 66) that support including the Fort Ross–Seaview AVA in the proposed AVA. In comment 34, he expressed his belief that including the Fort Ross–Seaview AVA in the proposed West Sonoma Coast AVA would ''help bring clarity to consumers'' because wines from the proposed AVA ''have much in common with each other and very little in common with wines from other areas'' of the larger Sonoma Coast AVA. In comment 66, he states that both the Fort Ross–Seaview AVA and the proposed West Sonoma Coast AVA are ''supported by the facts and can co-exist without impacting each other.'' Comment 63, submitted jointly by six wineries and vineyards within the Fort Ross–Seaview AVA, believes that ''growers, winemakers, wine writers, other wine professionals, and many consumers recognize the similarities between the Fort Ross–Seaview AVA and the greater West Sonoma Coast'' and that ''[t]hese similarities set the entire West Sonoma Coast region apart from the greater Sonoma Coast AVA including the Russian River Valley and Petaluma Gap AVAs.''

Comment 59 uses the example of the AVAs located within the Napa Valley AVA (27 CFR 9.23) to illustrate the belief that inclusion in the proposed AVA would not harm the reputation of the Fort Ross–Seaview AVA. The comment notes that, while there are ''significant distinctions'' between each of the smaller AVAs within Napa Valley, they all share the overarching characteristics of the ''long established and much appreciated Napa Valley AVA.'' The comment also notes the lack of petitions requesting the removal of the smaller AVAs from the Napa Valley AVA, and suggests this demonstrates that the Napa Valley AVA and the smaller AVAs within it benefit from each other, as the Fort Ross–Seaview AVA and the proposed West Sonoma Coast AVA would benefit from each other.

Comment 61, from the sales director of a vineyard located within the Napa Valley AVA, also compares the inclusion of the Fort Ross–Seaview AVA in the proposed West Sonoma Coast AVA to the smaller AVAs located within the Napa Valley AVA. He claims that, although the Napa Valley AVA name is ''the most valuable designation in American viticulture,'' the appellation does not ''diminish the usefulness of distinguishing wines'' made within the smaller nested AVAs. The comment concludes that the Fort Ross–Seaview AVA is ''undoubtedly as Western Sonoma and as coastal as Rutherford [AVA] and Oakville [AVA] are Napa Valley [AVA].''

iii. TTB Response

After careful review of the petition and comments, TTB believes that, although it has unique features, the Fort Ross–Seaview AVA still shares the broad distinguishing characteristics of the proposed West Sonoma Coast AVA. In particular, both regions have steep mountainous terrain, sedimentary soil, and a maritime-influenced climate that is generally cooler during the day and warmer during the night than the more inland regions of Sonoma County. Because both regions share these similarities, TTB does not believe that including the Fort Ross–Seaview AVA within the proposed AVA would mislead consumers. Furthermore, establishment of the proposed West Sonoma Coast AVA would not require winemakers to discontinue use of the Fort Ross–Seaview AVA name or to adopt the West Sonoma Coast AVA name. Such decisions would be entirely up to the individual proprietors.

TTB also does not find that the commenters provided evidence to support their claims that the reputation of the Fort Ross–Seaview AVA would be harmed by the establishment of the proposed West Sonoma Coast AVA, or that the inclusion of an established AVA

within a larger AVA would be detrimental to the smaller AVA's image. TTB notes that many well-known AVAs are located within other AVAs, including the Arroyo Seco (27 CFR 9.59), Sta. Rita Hills (27 CFR 9.162), Red Mountain (27 CFR 9.167), Yakima Valley (27 CFR 9.69), and Eola–Amity Hills (27 CFR 9.202) AVAs. The reputation of an AVA and any benefit derived from the use of a viticultural area name would be the result of a proprietor's efforts and consumer acceptance of wines from that area.

2. Previous TTB Rulings

i. Opposing Comments

Three comments oppose including the Fort Ross–Seaview AVA in the proposed AVA because they believe doing so would contradict previous TTB rulings, specifically T.D. TTB–98, which established the Fort Ross–Seaview AVA. Only one of these comments (comment 51) was from a wine industry member located within the Fort Ross–Seaview AVA.

Comment 38 notes that T.D. TTB–98 established the Fort Ross–Seaview based on its unique climate and geology. The commenter asserts that including it ''as part of a larger area simply confuses that prior designation without any evidence that the prior AVA's boundaries were mistakenly restrictive.'' Comments 51 and 52 both cite TTB's decision in T.D. TTB–98 not to include the region near Annapolis in the Fort Ross–Seaview AVA. According to these two comments, TTB's decision demonstrates that the two regions are too dissimilar to be included in a single AVA. Comment 51 also asserts that TTB's initial acceptance of a petition to establish a Freestone–Occidental AVA in 2008 further demonstrates that the region of the proposed West Sonoma Coast AVA which includes Freestone and Occidental is a distinct region that should not be included in an AVA that also includes the Fort Ross–Seaview AVA. To include the Fort Ross–Seaview in a single AVA that contains such different regions would, according to comment 51, be ''requesting TTB to create a new type of hybrid AVA.''

Comment 51 also asserts that, by establishing the Fort Ross–Seaview AVA, TTB has already determined that it is ''viticulturally distinguishable'' from the surrounding regions. Therefore, including it in the proposed West Sonoma Coast AVA would ''undermine the credibility and the integrity of the AVA system,'' as well as negate the findings of T.D. TTB–98. First, the comment states that rainfall is substantially higher in the Fort Ross–Seaview AVA than in the Annapolis, Freestone, and Occidental regions of the proposed West Sonoma Coast AVA. The comment also states that T.D. TTB–98 determined that the Fort Ross–Seaview AVA was in the Coastal Cool zone, not the Marine zone, and is therefore not as influenced by marine fog as other regions in the proposed West Sonoma Coast AVA. Elevations within the Fort Ross–Seaview AVA are above the fog line, allowing greater solar radiation exposure and warmer daytime temperatures than are generally found within the proposed West Sonoma Coast AVA. The comment cites the exclusion of the Santa Cruz Mountains AVA (27 CFR 9.31) from both the larger San Francisco Bay AVA (27 CFR 9.157) and Central Coast AVA (27 CFR 9.75) as an example of an instance where a smaller AVA was determined to be too distinct to be included in a larger overlapping AVA.

ii. Supporting Comments

Comment 67, submitted by the petitioner, was the only comment to address how the inclusion of the Fort Ross–Seaview AVA in the proposed West Sonoma Coast AVA would affect TTB's determination in T.D. TTB–98.

In comment 67, the petitioner responds to the reasons cited in comment 51 to exclude the Fort Ross–Seaview AVA from the proposed AVA. He first states that the proposed AVA petition is not an effort ''to apply the characteristics that define the Fort Ross–Seaview AVA to the entire West Sonoma Coast region,'' and that the proposed West Sonoma Coast AVA is not defined by all of the same distinguishing criteria as the Fort Ross–Seaview AVA. Referencing a 2010 letter submitted to TTB during the rulemaking process that led to the creation of the Fort Ross–Seaview AVA, the petitioner notes that the Fort Ross–Seaview is a ''local wine growing area,'' while the proposed West Sonoma Coast AVA is a ''regional viticultural area'' which may encompass smaller, more localized AVAs. Establishing the proposed West Sonoma Coast AVA, he claims, would have no impact on the continued existence of the Fort Ross–Seaview AVA.

The petitioner also shows that the exclusion of the Annapolis region from the Fort Ross–Seaview AVA does not preclude the two regions from being included in a larger, regional AVA. He states that including the Annapolis region in the Fort Ross–Seaview AVA in T.D. TTB–98 would not have been appropriate because the primary feature of the Fort Ross–Seaview AVA was a location that was generally above the fog line. The Annapolis region did not meet this criteria, nor did the name ''Fort Ross–Seaview'' apply to the Annapolis region. He states that, for these reasons, the Annapolis region did not belong in the Fort Ross–Seaview AVA. However, including both regions in a larger coastal AVA that also includes other coastal regions of Sonoma County would be appropriate because the regions all share the broad characteristics of the proposed West Sonoma Coast AVA, such as sedimentary soils, a marine-influenced climate, and steep coastal ridges.

iii. TTB Response

After reviewing the petition and the comments, TTB does not believe that including the Fort Ross–Seaview AVA within the proposed West Sonoma Coast AVA would be inconsistent with the findings of T.D. TTB–98, which established the Fort Ross–Seaview AVA. TTB believes it is appropriate to include the Fort Ross–Seaview AVA within the proposed West Sonoma Coast AVA, as the Fort Ross–Seaview AVA shares the mountainous topography and marine-influenced climate of the surrounding regions. T.D. TTB–98 describes the Fort Ross–Seaview AVA as having steep, mountainous terrain, soils derived from sedimentary rock, and temperatures that are moderated by the convection and conduction of fog from the Pacific Ocean. These distinguishing features are similar to the proposed West Sonoma Coast AVA, which is described in TTB Notice No. 177 as containing steep, rugged mountains and ridgelines, soils derived from the sedimentary rock of the Franciscan Complex, and a climate influenced by the cold marine air and heavy marine fog from the Pacific Ocean. Further, while Comment 51 notes the Fort Ross–Seaview AVA is distinguished by elevations that are generally above the fog line, T.D. TTB–98 does show that vineyards in the AVA benefit from being near the fog line. T.D. TTB–98 states that the Fort-Ross Seaview AVA is ''in the heaviest fog intrusion area,'' and the vineyards still receive ''some cooling via conduction due to the close proximity of the fog layer.'' Last, while Comment 51 asserts rainfall amounts in the Fort Ross–Seaview AVA may differ from those in the rest of the proposed West Sonoma Coast AVA, TTB notes that rainfall amounts were not determined to be a distinguishing feature of either the proposed West Sonoma Coast AVA, as described in Notice No. 177, or the Fort Ross–Seaview AVA, as described in T.D. TTB–98.

TTB also disagrees that including the Fort Ross–Seaview AVA within a larger

AVA would create a ''new hybrid type of AVA,'' as asserted in comment 51. TTB regulations allow for the creation of smaller AVAs within larger AVAs, as well as the creation of larger AVAs that encompass one or more smaller AVAs. TTB and its predecessor agency, ATF, have both established numerous AVAs that are within or contain other AVAs, and TTB believes that consumers and industry members generally understand and accept the concept of these so-called ''nested'' AVAs. TTB notes that the Fort Ross–Seaview AVA is already within the established Sonoma Coast AVA and the North Coast AVA. Also, as discussed above, TTB notes the examples of the Arroyo Seco, Sta. Rita Hills, Red Mountain, Yakima Valley, and Eola–Amity Hills AVAs, which are all located within other larger established AVAs.

TTB also does not believe that either the decision to exclude the Annapolis region from the Fort Ross–Seaview AVA in T.D. TTB–98 or the previous attempt to establish a Freestone–Occidental AVA means that the two regions are too dissimilar to be included along with the Fort Ross–Seaview AVA in a single new West Sonoma Coast AVA. As stated in comment 67, the Fort Ross–Seaview AVA encompasses a very localized microclimate within the larger established Sonoma Coast and North Coast AVAs. The characteristics of the Annapolis region were determined to be too distinctive to be a part of the same limited Fort Ross–Seaview AVA microclimate. Additionally, TTB found that the ''Fort Ross–Seaview'' name did not apply to the Annapolis region. However, the proposed West Sonoma Coast AVA represents the more regional microclimate found throughout the extreme coastal regions of Sonoma County. Although the Freestone–Occidental and Annapolis regions and the Fort Ross–Seaview AVA each have some unique features, they all share the characteristics of this larger regional microclimate.

3. Name Recognition

i. Opposing Comments

Comment 51 states that the Fort Ross–Seaview AVA should not be included in the proposed West Sonoma Coast AVA because ''the smaller Fort Ross–Seaview AVA has name recognition that clearly distinguishes it'' from the proposed AVA. The comment also asserts that the proposed West Sonoma Coast AVA petition did not state or explain ''why the name West Sonoma Coast is applicable or appropriate for the existing approved Fort Ross–Seaview AVA which * * * has not itself even been known as the West Sonoma Coast AVA.'' The comment included multiple images of wine bottles bearing ''Fort Ross–Seaview'' as an appellation of origin, as well as links to images and maps depicting the Fort Ross–Seaview AVA. The comment also notes that the Fort Ross–Seaview AVA has its own page on the Sonoma County Tourism Bureau website [40] and is identified ''as a prominent and clearly delimited AVA'' on a map of Sonoma County AVAs on the Sonoma County Winegrowers Association website.[41] Finally, comment 51 states that there have been ''a number of education and promotional seminars'' exclusively about the Fort Ross–Seaview AVA, including two separate seminars entitled ''Pinot'' and ''Diamonds in the Sky,'' which were both held in 2016. The commenter suggests that these seminars further demonstrate that the Fort Ross–Seaview AVA is recognized independently of the proposed West Sonoma Coast AVA.

ii. Supporting Comments

Comment 67, submitted by the petitioner, was the only supporting comment to address the applicability of the proposed West Sonoma Coast AVA name to the Fort Ross–Seaview AVA. The petitioner notes that several vineyards and wineries within the Fort Ross–Seaview also identify themselves as being in a region known as ''West Sonoma Coast.'' For example, the Hirsch Vineyards website states, ''The Fort Ross–Seaview AVA was granted official status in 2012, although the oldest plantings, including Hirsch, date from the 1970s, making it the oldest grape-growing region on the West Sonoma Coast.'' [42] The Red Car Wines website states, ''The coastal ridgetop vineyards in the West Sonoma Coast are situated in one of the most dramatically beautiful places in California.'' [43]

Comment 67 also states that several wineries and vineyards within the Fort Ross–Seaview AVA are members of the West Sonoma Coast Vintners, indicating that they also choose to associate their businesses with the region known as ''West Sonoma Coast.'' Members include Failla Wines, Flowers Winery & Vineyards, Hirsch Vineyards, Red Car Wines, and Wayfarer. Comment 67 also notes that Fort Ross Vineyards was a member of the association until 2018. Finally, the comment notes that the 2018 West of the West Festival, which celebrates wines from the West Sonoma Coast region, featured wines from Failla Wines, Flowers Vineyards & Winery, Fort Ross Vineyards, Hirsch Vineyards, Red Car Wines, and Wayfarer, which are all located within the Fort Ross–Seaview AVA. The petitioner therefore illustrates the ''West Sonoma Coast'' name includes wineries and vineyards within the Fort Ross–Seaview AVA. However, he continues by saying, ''Given the widespread usage of the name Fort Ross–Seaview AVA, as presented by Mr. Schwartz and Mr. Schoenfeld [in comment 51], there should be little concern that the West Sonoma Coast AVA would have any impact on the recognition of Fort Ross–Seaview as a place of wine origin.''

iii. TTB Response

After reviewing the comments, TTB agrees that there is widespread recognition of the Fort Ross–Seaview AVA name. However, TTB also believes the petition and the additional information provided by petitioner in comment 67 demonstrate there is sufficient evidence that the Fort Ross–Seaview AVA is considered to be within a larger region known as the ''West Sonoma Coast.'' Therefore, TTB does not believe it would be misleading or inappropriate to allow winemakers in the Fort Ross–Seaview AVA the option of labeling and marketing their wines using ''West Sonoma Coast'' as an appellation of origin.

TTB notes that establishment of the proposed West Sonoma Coast AVA would not prevent any label holder from using ''Fort Ross–Seaview'' as an appellation of origin on their wines, nor would they be required to use ''West Sonoma Coast'' as an appellation of origin. However, winemakers in the Fort Ross–Seaview AVA would have the option of using the West Sonoma Coast AVA name on their labels and marketing material, just as they currently have the option to use ''Sonoma Coast'' or ''North Coast.'' Additionally, wine makers and grape growers within the Fort Ross–Seaview AVA could continue to have a separate association for its industry members, as well as have separate festivals, seminars, and promotional events related to the Fort Ross–Seaview AVA.

IV. TTB Determination

After careful review of the petition and the comments received in response to Notice No. 177, TTB finds that the evidence provided by the petitioner supports the establishment of the West Sonoma Coast AVA. Notwithstanding the arguments of those who oppose the

[40] *https://www.sonomacounty.com/articles/fort-ross-seaview-wine-region-and-appellation.*

[41] *https://sonomawinegrape.org/about/sonoma-county-terroir.*

[42] *https://www.hirschvineyards.com/The-Site/West-Sonoma-Coast.*

[43] *https://redcarwine.com/.*

AVA, the petitioners' request for approval of the proposed West Sonoma Coast AVA satisfied all of the regulatory criteria needed for the approval of a new AVA. Accordingly, under the authority of the FAA Act, section 1111(d) of the Homeland Security Act of 2002, and parts 4 and 9 of the TTB regulations, TTB establishes the ''West Sonoma Coast'' AVA in Sonoma County, California, effective 30 days from the publication date of this document.

TTB has also determined that the West Sonoma Coast AVA will remain part of the established Sonoma Coast AVA and North Coast AVA. As discussed in Notice No. 177, the West Sonoma Coast AVA shares some broad characteristics with the both established AVAs. For example, all three AVAs have temperatures that are moderated by marine air and fog. However, the West Sonoma Coast AVA is located within the portion of Sonoma County that experiences the highest degree of maritime influence. Additionally, because it is a smaller region, the West Sonoma Coast AVA is more uniform in its soils and topography than both the larger Sonoma Coast AVA and the multi-county North Coast AVA.

Finally, TTB has determined that the Fort Ross–Seaview AVA will remain a part of the West Sonoma Coast AVA because the two AVAs share a similar geology, topography, and maritime-influenced climate. The Fort Ross–Seaview AVA is still distinguishable from the West Sonoma Coast AVA because its elevations are primarily above the fog line, whereas the West Sonoma Coast AVA also contains elevations within and below the fog line. However, the Fort Ross–Seaview AVA still benefits from the cooling influence of the marine fog and breezes, as does the West Sonoma Coast AVA.

V. Boundary Description

See the narrative description of the boundary of the West Sonoma Coast AVA in the regulatory text published at the end of this final rule.

VI. Maps

The petitioner provided the required maps, and they are listed below in the regulatory text. You may also view the West Sonoma Coast AVA boundary on the AVA Map Explorer on the TTB website, at *https://www.ttb.gov/wine/ava-map-explorer.*

VII. Impact on Current Wine Labels

Part 4 of the TTB regulations prohibits any label reference on a wine that indicates or implies an origin other than the wine's true place of origin. For a wine to be labeled with an AVA name or with a brand name that includes an AVA name, at least 85 percent of the wine must be derived from grapes grown within the area represented by that name, and the wine must meet the other conditions listed in 27 CFR 4.25(e)(3). If the wine is not eligible for labeling with an AVA name and that name appears in the brand name, then the label is not in compliance and the bottler must change the brand name and obtain approval of a new label. Similarly, if the AVA name appears in another reference on the label in a misleading manner, the bottler would have to obtain approval of a new label. Different rules apply if a wine has a brand name containing an AVA name that was used as a brand name on a label approved before July 7, 1986. See 27 CFR 4.39(i)(2) for details.

With the establishment of this AVA, its name, ''West Sonoma Coast'' will be recognized as a name of viticultural significance under § 4.39(i)(3) of the TTB regulations (27 CFR 4.39(i)(3)). The text of the regulation clarifies this point. Consequently, wine bottlers using the name ''West Sonoma Coast'' in a brand name, including a trademark, or in another label reference as to the origin of the wine, will have to ensure that the product is eligible to use the AVA name as an appellation of origin. TTB notes that the term ''Sonoma Coast'' already has viticultural significance as it is the name of an established AVA. However, because the West Sonoma Coast AVA is located within the Sonoma Coast AVA, the establishment of this new AVA will have no effect on the use of the term ''Sonoma Coast'' on wine labels.

The establishment of the West Sonoma Coast AVA will not affect any existing AVA, and any bottlers using ''North Coast,'' ''Sonoma Coast,'' or ''Fort Ross–Seaview'' as an appellation of origin or in a brand name for wines made from grapes grown within these AVAs will not be affected by the establishment of this new AVA. The establishment of the West Sonoma Coast AVA will allow vintners to use ''West Sonoma Coast,'' ''Sonoma Coast,'' and ''North Coast'' as appellations of origin for wines made primarily from grapes grown within the West Sonoma Coast AVA if the wines meet the eligibility requirements for the appellation. Additionally, any bottlers using ''Fort Ross–Seaview'' as an appellation of origin for wines made primarily from grapes grown in the Fort Ross–Seaview AVA will be able to use ''Fort Ross–Seaview,'' ''Sonoma Coast,'' ''North Coast,'' and ''West Sonoma Coast'' as appellations of origin of their wines.

Bottlers who wish to label their wines with ''West Sonoma Coast'' as an appellation of origin must obtain a new Certificate of Label Approval (COLA) for the label, even if the currently approved label already contains another AVA appellation of origin. Please do not submit COLA requests to TTB before the date shown in the **DATES** section of this document or your request will be rejected.

VIII. Regulatory Analysis and Notices

A. Regulatory Flexibility Act

TTB certifies that this regulation will not have a significant economic impact on a substantial number of small entities. The regulation imposes no new reporting, recordkeeping, or other administrative requirement. Any benefit derived from the use of an AVA name would be the result of a proprietor's efforts and consumer acceptance of wines from that area. Therefore, no regulatory flexibility analysis is required.

B. Executive Order 12866

It has been determined that this final rule is not a significant regulatory action as defined by Executive Order 12866 of September 30, 1993. Therefore, no regulatory assessment is required.

IX. Drafting Information

Karen A. Thornton of the Regulations and Rulings Division drafted this final rule.

List of Subjects in 27 CFR Part 9

Wine.

The Regulatory Amendment

For the reasons discussed in the preamble, TTB amends title 27, chapter I, part 9, Code of Federal Regulations, as follows:

PART 9—AMERICAN VITICULTURAL AREAS

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

Subpart C—Approved American Viticultural Areas

■ 2. Subpart C is amended by adding § 9.283 to read as follows:

§ 9.283 West Sonoma Coast.

(a) *Name.* The name of the viticultural area described in this section is ''West Sonoma Coast''. For purposes of part 4 of this chapter, ''West Sonoma Coast'' is a term of viticultural significance.

(b) *Approved maps.* The 14 United States Geological Survey (USGS) 1:24,000 scale topographic maps used to determine the boundary of the West

Sonoma Coast viticultural area are titled:

(1) McGuire Ridge, California, 1991 (provisional edition);

(2) Stewarts Point, California, 1978;

(3) Annapolis, California, 1977;

(4) Tombs Creek, California, 1978;

(5) Fort Ross, California, 1998;

(6) Cazadero, California, 1998;

(7) Duncans Mills, California, 1979;

(8) Camp Meeker, California, 1995;

(9) Valley Ford, California, 1954; photorevised 1971;

(10) Two Rock, California, 1954; photorevised 1971;

(11) Bodega Head, California, 1972;

(12) Arched Rock, California, 1977;

(13) Plantation, California, 1977; and

(14) Gualala, California, 1998.

(c) *Boundary.* The West Sonoma Coast viticultural area is located in Sonoma County, California. The boundary of the West Sonoma Coast viticultural area is as described as follows:

(1) The beginning point is on the McGuire Ridge map at the intersection of the Sonoma County/Mendocino County boundary and the northwest corner of section 29, T11N/R14W. From the beginning point, proceed southeast in a straight line for 0.4 mile to an unnamed hilltop with a marked elevation of 820 feet in section 29, T11N/R14W; then

(2) Proceed southeast in a straight line for 1.4 miles to the intersection of the eastern boundary of section 32 and the 800-foot elevation contour, T11N/R14W; then

(3) Proceed southeast along the 800-foot elevation contour for 3.1 miles, crossing onto the Stewarts Point map, to its intersection with the northern boundary of section 3, T10N/R14W; then

(4) Proceed east along the northern boundary of section 3 and then along the northern boundary of section 2 for a total of 0.8 mile to the intersection of the northern boundary of section 2 and the 600-foot elevation contour, T10N, R14W; then

(5) Proceed generally southeast along the 600-foot elevation contour for 3.3 miles, crossing onto the Annapolis map, to its intersection with the northern boundary of section 12, T10N/R14W; then

(6) Proceed east along the northern boundary of section 12, T10N/R14W, for 0.1 mile to its intersection with the 600-foot elevation contour; then

(7) Proceed north then generally east along the meandering 600-foot elevation contour for 4.8 miles to its sixth intersection with the northern boundary of section 7, T10N/R13W; then

(8) Continue northeasterly along the 600-ft elevation contour for an additional 3 miles to its intersection with Springs Creek in section 5, T10N/R13W; then

(9) Proceed southeasterly along Springs Creek for 1 mile to its intersection with the northern boundary of section 9, T10N/R13W; then

(10) Proceed east along the northern boundary of section 9 for 0.42 mile to its intersection with an unnamed, intermittent tributary of Grasshopper Creek; then

(11) Proceed southwest along the unnamed, intermittent tributary of Grasshopper Creek for 0.63 mile to its intersection with the main stem of Grasshopper Creek in section 9, T10N/R13W; then

(12) Proceed generally west along the main stem of Grasshopper Creek to its intersection with the eastern boundary of section 7, T10N/R13W; then

(13) Proceed south along the eastern boundary of section 7 for 0.17 mile; then

(14) Proceed in a straight line southeast for 1.6 miles to the intersection of the eastern boundary of section 17, T10N/R13W, and the 800-foot elevation contour; then

(15) Proceed southeast along the 800-foot elevation contour for 2.6 miles to its intersection with an unnamed, unimproved road near the 862-foot benchmark in section 21, T10N/R13W; then

(16) Proceed southeast in a straight line for 0.2 mile to the intersection of the 600-foot elevation contour and an intermittent stream in section 28, T10N/R13W; then

(17) Proceed south along the 600-foot elevation contour for 1.7 miles to its intersection with the eastern boundary of section 33, T10N/R13W; then

(18) Proceed southeast in a straight line for 0.5 mile to the intersection of an unnamed light-duty road known locally as Skaggs Springs Road and an unnamed, unimproved road near the Mendosoma Fire Station in section 34, T10N/R13W; then

(19) Proceed southeast along the unnamed, unimproved road for total of 5.9 miles as it follows Skyline Ridge and crosses onto the Tombs Creek map, back onto the Annapolis map, then back on to the Tombs Creek map, to the second intersection of the road with the 1,200-foot elevation contour in section 13, T9N/R13W; then

(20) Proceed southeast along the 1,200-foot elevation contour for 0.6 mile to the intersection with Allen Creek in section 18, T9N/R12W; then

(21) Proceed north along Allen Creek for 0.2 mile to the intersection with the 920-foot elevation contour in section 18, T9N/R12W; then

(22) Proceed east and then southeast along the meandering 920-foot elevation contour, crossing onto the Fort Ross map, then onto the Tombs Creek map, and then back onto the Fort Ross map, to the intersection of the elevation contour with Jim Creek in section 21, T9N/R12W; then

(23) Proceed southeast along Jim Creek for 0.7 mile to the intersection of the creek with the northern boundary of section 27, T9N, R12W; then

(24) Proceed east along the northern boundary of section 27 for 0.5 mile to the northeast corner of section 27; then

(25) Proceed south along the eastern boundaries of sections 27, 34, 3, 10, 15, and 22 for 5.1 miles to the intersection of the eastern boundary of section 22 and Fort Ross Road, T9N/R12W; then

(26) Proceed east along Fort Ross Road for approximately 262 feet to the intersection of the road with the middle branch of Russian Gulch Creek in section 23, T8N/R12W; then

(27) Proceed south along the middle branch of Russian Gulch Creek for 1.2 miles to the intersection with the 920-foot elevation contour in section 26, T8N/R12W; then

(28) Proceed southeast in a straight line for 2 miles, crossing onto the Cazadero map, to the summit of Pole Mountain in section 30, T8N/R11W; then

(29) Proceed southeast in a straight line for 4.7 miles, crossing onto the Duncans Mills map, to the confluence of Austin Creek and the Russian River, T7N/R11W; then

(30) Proceed generally east (upstream) along the Russian River for 3.1 miles to the intersection of the Russian River and the Bohemian Highway in section 7, T7N/R10W; then

(31) Proceed southeast along the Bohemian Highway for a total of 10.1 miles, crossing onto the Camp Meeker map and through the towns of Camp Meeker and Occidental, then crossing onto the Valley Ford map and through the town of Freestone, to the intersection of the Bohemian Highway and an unnamed medium-duty road known locally as Bodega Road near benchmark (BM) 214 in section 12, T6N/R10W; then

(32) Proceed northeast along Bodega Road for 0.9 mile, crossing onto the Camp Meeker map, to the intersection of the road with an unnamed light-duty road known locally as Barnett Valley Road north of the marked 486-foot elevation point in the Cañada de Jonive land grant, T6N/R10W; then

(33) Proceed south then east along Barnett Valley Road for 2.2 miles, crossing onto the Valley Ford map and then onto the Two Rock map, to the

intersection of Bennett Valley Road with Burnside Road in section 17, T6N/R9W; then

(34) Proceed southeast along Burnside Road for 3.2 miles to its intersection with the 400-foot elevation contour just north of an unnamed light duty road known locally as Bloomfield Road in the Cañada de Pogolimi land grant, T5N/R9W; then

(35) Proceed west along the 400-foot elevation contour for 6.7 miles, crossing onto the Valley Ford map, to the intersection of the elevation contour with an unimproved road, Cañada de Pogolimi land grant, T6N/R9W; then

(36) Proceed northwest then southwest along the unnamed, unimproved road for 0.9 mile to its terminus, Cañada de Pogolimi land grant, T6N/R9W; then

(37) Proceed northwest in a straight line for 0.1 mile to the marked 448-foot summit of an unnamed hilltop, Cañada de Pogolimi land grant, T6N/R10W; then

(38) Proceed northwest in a straight line for 0.6 mile to the 61-foot benchmark along an unnamed secondary highway known locally as Freestone Valley Ford Road, Cañada de Pogolimi land grant, T6N/R10W; then

(39) Proceed west-northwest in a straight line for 0.8 mile to VABM 724 in the Estero Americano land grant, T6N/R10W; then

(40) Proceed west in a straight line for 1.0 mile to the intersection of Salmon Creek and an intermittent stream, Estero Americano land grant, T6N/R10W; then

(41) Proceed west (downstream) along Salmon Creek for 9.6 miles, crossing onto the Bodega Head map, to the mouth of the creek at the Pacific Ocean; then

(42) Proceed north along the Pacific coastline for 51.4 miles, crossing over the Duncan Mills, Arched Rock, Fort Ross, Plantation, and Stewarts Point maps and onto the Gualala map to the intersection of the coastline with the Sonoma County/Mendocino County line; then

(43) Proceed east along the Sonoma County/Mendocino County line for 5.6 miles, crossing onto the McGuire Ridge map, and returning to the beginning point, T11N, R14W.

Signed: May 11, 2022.

Mary G. Ryan,

Administrator.

Approved: May 11, 2022.

Timothy E. Skud,

Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).

[FR Doc. 2022–10590 Filed 5–20–22; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2022–0221]

Drawbridge Operation Regulation; Rancocas Creek, Burlington County, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations; request for comments.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the US Route 543 (Riverside-Delanco) Bridge across Rancocas Creek, mile 1.3, at Burlington County, NJ. This deviation will test a change to the drawbridge operation schedule to determine whether a permanent change to the schedule is needed. The Coast Guard is seeking comments from the public regarding these proposed changes.

DATES: This deviation is effective from May 23, 2022 through 7:59 p.m. on October 15, 2022. For the purpose of enforcement, actual notice will be used from 1 p.m. on May 4, 2022, until May 23, 2022. Comments and related material must reach the Coast Guard on or before August 1, 2022.

ADDRESSES: You may submit comments identified by docket number USCG–2022–0221 using Federal Decision Making Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this test deviation, call or email Mr. Mickey D. Sanders, Fifth Coast Guard District (dpb); telephone (757) 398–6587, email *Mickey.D.Sanders2@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Background, Purpose and Legal Basis

The purpose of the deviation is to test the seasonal operating regulation of the US Route 543 (Riverside-Delanco) Bridge across Rancocas Creek, mile 1.3, at Burlington County, NJ. The US 543 (Riverside-Delanco) Bridge across Rancocas Creek, mile 1.3, at Burlington County, NJ, has a vertical clearance of 4 feet above mean high water in the closed-to-navigation position. The bridge currently operates under 33 CFR 117.745(b).

The Burlington County Bridge Commission who owns and operates the bridge has requested this change in the operation schedule to reduce the number of bridge openings during off-peak hours, while providing for the reasonable needs of navigation. The Rancocas Creek is used predominately by recreational vessels and pleasure crafts.

The bridge will be maintained in the closed-to-navigation position from 7 a.m. to 3 p.m., and from 8 p.m. to 11 p.m., Monday through Friday, from 7 a.m. to 1 p.m., and from 8 p.m. to 11 p.m., Saturday and Sunday, and from 11 p.m. to 7 a.m., daily, from May 4, 2022, through October 15, 2022.

The three-year, monthly average number of bridge openings from 7 a.m. to 3 p.m., Monday through Friday, 7 a.m. to 1 p.m., Saturday and Sunday, and from 8 p.m. to 11 p.m., daily, as drawn from the data contained in the bridge tender logs, is presented below.

April to October (2018, 2019 and 2020)	Average monthly openings
Monday–Friday, 7 a.m. to 3 p.m	4
Saturday & Sunday, 7 a.m. to 1 p.m	2
Daily, 8 p.m. to 11 p.m	7

Vessels able to pass through the bridge in the closed-to-navigation position may do so at any time. The bridge will be able to open in case of an emergency and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the test deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to normal operation at the end of the effective period of this test deviation. This deviation is authorized under 33 CFR 117.35.

II. 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.

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–2022–0221 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 your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

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. 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.

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

Dated: May 17, 2022.

Hal R. Pitts,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2022–10947 Filed 5–20–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0411]

RIN 1625–AA00

Safety Zone; Lower Mississippi River, Mile Marker 807, Barfield Bend, TN

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters of the Lower Mississippi River (LMR), Mile Marker 805 through 810. The safety zone is needed to protect persons, property, and the marine environment from the potential safety hazards associated with a rock replacement project in the vicinity of Barfield Bend, TN. Entry of persons or vessels into this zone is prohibited unless authorized by the Captain of the Port Sector Lower Mississippi River or a designated representative.

DATES: This rule is effective without actual notice from May 23, 2022 until June 15, 2022. For the purposes of enforcement, actual notice will be used from May 13, 2022 until May 23, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2022–0411 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MSTC Lindsey Swindle, U.S. Coast Guard; telephone 901–521–4813, email *Lindsey.M.Swindle@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector Lower Mississippi River
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

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. Immediate action is needed to protect persons and property from the potential safety hazards associated with the rock replacement project. The NPRM process would delay the establishment of the safety zone until after the date of the event and compromise public safety. We must establish this temporary safety zone immediately and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

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 contrary to the public interest because immediate action is needed to respond to the potential safety hazards associated with the rock replacement project in the vicinity of Barfield Bend, TN.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sector Lower Mississippi River (COTP) has determined that potential hazards associated with the rock replacement project would be a safety concern for all persons and vessels on the Lower Mississippi River between MM 805 and MM 810 in the vicinity of Barfield Bend, TN. This rule is needed to protect persons, property, infrastructure, and the marine environment in all waters of the LMR within the safety zone while the rock replacement project are being conducted.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from May 13, 2022 through June 15, 2022. The safety zone will cover all navigable waters of the LMR from MM 805 through MM 810 in the vicinity of Barfield Bend, TN. The duration of this safety zone is intended to ensure the safety of waterway users on these navigable waters during the rock replacement project.

Entry of persons or vessels into this safety zone is prohibited unless authorized by the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Lower Mississippi River. Persons or vessels seeking to enter the safety zones must request permission from the COTP or a designated representative on VHF–FM channel 16 or by telephone at 901–521–4822. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative. The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs), as appropriate.

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, and we discuss First Amendment rights of protestors.

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).

This regulatory action determination is based on the size, location, and duration of the safety zone. This emergency safety zone will temporarily restrict navigation on the LMR at MM 805 through 810 in the vicinity of Barfield Bend, TN., from May 13, 2022 through June 15, 2022. Moreover, The Coast Guard will issue Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs), as appropriate. The rule allows vessels to seek permission to enter the zone.

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 rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the temporary safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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 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.

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 rule involves a temporary safety zone on the LMR at MM 805 through 810 in the vicinity of Barfield Bend, TN, that will prohibit entry into this zone. The safety zone will only be enforced while operations preclude the safe navigation of the established channel. It is 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.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

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 amends 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; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0411 to read as follows:

§ 165.T08–0411 Safety Zone; Lower Mississippi River, Mile Marker 807, Barfield Bend, TN.

(a) *Location.* The following area is a safety zone: All navigable waters of the Lower Mississippi River at Mile Marker (MM) 805 through 810 in the vicinity of Barfield Bend, TN.

(b) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the Captain of the Port Sector Lower Mississippi River (COTP) or the COTP's designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Lower Mississippi River.

(2) To seek permission to enter, contact the COTP or the COTP's representative via VHF–FM channel 16 or by telephone at 901–521–4822. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(c) *Effective period.* This section is effective from May 13, 2022 until June 15, 2022.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners, Local Notices to Mariners, and/or Safety Marine Information Broadcasts, as appropriate.

Dated: May 12, 2022.

R.S. Rhodes,

Captain, U.S. Coast Guard, Captain of the Port Sector Lower Mississippi River.

[FR Doc. 2022–10995 Filed 5–20–22; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2020–0148; FRL–7527–02–OAR, EPA–HQ–OAR–2020–0505; FRL–7523–03–OAR, EPA–HQ–OAR–2020–0532; FRL–7523–03–OAR, FRL–9751–01–OAR]

RIN 2060–AU67, 2060–AU66

National Emission Standards for Hazardous Air Pollutants: General Provisions; Technical Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: In this action, the U.S. Environmental Protection Agency (EPA) is making technical corrections to the general provisions of the National Emission Standards for Hazardous Air Pollutants (NESHAP). Specifically, on November 19, 2021, EPA finalized changes to the NESHAPs for Refractory Products Manufacturing, Carbon Black Production (major sources), Cyanide Chemicals Manufacturing, and Carbon Black Production Area Sources and, also amended the general provisions. Following signature, the EPA discovered inadvertent minor errors in the ordering of the standards and methods that were being incorporated by reference in these rules. The Office of the Federal Register (OFR) was unable to complete the amendatory instructions, resulting in regulatory text intended for the general provisions to be omitted.

DATES: This technical correction is effective on May 23, 2022. The incorporation by reference (IBR) of certain publications listed in the rule was approved by the Director of the Federal Register as of November 19, 2021.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Mr. Muntasir Ali, Sector Policies and Programs Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0833; and email address: *ali.muntasir@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Summary of This Action

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3)(B), provides that, when an agency for good cause finds that notice and public procedures are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. The EPA has determined that for this action, there is good cause for making these technical corrections final without a prior proposal and the opportunity for comment because the Agency is correcting minor errors that do not substantially change the Agency's action taken in each of the three final rules discussed. These technical corrections will ensure that the regulatory text agrees with the description of the rule that the EPA provided in the final rule preamble for each of the three rules discussed in this action. Thus, notice and comment public procedures are unnecessary. The Agency finds that this constitutes a good cause under 5 U.S.C. 553(b)(3)(B). See also the final sentence of section 307(d)(1) of the Clean Air Act (CAA), 42 U.S.C. 307(d)(1), indicating that the good cause provisions in subsection 553(b) of the APA continue to apply to this type of rulemaking under section 307(d) of the CAA.

On the November 19, 2021, the EPA finalized amendments to multiple NESHAPs. The first rule finalized the Refractory Products Manufacturing Residual Risk and Technology Review (86 FR 66045). The second rule finalized the Carbon Black Production (major sources) and Cyanide Chemical Manufacturing Residual Risk and Technology Reviews and the Carbon Black Production Area Source Technology Review (86 FR 66096). Both actions incorporated by reference three different test methods: ASTM D4282–15, Standard Test Method for Determination of Free Cyanide in Water and Wastewater by Microdiffusion, approved July 15, 2015; ASTM D6784–16; Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method), approved March 1, 2016; and ASTM D7237–18, Standard Test Method for Free Cyanide and Aquatic Free Cyanide with Flow Injection Analysis (FIA) Utilizing Gas Diffusion Separation and Amperometric Detection, approved December 1, 2018. This was the first time these test methods were incorporated by reference under the Code of Federal Regulations (CFR). Because the methods were incorporated by reference for the first time and the final rules published on the same date, there was an error in alphanumerically ordering the test methods in 40 CFR 63.14. The ordering and instructions of the standards in the centralized IBR section were incorrect. Thus, the redesignations and additions of the standards were unable to be published in the CFR. Therefore, the EPA finds good cause to make the correction in this direct final action.

II. Summary of Cost, Environmental, and Economic Impacts

This action will have no cost, environmental, energy, or economic impacts beyond those impacts presented in the NESHAPs for Refractory Products Manufacturing Residual Risk and Technology Review (86 FR 66045), Carbon Black Production (major sources) and Cyanide Chemicals Manufacturing Residual Risk and Technology Reviews and Carbon Black Production Area Source Technology Review (86 FR 66096) published on November 19, 2021. These technical corrections are cost neutral.

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practices and procedures, Air pollution control, Hazardous substances, Incorporation by reference.

Joseph Goffman,

Acting Assistant Administrator, Office of Air and Radiation.

For the reasons set out in the preamble, 40 CFR part 63 is corrected as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart A—General Provisions

■ 2. Section 63.14 is amended by:

■ a. Redesignating paragraphs (h)(105) through (116) as (h)(108) through (119);

■ b. Redesignating paragraphs (h)(103) and (104) as (h)(105) and (106), respectively;

■ c. Redesignating paragraphs (h)(63) through (102) as (h)(64) through (103); and

■ d. Adding new paragraphs (h)(63), (104), and (107).

§ 63.14 Incorporations by reference.

* * * * *

(h) * * *

(63) ASTM D4282–15, Standard Test Method for Determination of Free Cyanide in Water and Wastewater by Microdiffusion, Approved July 15, 2015, IBR approved for § 63.1103(g).

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(104) ASTM D6784–16, Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method), Approved March 1, 2016, IBR approved for table 4 to subpart SSSSS.

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(107) ASTM D7237–18, Standard Test Method for Free Cyanide and Aquatic Free Cyanide with Flow Injection Analysis (FIA) Utilizing Gas Diffusion Separation and Amperometric Detection, Approved December 1, 2018, IBR approved for § 63.1103(g).

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[FR Doc. 2022–10842 Filed 5–20–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0728; FRL–9622–01–OCSPP]

Fluopicolide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluopicolide in or on multiple commodities which are identified and discussed later in this document. Valent U.S.A. LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 23, 2022. Objections and requests for hearings must be received on or before July 22, 2022 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2020–0728, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001.

The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and OPP Docket is (202) 566–1744. Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2020–0728 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before July 22, 2022. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2020–0728, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/

DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 1, 2021 (86 FR 29229) (FRL–10023–95), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F8838) by Valent U.S.A. LLC, 1600 Riviera Avenue, Suite 200 Walnut Creek, CA 94596 U.S.A. The petition requested that 40 CFR part 180 be amended by establishing tolerances for indirect or inadvertent residues of the fungicide Fluopicolide, 2,6-dichloro-*N*-[[3-chloro-5-(trifluoromethyl)-2-pyridyl]methyl]-benzamide, in or on Cereal grains (crop group 15), aspirated grain fractions at 0.07 parts per million (ppm); Cereal grains (crop group 15), grain at 0.02 ppm; Cereal grains (crop group 15), milled byproducts at 0.07 ppm; Cotton gin byproducts at 0.20 ppm; Foliage of legume vegetables (crop group 7), forage at 0.15 ppm; Foliage of legume vegetables (crop group 7), hay, straw, and vines at 0.20 ppm; Forage, fodder and straw of cereal grains (crop group 16) at 0.50 ppm; Grass forage, fodder, and hay (crop group 17) at 0.50 ppm; Legume vegetables (crop group 6), seed, pea, bean (succulent or dried, except listed beans) at 0.03 ppm; Nongrass animal feeds (crop group 18), forage, fodder, straw and hay at 0.50 ppm; Oilseeds (crop group 20), seed at 0.04 ppm; Oilseeds (crop group 20), refined oil at 0.10 ppm; Peanut nutmeat at 0.04 ppm; Peanut hay at 0.60 ppm; Peanut, refined oil at 0.10 ppm; and Soybean, refined oil at 0.08 ppm. That document referenced a summary of the petition prepared by Valent U.S.A. LLC, the registrant, which is available in the docket, EPA–HQ–OPP–2020–0728, *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised commodity definitions and is establishing several tolerances at different levels than petitioned-for. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluopicolide including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluopicolide follows.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections of the rule that would repeat what has been previously published in tolerance rulemakings for the same pesticide chemical. Where scientific information concerning a particular pesticide chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a number of tolerance rulemakings for fluopicolide, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to fluopicolide and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the Toxicological Profile of fluopicolide and one of its metabolites, 2,6-dichlorobenzamide (BAM), see Unit III.A. of the previous tolerance rulemaking for fluopicolide published in the **Federal Register** of March 7, 2018 (83 FR 9703) (FRL–9973–44). Since the March 7, 2018, rulemaking, an additional oral toxicity study that included evaluation of the olfactory system was submitted for BAM, and the results have been incorporated into the current risk assessment. Toxicity to the olfactory sensory neurons was observed following a single intraperitoneal exposure of mice to BAM, as were clinical signs of toxicity (slightly decreased muscle tone, slight loss of pinnae reflexes) following oral exposure in several short-term assays. In the newly submitted oral toxicity study in rats, ataxia was observed in males; however, there were no effects on the olfactory system.

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern for both fluopicolide and BAM used for the risk assessment, see Unit III.B. of the March 7, 2018, rulemaking. The only change is for BAM, where the current risk assessment reports the no-observed adverse-effect concentration (NOAEC) as 12.1 mg/m^3 for Inhalation Short- and Intermediate-Term (1–30 days and 1–6 months). The previous rulemaking reported this point of departure as a no-observed adverse-effect level (NOAEL) rather than a NOAEC, but the value remains the same.

Exposure assessment. Much of the exposure assessment remains the same, although the dietary exposure and risk assessments for fluopicolide and BAM were updated to account for exposures from the petitioned-for tolerances. These updates are discussed in this section; for a description of the rest of EPA's approach to and assumptions for the exposure assessment, including with respect to drinking water, non-occupational, and cumulative exposures, see Unit III.C. of the March 7, 2018, rulemaking.

EPA's dietary exposure assessments have been updated to include the additional exposures for the new tolerances for indirect or inadvertent residues of fluopicolide in the commodities identified in this action that are necessary to support revised rotational crop restrictions. There are no new use sites proposed. In addition, the dietary exposure assessments were revised to reflect the updated Dietary Exposure Evaluation Model that incorporates the What We Eat in

America (WWEIA) consumption data from 2005–2010.

Fluopicolide acute dietary exposure and risk assessments are not required because an endpoint attributable to a single dose has not been identified. This is the same as in the 2018 rulemaking. Fluopicolide chronic dietary exposure used the same assumptions as the 2018 rulemaking concerning tolerance level residues or maximum field trial residues, 100 percent crop treated (PCT), default processing factors, and modeled drinking water estimates.

For BAM, the acute and chronic dietary exposure assessments assumed the maximum BAM residues from field trial data for either fluopicolide or dichlobenil (another active ingredient for which BAM is a metabolite), which is the same as in the 2018 rulemaking. The current acute and chronic dietary assessments were updated to assume 100 PCT, default processing factors, and high-end estimates of fluopicolide in drinking water.

Cancer. Fluopicolide has been classified as ''not likely to be carcinogenic to humans.''

Therefore, a cancer dietary exposure assessment was not conducted for the parent fluopicolide. Additionally, EPA has determined BAM's potential for carcinogenicity is similar to that of dichlobenil, which is classified as ''group C, possible human carcinogen.'' Quantification of cancer risk is based on the reference dose (RfD) approach which requires comparison of the chronic exposure to the RfD. Using this methodology will adequately account for all chronic toxic effects, including carcinogenicity, likely to result from exposure to BAM. Hence, a separate cancer exposure assessment to BAM was not conducted.

Anticipated residue information. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticides in or on food and the actual residue levels of pesticides that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the residue levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor to 1X for fluopicolide. For BAM, EPA continues to retain the FQPA safety factor of 10X for the acute dietary exposure scenario for the general population to account for the use of a lowest-observed-adverse-effect-level (LOAEL) to extrapolate to a NOAEL. For all other exposure scenarios, EPA continues to conclude that there are reliable data to support the reduction of the FQPA safety factor to 1X. See Unit III.D. of the March 7, 2018, rulemaking for a discussion of the Agency's rationale for these determinations.

Aggregate risks and determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute population-adjusted dose (aPAD) and the chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. There were no endpoints attributable to a single dose identified in the hazard database and an acute dietary endpoint was not selected for fluopicolide. Therefore, fluopicolide is not expected to pose an acute risk.

For BAM, acute dietary risks are below the Agency's level of concern of 100% of the aPAD; they are 45% of the aPAD for infants less than 1 year old, which is the population subgroup with the highest exposure estimate. The acute aggregate risk estimates for BAM are equal to acute dietary (food and drinking water) risk estimates and therefore are not of concern. For fluopicolide, chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 15% of the cPAD for children 1–2 years old, which is the population subgroup with the highest exposure estimate.

For BAM, the chronic dietary risks are also below the Agency's level of concern; they are 40% of the cPAD for infants less than 1 year old, which is the population subgroup with the highest exposure estimate. As stated in the March 7, 2018, rulemaking, chronic residential exposure to residues of fluopicolide or BAM is not expected, so chronic aggregate risks are equal to chronic dietary risks and are not of concern.

Short-term aggregate risk estimates are equal to the most conservative residential exposure estimates plus chronic dietary exposure estimates (considered to be background dietary exposure). For adults and children 6 to <11 years old, the post-application dermal exposures from gardens treated with fluopicolide represent the most conservative residential exposure estimate. For children 1–2 years old, the most conservative residential exposure estimate is combined dermal and incidental oral exposure through high contact lawn activity. EPA has concluded the short-term aggregate MOEs are 500, 670, and 480 for adults, children 6 to <11 and children 1–2 years old, respectively, which are above the level of concern of 100 and therefore are not of concern. For BAM, dermal and inhalation exposures may not be combined with oral exposures due to different toxicological effects used as the basis of the selected endpoints. As a result, the aggregate risk estimates are equivalent to the dietary risk estimates and are not of concern.

Due to the absence of treatment-related tumors in two adequate rodent carcinogenicity studies, fluopicolide is classified as ''not likely to be carcinogenic to humans''; therefore, a quantitative cancer assessment is not required.

EPA has assumed BAM's potential for carcinogenicity is similar to that of dichlobenil, which is classified as ''group C, possible human carcinogen.'' Quantification of cancer risk is based on the RfD approach which requires comparison of the chronic exposure to the RfD. Therefore, the chronic aggregate risk estimates, which do not trigger concerns based on exposures associated with the registered uses, are considered protective of both non-cancer and cancer effects.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to fluopicolide residues, including its metabolite. More detailed information on this action to establish indirect or inadvertent tolerances in or on multiple commodities can be found in the document entitled, ''Fluopicolide. Human Health Risk Assessment to Support a Petition to Establish Tolerances for Indirect or Inadvertent Residues in/on Legume Vegetables, Cereal Grains, Grasses, Nongrass Animal Feeds, Oilseeds, and Peanuts'' at *https://*

www.regulations.gov, under docket ID number EPA–HQ–OPP–2020–0728.

IV. Other Considerations

A. Analytical Enforcement Methodology

For the analytical enforcement methodology for fluopicolide and BAM, see Unit IV.A. of the March 7, 2018, rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has established MRLs for fluopicolide in or on straw and fodder (dry) of cereal grains at 0.2 ppm, which is the only Codex MRL for the commodities covered by this rulemaking. This MRL is different than the U.S. tolerance at 0.5 ppm that is being established for residues of fluopicolide in/on grain, cereal, forage, fodder, and straw, group 16. EPA cannot harmonize the U.S. tolerance for group 16 with the corresponding Codex MRL because it could put U.S. growers at risk of violative residues despite legal use of fluopicolide.

C. Revisions to Petitioned-For Tolerances

EPA is not establishing the petitioned-for tolerances on Oilseeds (crop group 20), refined oil at 0.10 ppm or Peanut, refined oil at 0.10 ppm because the Agency is establishing tolerances for the respective raw agricultural commodities, Oilseed group 20 at 0.03 ppm, and Peanut at 0.03 ppm, which are adequate to cover the refined oils.

EPA is establishing the tolerance level for Soybean, refined oil at 0.03 ppm, which is the level calculated by multiplying average residue by the processing factor. This tolerance level is lower than the petitioned-for tolerance level of 0.08 ppm. The petitioner did not provide a rationale for the petitioned-for tolerance level, so the reason for this difference is unclear.

Additionally, EPA is revising many of the commodity definitions for consistency with the Agency's preferred terminology for tolerances. EPA is also establishing several tolerances at different levels than petitioned-for to be consistent with Organization for Economic Cooperation and Development (OECD) rounding class practice. Specifically, EPA is:

- Revising ''Nongrass animal feeds (crop group 18), forage, fodder, straw and hay'' to ''Animal feed, nongrass, group 18'' and establishing the tolerance level at 0.5 ppm instead of the petitioned-for 0.50 ppm;
- Revising ''Cereal grains (crop group 15), aspirated grain fractions'' to ''Grain, aspirated fractions'' and establishing the tolerance level at 0.07 ppm;
- Revising ''Cereal grains (crop group 15), grain'' to ''Grain, cereal, group 15'' and establishing the tolerance level at 0.02 ppm;
- Revising ''Cereal grains (crop Group 15), milled byproducts'' to ''Grain, cereal, group 15, milled byproducts'' and establishing the tolerance level at 0.07 ppm;
- Establishing the tolerance level for ''Cotton, gin byproducts'' at 0.2 ppm instead of the petitioned-for 0.20 ppm;
- Revising ''Forage, fodder and straw of cereal grains (crop group 16)'' to ''Grain, cereal, forage, fodder, and straw, group 16'' and establishing the tolerance level at 0.5 ppm instead of the petitioned-for 0.50 ppm;
- Revising ''Grass forage, fodder, and hay (crop group 17)'' to ''Grass forage, fodder and hay, group 17'' and establishing the tolerance level at 0.5 ppm instead of the petitioned-for 0.50 ppm;
- Revising ''Oilseeds (crop group 20), seed'' to ''Oilseed group 20'' and establishing the tolerance level at 0.03 ppm instead of the petitioned-for 0.04 ppm;
- Revising ''Peanut nutmeat'' to ''Peanut'' and establishing the tolerance level at 0.03 ppm instead of the petitioned-for 0.04 ppm;
- Establishing the tolerance level for ''Peanut, hay'' at 0.7 ppm instead of the petitioned-for 0.60 ppm;
- Revising the petitioned-for tolerances for ''Foliage of legume vegetables (crop group 7), forage'' at 0.15 ppm and ''Foliage of legume vegetables (crop group 7), hay, straw, and vines'' at 0.20 ppm to ''Vegetable, foliage of legume, group 7'' at 0.2 ppm; and
- Revising ''Legume vegetables (crop group 6), seed, pea, bean (succulent or dried, except listed beans)'' to ''Vegetable, legume, group 6'' and establishing the tolerance level at 0.02 ppm instead of the petitioned-for 0.03 ppm.
- In addition, EPA is removing the existing tolerances for indirect or inadvertent residues in 40 CFR 180.627(d) because these commodities are included in the groups 15 and 16 tolerances that the Agency is establishing in this action. For example, the commodities ''corn, field, grain'' (with an existing tolerance level of 0.01 ppm) and ''wheat, grain'' (with an existing tolerance level of 0.02 ppm) are included in the new tolerance for indirect or inadvertent residues in ''grain, cereal, group 15'' at 0.02 ppm. The new tolerances are equal to or higher than the existing tolerances and are therefore adequate to cover indirect or inadvertent residues on these commodities.

V. Conclusion

Therefore, tolerances are established for indirect or inadvertent residues of Fluopicolide, [2,6-dichloro-*N*-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide], including its metabolites and degradates, in or on Animal feed, nongrass, group 18 at 0.5 ppm; Cotton, gin byproducts at 0.2 ppm; Grain, aspirated fractions at 0.07 ppm; Grain, cereal, group 15 at 0.02 ppm; Grain, cereal, group 15, milled byproducts at 0.07 ppm; Grain, cereal, forage, fodder, and straw, group 16 at 0.5 ppm; Grass, forage, fodder and hay, group 17 at 0.5 ppm; Oilseed group 20 at 0.03 ppm; Peanut at 0.03 ppm; Peanut, hay at 0.7 ppm; Soybean, refined oil at 0.03 ppm; Vegetable, foliage of legume, group 7 at 0.2 ppm; and Vegetable, legume, group 6 at 0.02 ppm.

Upon establishment of the aforementioned tolerances, the established tolerances for indirect or inadvertent residues of fluopicolide in 40 CFR 180.627(d) will be removed, as they are superseded by the new tolerances.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not

contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 17, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, 40 CFR chapter I is amended as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.627 amend paragraph (d) by designating the table as table 1 and revising newly designated table 1 to read as follows:

§ 180.627 Fluopicolide; tolerances for residues.

* * * * *

(d) * * *

TABLE 1 TO PARAGRAPH (d)

Commodity	Parts per million
Animal feed, nongrass, group 18	0.5
Cotton, gin byproducts	0.2
Grain, aspirated fractions	0.07
Grain, cereal, group 15	0.02
Grain, cereal, group 15, milled byproducts	0.07
Grain, cereal, forage, fodder, and straw, group 16	0.5
Grass, forage, fodder and hay, group 17	0.5
Oilseed group 20	0.03
Peanut	0.03
Peanut, hay	0.7
Soybean, refined oil	0.03
Vegetable, foliage of legume, group 7	0.2
Vegetable, legume, group 6	0.02

[FR Doc. 2022–10868 Filed 5–20–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 1710319998630–02; RTID 0648–XB997]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-Grouper Resources of the South Atlantic; 2022 Red Snapper Commercial and Recreational Fishing Seasons

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

ACTION: Temporary rule; 2022 fishing seasons notice.

SUMMARY: NMFS announces the limited opening of commercial and recreational red snapper in the exclusive economic zone (EEZ) of the South Atlantic for the 2022 fishing year. This notice announces the 2022 red snapper commercial season opening date and the opening and closing dates for the red snapper recreational season, according to the accountability measures (AMs). This season announcement for South Atlantic red snapper allows fishers to maximize their opportunity to harvest the commercial and recreational annual catch limits (ACLs) while also managing harvest to protect the red snapper resource.

DATES: The 2022 commercial red snapper season opens at 12:01 a.m., local time, July 11, 2022, until 12:01 a.m., local time, January 1, 2023, unless changed by subsequent notification in the **Federal Register**. The 2022 recreational red snapper season opens at 12:01 a.m., local time, on July 8, 2022, and closes at 12:01 a.m., local time, on July 10, 2022.

FOR FURTHER INFORMATION CONTACT: Mary Vara, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *mary.vara@noaa.gov.*

SUPPLEMENTARY INFORMATION: The South Atlantic snapper-grouper fishery includes red snapper and is managed under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The South Atlantic Fishery Management Council (Council) prepared the FMP, and the FMP is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

For South Atlantic red snapper, the commercial AM requires the sector to

close when commercial landings reach or are projected to reach the commercial ACL. The recreational AM is the length of the recreational season, with NMFS projecting the season length based on catch rate estimates from previous years.

The commercial ACL is 124,815 lb (56,615 kg), round weight, and in 2021, NMFS closed the commercial sector on September 14 as a result of the commercial ACL being projected to be met (86 FR 50861; September 13, 2021). Subsequent to the commercial closure NMFS determined that the commercial ACL had not been met and reopened the commercial sector for 4 days beginning on November 2, 2021 (86 FR 60373; November 2, 2021). After the commercial 4-day reopening it was determined that in 2021 the commercial ACL was exceeded by 3,305 lb (1,499 kg), round weight. The recreational ACL is 29,656 fish, and preliminary landings information show this ACL was exceeded in the 2021 3-day fishing season by 9,413 fish. For 2022, NMFS has determined that recreational landings are expected to reach the recreational ACL in a 2-day season.

The commercial season for South Atlantic red snapper begins each year on the second Monday in July and closes when the commercial ACL is reached or is projected to be reached. Accordingly, the 2022 commercial season opens on July 11, 2022, and will remain open until 12:01 a.m., local time, on January 1, 2023, unless the commercial ACL is reached or projected to be reached prior to this date. During the commercial fishing season, the commercial trip limit is 75 lb (34 kg), gutted weight. NMFS will monitor commercial landings during the open season, and if commercial landings reach or are projected to reach the commercial ACL, then NMFS will file a notification with the Office of the Federal Register to close the commercial sector for red snapper for the remainder of the fishing year.

The recreational season for South Atlantic red snapper begins on the second Friday in July. Accordingly, the 2022 recreational red snapper season opens at 12:01 a.m., local time, on July 8, 2022, and closes at 12:01 a.m., local time, on July 10, 2022. During the recreational season, the recreational bag limit is one red snapper per person, per day. After the closure of the recreational sector, the bag and possession limits for red snapper are zero.

There is not a red snapper minimum or maximum size limit for the commercial and recreational sectors during the open seasons.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 622.183(b)(5)(i) and 622.193(y), which were issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be unnecessary and contrary to the public interest. Such procedures are unnecessary because the rule establishing the red snapper ACLs and AMs has already been subject to notice and comment, and all that remains is to notify the public of the respective commercial and recreational fishing seasons. In addition, providing prior notice and an opportunity for public comment is contrary to the public interest because the seasons begin in early July and announcing the length of the fishing seasons now allows each sector to prepare for the upcoming harvest, provides opportunity to for-hire fishing vessels to book trips that could increase their revenues and profits, and gives the South Atlantic states the time needed to prepare for their respective data collection needs for the season.

For the aforementioned reasons, there is good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in the effectiveness of this action.

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

Dated: May 17, 2022.

Jennifer M. Wallace,

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

[FR Doc. 2022–10974 Filed 5–20–22; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 87, No. 99
Monday, May 23, 2022

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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0524; Airspace Docket No. 22–AEA–8

Proposed Amendment of Class D Airspace and Class E Airspace, and Proposed Revocation of Class E Airspace; Poughkeepsie, NY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class D airspace and Class E surface airspace, and remove Class E airspace designated as an extension to a Class D surface area for Hudson Valley Regional Airport (POU), Poughkeepsie, NY, as an airspace evaluation determined an update is necessary. This action would update the airport's name and remove Kingston VORTAC from the Class E surface airspace description, as well as replace Airport/Facility Directory with Chart Supplement in the descriptions. This action would enhance the safety and management of controlled airspace within the national airspace system.

DATES: Comments must be received on or before July 7, 2022.

ADDRESSES: Send comments on this proposal to: The U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; Telephone: (800) 647–5527, or (202) 366–9826. You must identify the Docket No. FAA–2022–0524; Airspace Docket No. 22–AEA–8, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This proposed rulemaking is promulgated under the authority described in Subtitle VII, part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class D airspace and Class E surface airspace, and remove Class E airspace designated as an extension to a Class D surface area for Hudson Valley Regional Airport (POU), Poughkeepsie, NY, to support IFR operations in the area.

Comments Invited

Interested persons are invited to comment on this rule by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2022–0524 and Airspace Docket No. 22–AEA–8) and be submitted in triplicate to the DOT Docket Operations (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2022–0524; Airspace Docket No. 22–AEA–8.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays, at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists

Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to 14 CFR 71 to amend Class D airspace and Class E surface airspace, by increasing the radius to 4.4 miles (previously 4.0 miles), and amending the surface extensions. Also, this action would remove Class E airspace designated as an extension to a Class D surface area for Hudson Valley Regional Airport (POU), Poughkeepsie, NY, as the extensions will be included in the Class D description. This action would update the airport's name to Hudson Valley Regional Airport (formerly Dutchess County Airport), and remove Kingston VORTAC from the Class E surface airspace description, as well as replace Airport/Facility Directory with Chart Supplement in the descriptions. In addition, the city name would be removed from the airport's header, as per FAA Order 7400.2. This action would enhance the safety and management of controlled airspace within the national airspace system.

Class D and Class E airspace designations are published in Paragraphs 5000, 6002, and 6004, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal would be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AEA NY D Poughkeepsie, NY [Amended]

Hudson Valley Regional Airport, NY
(Lat. 41°37′36″ N, long. 73°53′03″ W)

That airspace extending upward from the surface to and including 2,700 feet MSL within a 4.4-mile radius of Hudson Valley Regional Airport (POU), and within 1.8 miles each side of the 051° bearing of the airport, extending from the 4.4-mile radius to 6.2 miles northeast of the airport, and within 1.0-miles each side of the 231° bearing of the airport, extending from the 4.4-mile radius to 6.2-miles southwest of the airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Surface Airspace.

* * * * *

AEA NY E2 Poughkeepsie, NY [Amended]

Hudson Valley Regional Airport, NY
(Lat. 41°37′36″ N, long. 73°53′03″ W)

That airspace extending upward from the surface within a 4.4-mile radius of Hudson Valley Regional Airport, and within 1.8 miles each side of the 051° bearing of the airport, extending from the 4.4-mile radius to 6.2 miles northeast of the airport, and within 1.0-miles each side of the 231° bearing of the airport, extending from the 4.4-mile radius to 6.2-miles southwest of the airport. This Class E airspace is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Designated as an Extension to Class D or E Surface Area.

* * * * *

AEA NY E4 Poughkeepsie, NY [Removed]

Issued in College Park, Georgia, on May 16, 2022.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2022–10839 Filed 5–20–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0432; Airspace Docket No. 22–ASO–5]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Greenwood, SC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace extending upward from 700 feet above the surface at Greenwood County Airport (GRD) Greenwood, SC, due to the decommissioning of the Coronaca non-directional beacon (NDB) and cancellation of associated approaches, as well as updating the airport's geographic coordinates. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Comments must be received on or before July 7, 2022.

ADDRESSES: Send comments on this proposal to: The U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; Telephone: (800) 647–5527, or (202) 366–9826. You must identify the Docket No. FAA–2022–0432; Airspace Docket No. 22–ASO–5 at the beginning of your comments. You may also submit

comments through the internet at *https://www.regulations.gov.*

FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would amend airspace in Greenwood, SC, to support IFR operations in the area.

Comments Invited

Interested persons are invited to comment on this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2021–0432 and Airspace Docket No. 22–ASO–5) and be submitted in triplicate to DOT Docket Operations (see **ADDRESSES** section for the address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2021–0432; Airspace Docket No. 22–ASO–5.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays, at the office of the Eastern Service Center, Federal Aviation Administration, Room 350,1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to 14 CFR part 71 to amend Class E airspace extending upward from 700 feet above the surface at Greenwood County Airport (GRD), Greenwood, SC, due to the decommissioning of the Coronaca NDB and cancellation of associated approaches. This action would eliminate the east extension and create an extension to the west. This action would also update the airport's geographic coordinates to coincide with the FAA's database.

Class E airspace designations are published in Paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO SC E5 Greenwood, SC [Amended]

Greenwood County Airport, SC
(Lat. 34°15′01″ N, long. 82°9′28″ W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Greenwood County Airport, and within 2-miles each side of the 265° bearing of the airport extending to 9.1-miles west of the airport.

Issued in College Park, Georgia, on May 16, 2022.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2022–10838 Filed 5–20–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 740, 742 and 774

[Docket No. 220516–0114]

RIN 0694–AI21

Commerce Control List: Controls on Certain Marine Toxins

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: The Bureau of Industry and Security (BIS), Department of Commerce, maintains controls on the export, reexport and transfer (in-country) of dual-use items and less sensitive military items through the Export Administration Regulations (EAR), including the Commerce Control List (CCL). This rule proposes new unilateral export controls on four naturally occurring, dual-use biological toxins (specifically, the marine toxins brevetoxin, gonyautoxin, nodularin and palytoxin), the synthesis and collection of which BIS has identified for evaluation according to the criteria in Section 1758 of the Export Control Reform Act of 2018 (ECRA) pertaining to emerging and foundational technologies. These toxins have the potential (through either accidental or deliberate release) to cause casualties in humans or animals, degrade equipment, or damage crops or the environment. As these toxins are now capable of being more easily isolated and purified due to novel synthesis methods and equipment, the absence of export controls on such toxins could be exploited for biological weapons purposes. To address this concern, BIS proposes to amend the CCL by adding these toxins to Export Control Classification Number (ECCN) 1C351. This rule also proposes several conforming changes to the EAR to reflect the proposed addition of these marine toxins to ECCN 1C351. In addition, this document requests public comments to ensure that the scope of these proposed controls will be effective and appropriate (with respect to their potential impact on legitimate commercial or scientific applications).

DATES: Comments must be received by BIS no later than June 22, 2022.

ADDRESSES: You may submit comments, identified by docket number BIS–2022–0013 or RIN 0694–AI21, through any of the following:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. You can find this proposed rule by searching for its *regulations.gov* docket number, which is BIS–2022–0013.
- *Email: PublicComments@bis.doc.gov.* Include RIN 0694–AI21 in the subject line of the message.

All filers using the portal or email should use the name of the person or entity submitting the comments as the name of their files, in accordance with the instructions below. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential submission.

For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters ''BC.'' Any page containing business confidential information must be clearly marked ''BUSINESS CONFIDENTIAL'' on the top of that page. The corresponding non-confidential version of those comments must be clearly marked ''PUBLIC.'' The file name of the non-confidential version should begin with the character ''P.'' The ''BC'' and ''P'' should be followed by the name of the person or entity submitting the comments. Any submissions with file names that do not begin with a ''P'' or ''BC'' will be assumed to be public and will be made publicly available through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For questions on the chemical and biological (CB) controls that would apply to the marine toxins proposed for control under ECCN 1C351, contact Dr. Tara Gonzalez, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 482–3343, Email: *Tara.Gonzalez@bis.doc.gov.* For questions on the submission of comments, contact Willard Fisher, Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce, (202) 482–6057, Email: *RPD2@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

Identification of Section 1758 Technologies

As part of the National Defense Authorization Act (NDAA) for Fiscal Year 2019, Public Law 115–232, Congress enacted the Export Control Reform Act of 2018 (ECRA), 50 U.S.C. 4801–4852. Section 1758 of ECRA (as codified under 50 U.S.C. 4817) authorizes the Bureau of Industry and Security (BIS) to establish appropriate controls on the export, reexport or transfer (in-country) of emerging and foundational technologies that are essential to the national security of the United States.

Neither Section 1758 nor any other section of ECRA defines the terms ''emerging technology'' or ''foundational technology.'' Further, ECRA does not provide guidance on how to differentiate between ''emerging technology'' and ''foundational technology.'' Since ECRA's enactment, BIS has solicited public comment on these two terms with the idea that defining the terms would assist in the identification of the technologies. To that end, BIS published numerous rules adding technologies to the CCL pursuant to Section 1758 without defining either term. Notably, pursuant to Section 1758, on November 19, 2018, BIS published an advance notice of proposed rulemaking, ''Review of Controls for Certain Emerging Technologies'' (83 FR 58201) (November 19 ANPRM). The November 19 ANPRM identified biotechnology in a representative list of fourteen

technology categories concerning which BIS sought public comment to determine whether there are specific emerging technologies that are essential to U.S. national security and for which effective controls can be implemented. The biotechnology-related comments submitted to BIS in response to its November 19 ANPRM did not specifically address the question of export controls on marine toxins and, consequently, this proposed rule does not address those comments. Since the publication of the November 19 ANPRM, BIS has published several rules imposing controls on emerging technologies and advance notices of proposed rulemaking that requested the public to comment on potential emerging technologies. Additionally, on August 27, 2020, BIS published an advance notice of proposed rulemaking (85 FR 52934) (August 27 ANPRM) that sought public comment on the definition of, and criteria for, identifying foundational technologies. BIS has found, however, that the categorization of the technologies has sometimes delayed the imposition of controls. Further, ECRA does not mandate that BIS define either term nor does ECRA require that either of the two categories be treated differently from the other.

Distinguishing Between Emerging and Foundational Technologies

Based on its prior experience with implementing the requirements of Section 1758 of ECRA, in making future determinations, BIS will not characterize a specific technology as ''emerging'' or ''foundational'' for purposes of Section 1758 of ECRA. Instead, BIS will characterize all technologies identified pursuant to Section 1758 as ''Section 1758 technologies'' without drawing a distinction between ''emerging'' or ''foundational'' technologies. This characterization will not affect the designation of ''critical technologies,'' for purposes of Committee on Foreign Investment in the United States (CFIUS) screenings, because technologies identified pursuant to Section 1758 of ECRA are ''critical technologies,'' pursuant to 50 U.S.C. 4565(a)(6)(A)(vi), regardless of whether such technologies are characterized as ''emerging'' or ''foundational.'' This characterization will also not affect the scope of controls on any technologies controlled consistent with Section 1758 of ECRA.

BIS is adopting this approach based on, among other sources, consultations with its interagency partners and a review of certain comments submitted in response to the November 19 ANPRM and the August 27 ANPRM, which sought public comment on ''emerging'' and ''foundational'' technologies, respectively.

One key consideration drawn from BIS and interagency experience is that technologies cannot always be readily categorized as either ''emerging'' or ''foundational'' technologies. A technology may be ''foundational'' in the sense of constituting an iterative improvement on technology already in production and use by one company, but simultaneously be ''emerging'' if such technology is only in the ''development'' stage (hence not in use) by other manufacturers. These challenges apply to the technologies that are the subject of this proposed rule.

Specifically, the four marine toxins (brevetoxin, gonyautoxin, nodularin and palytoxin) addressed in this proposed rule are naturally occurring and are not necessarily considered, by themselves, to be ''emerging'' technologies. Consequently, they could be evaluated as ''foundational,'' rather than ''emerging'' technologies. However, the synthesis and collection of these toxins could be evaluated as an ''emerging'' technology. Specifically, these toxins can now be more easily isolated and purified due to novel synthesis methods and equipment and, therefore, are capable of being more easily exploited for biological weapons purposes than in the past.

This proposed rule demonstrates some of the difficulties in attempting to draw meaningful and functional distinctions between ''emerging'' and ''foundational'' technologies, for the purpose of applying the criteria in ''Section 1758'' of ECRA to identify technologies essential to the national security of the United States that fall within the scope of this section. Similar challenges have made it difficult to characterize other technologies that have been proposed for addition to the Commerce Control List (CCL), Supp. No. 1 to part 774 of the EAR, pursuant to Section 1758 as ''emerging'' or ''foundational.'' Rather than attempting to continue to distinguish which new controls implemented pursuant to Section 1758 are ''emerging'' or ''foundational,'' BIS believes the government's resources and the mandate from Congress are better served identifying the technologies essential to U.S. national security under Section 1758.

BIS received several comments in response to the August 27 ANPRM that specifically requested that BIS set specific parameters by which foundational technologies would be defined. However, BIS does not believe the proposed parameters provided a meaningful distinction from ''emerging'' technologies. While BIS will not specify that a particular item is either ''foundational'' or ''emerging'' technology, it will continue to be informed by, among other things, the Statement of Policy in Section 1752 of ECRA (50 U.S.C. 4811), the reasons for control described in part 742 of the EAR, and relevant factors described in the November 19 and August 27 ANPRMs. Additionally, the identification of such technologies will take into account the statutory criteria in Section 1758(a)(2)(B) of ECRA: (i) The development of the emerging and foundational technologies in foreign countries; (ii) the effect export controls imposed pursuant to this section may have on the development of such technologies in the United States; and (iii) the effectiveness of export controls imposed pursuant to this section on limiting the proliferation of the emerging and foundational technologies in foreign countries.

Referring to these items as ''Section 1758 technologies'' without attempting to categorize individual technologies as ''emerging'' or ''foundational'' technology is consistent with the requirements of Section 1758, will facilitate more efficient interagency review of implementing regulations, and result in more timely implementation of such controls. As noted above, ECRA neither defines nor requires distinguishing between emerging and foundational technologies and there is no impact on the scope of controls on technologies whether they are described as emerging or foundational.

The Secretary of Commerce must establish appropriate controls on the export, reexport or transfer (in-country) of technology identified pursuant to the Section 1758 process, and in doing so, must consider the potential end-uses and end-users of emerging and foundational technologies, and the countries to which exports from the United States are restricted (*e.g.,* embargoed countries). While the Secretary has discretion to set the level of export controls, at a minimum a license must be required for the export of such technologies to countries subject to a U.S. embargo, including those countries subject to an arms embargo.

In addition, Section 1758(a)(2)(C) of ECRA (50 U.S.C. 4817(a)(2)(C)) requires that the interagency process for identifying Section 1758 technologies include a notice and comment period. Consequently, this proposed rule seeks public comments concerning the application of the criteria set forth in

ECRA Section 1758(a)(2), as well as the factors described above, to the proposed controls on four marine toxins as described below.

Proposed Section 1758 Controls on Four Marine Toxins

The synthesis and collection of four marine toxins (brevetoxin, gonyautoxin, nodularin and palytoxin) has been identified for evaluation, consistent with the interagency process described in Section 1758 of ECRA. This identification is based on a finding that, although these toxins are naturally occurring, dual-use biological toxins, they have the potential (through either accidental or deliberate release) to cause casualties in humans or animals, degrade equipment, or damage crops or the environment. As these toxins can now be more easily isolated and purified due to novel synthesis methods and equipment, the absence of export controls on such toxins could be exploited for biological weapons purposes.

Proposed Amendments to ECCN 1C351

Consistent with BIS's authority to evaluate the level of controls that would be appropriate for the export, reexport or transfer (in-country) of emerging technologies, this rule proposes to amend the CCL by adding the aforementioned marine toxins to ECCN 1C351.d. These toxins are not currently included on any of the Australia Group (AG) Common Control Lists—consequently, the Chemical/Biological (CB) controls that would apply to these toxins, as proposed by this rule, would be unilateral, absent the adoption of comparable controls by the AG. The toxins also would be controlled by ECCN 1C351.d for anti-terrorism (AT) reasons. The four marine toxins proposed for control by this proposed rule are described below.

Brevetoxins are neurotoxins produced by the marine dinoflagellate Karenia brevis [1] that bind to the voltage-gated sodium channels in nerve cells, leading to a disruption of normal neurological processes and causing neurotoxic shellfish poisoning. The potent neurotoxic and hemolytic properties of these neurotoxins can be fatal to fish, aquatic mammals, birds, and humans (although no fatalities have yet to be reported for humans [2]).

Gonyautoxins are part of the group of saxitoxins (currently controlled under ECCN 1C351.d.12) that are naturally produced in several marine dinoflagellates species.[3] Certain forms are included under Schedule 1 of the Chemical Weapons Convention (CWC) Annex on Chemicals. Gonyautoxins can bind to the α-subunit of the voltage dependent sodium channels in the postsynaptic membrane, blocking synaptic function (the transmission of nerve impulses between neurons or between neurons and muscle cells) and causing paralytic shellfish poisoning. Paralytic shellfish poisoning includes symptoms such as nausea, vomiting, dizziness, limb weakness, paralysis, or respiratory failure and can result in death.[4]

Nodularins are potent toxins that may cause irreversible liver damage.[5] Naturally produced in cyanobacteria, nodularin shares significant structural homology and, presumably, function with microcystins [6] (currently controlled under ECCN 1C351.d.9). Microcystins have been studied extensively, and due to the homology with nodularin, these data are often extended to nodularins.

Palytoxins are naturally produced in certain corals and dinoflagellates. These toxins are among the most toxic non-protein compounds and are of particular concern due to their thermostability and effective inhalation exposure route.[7] Palytoxins target the sodium-potassium pump protein, which may lead to vasoconstriction (the constriction of blood vessels through tightening of the small muscles in their walls). The most frequently reported routes of exposure/entry are through inhalation, ingestion, or via the cutaneous route (*i.e.,* direct contact with the skin or eyes). The symptoms of palytoxin poisoning, which may vary according to the route of exposure, include nausea, vomiting, diarrhea, lethargy, numbness, muscle spasms, slow heart rate, respiratory distress or kidney failure and can result in death. In lethal cases, death is generally caused by cardiac arrest.

This rule proposes to add these marine toxins, in alphabetical order, to ECCN 1C351.d and to amend the introductory text of 1C351.d by removing the reference to the AG control list (thereby reflecting the fact that these marine toxins would be subject to unilateral controls, absent the adoption of comparable controls by the AG). This rule also proposes to make conforming changes elsewhere in ECCN 1C351 to update references to certain toxins (*i.e.,* in the CW Reason for Control paragraph, License Requirements Notes 1 and 2, the License Exception STA eligibility paragraph and the Related Controls paragraph). The proposed conforming amendments to the Chemical Weapons Convention (CWC) and License Exception Strategic Trade Authorization (STA) provisions in the EAR are described below.

Proposed Expansion of ECCN 1E001 Controls

Although this rule does not propose to amend ECCN 1E001 (which controls, *inter alia,* ''technology'' for the ''development'' or ''production'' of the human and animal pathogens and ''toxins'' described in ECCN 1C351), the heading of ECCN 1E001 indicates that, with limited exceptions, ECCN 1E001 controls ''technology for the ''development'' or ''production'' of items listed under Category 1C of the CCL. Consequently, if the changes proposed in this rule were to go into effect, ECCN 1E001 would control ''technology'' for the ''development'' or ''production'' of the four marine toxins that would be added to ECCN 1C351. This expansion in the scope of ECCN 1E001 would be unilateral in nature, absent the adoption of comparable controls by the AG.

Other Conforming Amendments To Reflect the Proposed Reordering of Toxins in ECCN 1C351.d

This rule proposes to amend § 740.20—License Exception Strategic Trade Authorization (STA) to make conforming changes to the ECCN 1C351.d references in paragraph (b)(2)(v) and paragraph (b)(2)(vi). Specifically, § 740.20(b)(2)(v) would be amended to reference the exclusion of ECCN 1C351.d.15 and d.16 items from License Exception STA eligibility, consistent with the proposed renumbering of ricin and saxitoxin (which are currently controlled under ECCN 1C351.d.11 and d.12, respectively). Similarly, § 740.20(b)(2)(vi) would be amended, consistent with the proposed renumbering of the toxins in ECCN 1C351.d, by revising the references to

[1] Shen, H.H., et al. ''Profiling of Brevetoxin Metabolites Produced by Karenia Brevis 165 Based on Liquid Chromatography-Mass Spectrometry.'' *Toxins* 13.5 (2021).

[2] Per the NIH National Library of Medicine, National Center for Biotechnology Information.

[3] Visciano, P., et al. ''Marine Biotoxins: Occurrence, Toxicity, Regulatory Limits and Reference Methods.'' *Frontiers in Microbiology* 7 (2016).

[4] Clark, RF; Williams, SR; Nordt, SP; Manoguerra, AS (1999). ''A review of selected seafood poisonings.'' Undersea & Hyperbaric Medicine. 26 (3): 175–84.

[5] Dawson, R.M. ''The Toxicology of Microcystins.'' Toxicon. 36 (7): 953–962. (1998) doi:10.1016/S0041–0101(97)00102–5.

[6] Gehringer, M., et al. Nodularin, a cyanobacterial toxin, is synthesized in planta by symbiotic *Nostoc* sp.. *ISME* J 6, 1834–1847 (2012). *https://doi.org/10.1038/ismej.2012.25.*

[7] Ramos V, et al. ''Palytoxin and analogs: biological and ecological effects.'' *Marine Drugs.* 8 (7): 2021–37. (2010) doi:10.3390/md8072021.

the ECCN 1C351.d toxins that are authorized (with certain limitations) under License Exception STA to destinations indicated in Country Group A:5 (see Supplement No. 1 to part 740 of the EAR).

This rule also proposes to make conforming changes to § 742.18—Chemical Weapons Convention (CWC) and ECCN 1C991 (Vaccines, immunotoxins, medical products, diagnostic and food testing kits) to reflect the proposed renumbering of the toxins in ECCN 1C351.d. Specifically, § 742.18(a)(1), (b)(1)(i), and (b)(1)(ii) and (iii) would be amended to reference ECCN 1C351.d.15 and d.16, consistent with the proposed renumbering of ricin and saxitoxin described above. ECCN 1C991.c through 1C991.e would be amended to make conforming changes to the references therein to ECCN 1C351 that would be affected by the proposed renumbering of the toxins in ECCN 1C351.d.

None of the proposed conforming amendments described above would change the scope of the controls in the affected EAR provisions.

Request for Comments

BIS is publishing this proposed rule to obtain public comments on the proposed application of CB controls to the four marine toxins that are proposed for addition to ECCN 1C351 and to ''technology'' for the ''development'' or ''production'' of such toxins that would satisfy the control parameters described in ECCN 1E001. Consistent with Section 1758(a)(2)(C) of ECRA (50 U.S.C. 4817(a)(2)(C)), this proposed rule provides the public with notice and the opportunity to comment on controlling this technology as described herein. Specifically, BIS welcomes any comments on this proposed rule relevant to the following:

(1) Whether the proposed controls are clear and adequately identify ''emerging and foundational technologies'' within the context of biological weapons-related capabilities and developments (to the extent that this is not the case, comments should include specific control text that would be more appropriate to these ends);

(2) The current capability for the ''development'' or ''production'' of such toxins in the United States and other countries, including the extent to which the proposed controls would affect current production or sales of such toxins, either within or outside the United States (*e.g.,* whether the proposed controls would inadvertently control any toxins that are suitable almost exclusively for legitimate commercial or scientific applications);

(3) The effect that implementation of the proposed controls would have on the future ''development'' or ''production'' of such toxins and related ''technology'' in the United States; and

(4) The effectiveness of the proposed controls in terms of limiting the proliferation of such toxins and related ''technology'' abroad.

BIS also welcomes comments concerning whether these controls should be implemented multilaterally (rather than unilaterally), in the interest of increasing their effectiveness and minimizing their impact on U.S. industry. Several respondents who commented on BIS's November 19 ANPRM indicated their preference for multilateral export controls over unilateral export controls, because the former typically place U.S. industry on a more level playing field versus producers/suppliers in other countries. In this regard, note that Section 1758(c) of ECRA (50 U.S.C. 4817(c)) provides that ''the Secretary of State, in consultation with the Secretary [of Commerce] and the Secretary of Defense, and the heads of other Federal agencies, as appropriate, shall propose that any technology identified pursuant to subsection (a) [of ECRA] [which addresses the interagency process for identifying emerging technologies] be added to the list of technologies controlled by the relevant multilateral export control regimes.''

Public comments submitted to BIS in response to this proposed rule will help BIS and other U.S. Government agencies to apply the criteria set forth in Section 1758 of ECRA and identify and assess the appropriate level of controls that should apply to the four marine toxins proposed for control under ECCN 1C351 and ''technology'' for the ''development'' or ''production'' of such toxins, as proposed for control under ECCN 1E001.

Comments should address specific aspects of the proposed addition of these toxins to ECCN 1C351 on the CCL in relation to the criteria described above (*e.g.,* identify the specific aspects in which the proposed controls would satisfy these criteria or fail to do so). Comments should be submitted to BIS as described in the **ADDRESSES** section of this proposed rule and must be received by BIS no later than June 22, 2022.

Export Control Reform Act of 2018

The Export Control Reform Act of 2018 (ECRA), as amended, codified at 50 U.S.C. 4801–4852, serves as the authority under which BIS issues this proposed rule.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including: Potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits and of reducing costs, harmonizing rules, and promoting flexibility. This proposed rule has been designated a ''significant regulatory action,'' although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, this proposed rule has been reviewed by the Office of Management and Budget (OMB).

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This proposed rule contains the following collections of information subject to the requirements of the PRA:

- OMB control number 0694–0088 (Simplified Network Application Processing System)—this collection includes license applications and carries a burden estimate of 29.6 minutes per manual or electronic submission;
- OMB Control Number 0694–0096 (Five Year Records Retention Period)—this collection includes recordkeeping requirements and carries a burden estimate of less than 1 minute per response;
- OMB Control Number 0607–0152 (Automated Export System (AES) Program)—this collection carries a burden hour estimate of 3 minutes per electronic submission and contains the Electronic Export Information (EEI) filing requirements under the Automated Export System (AES).

Although this proposed rule would make important changes to the EAR for items controlled for CB reasons, BIS believes that these increases would not greatly exceed existing estimates. BIS does believe the number of applications will increase by 15 because, although there are few (if any) commercial applications for these marine toxins, a small number of these toxins may be exported for use in research and

development activities. BIS requests comments concerning the anticipated increase in burden hours and costs as a result of the changes proposed by this rule. Comments on the methodology associated with calculating the cost or burden increases, or any other aspect of this collection, may be submitted via *www.regulations.gov* by searching for OMB Control Number 0694–0088.

BIS expects the burden hours associated with OMB control numbers 0694–0088 and 0694–0096 to increase by 7 hours and 39 minutes (*i.e.,* 15 applications × 30.6 minutes per response) for a total estimated cost increase of $230 (*i.e.,* 7 hours and 39 minutes × $30 per hour). The $30 per hour cost estimate for OMB control number 0694–0088 is consistent with the salary data for export compliance specialists currently available through *glassdoor.com* (*glassdoor.com* estimates that an export compliance specialist makes $55,280 annually, which computes to roughly $26.58 per hour). Note that any increase in the burden hours associated with OMB control number 0607–0152 would not necessarily be in direct correlation with any increase in the aforementioned OMB information collections, because there could be multiple shipments (and, hence, multiple EEI filings) associated with an individual export license.

3. This proposed rule does not contain policies with federalism implications as that term is defined in Executive Order 13132.

4. Pursuant to Section 1762 of the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4821), this action is exempt from the Administrative Procedure Act (APA) (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation and delay in effective date. Notwithstanding, BIS believes this proposed rule would benefit from public comment prior to issuance. Consistent with the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq.*), BIS has prepared the following initial regulatory flexibility analysis (IRFA) of the impact that this proposed rule, if adopted, would have on small businesses.

Description of the Reasons Why Action Is Being Considered

The policy reasons for issuing this proposed rule are discussed in the background section of the preamble of this document and, consequently, are not repeated here.

Statement of the Objectives of, and Legal Basis for, the Proposed Rule; Identification of All Relevant Federal Rules Which May Duplicate, Overlap or Conflict With the Proposed Rule

The objective of this proposed rule, and all other Section 1758 technology proposed rules published by BIS, is to control emerging and foundational technologies identified by BIS and its interagency partners as being essential to U.S. national security. The legal basis for this proposed rule is as follows: 50 U.S.C. 4801–4852.

No other Federal rules duplicate, overlap, or conflict with this proposed rule.

Number and Description of Small Entities Regulated by the Proposed Action

This proposed rule would apply to all persons engaged in the export, reexport or transfer (in-country) of the marine toxins proposed for control under ECCN 1C351 and the related ''technology'' subject to the EAR. Presently, these toxins and related ''technology'' are used in research and development activities in the biotechnology field (*e.g.,* U.S. university and military laboratories). Therefore, BIS anticipates that the proposed controls would result in 'deemed' export license applications (for the release of ''technology'' to foreign nationals located within the United States) to allow access to this ''technology'' by foreign students and faculty at U.S. universities, as well as by non-U.S. employees of U.S. biochemical firms. There would most likely also be 'deemed' reexport license applications for the release of this ''technology'' to third-country foreign nationals located in foreign countries who are engaged in research and development activities involving this ''technology.''

BIS does not collect or maintain the data necessary to determine how many of the affected persons are small entities as that term is used by the Small Business Administration. Prior to issuing this proposed rule, BIS received 36 comments on biotechnology in response to its November 19 ANPRM. None of these commenters specifically identified themselves as small businesses, although small businesses may have chosen to provide input through larger entities, such as trade associations.

However, BIS was able to estimate the number of license applications that the agency anticipates receiving as a result of this proposed rule and is using that estimate as a means of assessing the impact on small businesses. Using the North American Industry Classification System Codes (NAICS) 541714 (Research and Technology in Biotechnology (except Nanobiotechnology)), BIS determined that the standard small business size in this industry is 1,000 employees. Using Table 1a of the Census Bureau's 2019 Exports by Company Type and Employment Size and extrapolating to 1,000 employees, BIS then estimated that approximately 40% of all identified companies that export in this industry are small businesses. BIS also estimates that it will receive 15 license applications per year for the items described in this proposed rule (see the PRA estimates described in Rulemaking Requirements #2, above). Based on that information, BIS estimates that the agency will receive approximately 6 license applications per year from small businesses, or roughly 40% of the 15 estimated license applications.

In addition, based on the burden estimate for OMB under control numbers 0694–0088 (Simplified Network Application Processing System) and 0694–0096 (Five Year Records Retention Period), BIS expects that the total burden hours for small businesses associated with these EAR-related collections would increase only slightly, by just under 3 hours and 4 minutes (*i.e.,* 6 applications × 30.6 minutes per response), for a total estimated cost increase of just under $92 (*i.e.,* 3 hours and 4 minutes × $30 per hour).

The amendments proposed in this rule, if implemented, also would trigger a small information collection burden under the U.S. Census Bureau's Foreign Trade Regulations (FTR) (15 CFR part 30), which contain the Electronic Export Information (EEI) filing requirements under the Automated Export System (AES). This FTR-related information collection has been approved by OMB under control number 0607–0152 (Automated Export System (AES) Program) and carries a burden hour estimate of 3 minutes per electronic submission. This collection, together with the aforementioned EAR-related information collections, would result in a total estimated cost increase to small businesses of just under $94 (*i.e.,* 3 hours and 7 minutes × $30 per hour). Note that, for purposes of consistency, the $30 per hour cost estimate used for the EAR-related information collections described above is also applied to this FTR-related information collection (which also would involve work performed by export compliance specialists).

Based on the analysis provided above, the amendments proposed in this rule would not impose a significant

economic impact on a substantial number of small businesses.

Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule

The changes proposed in this rule, if adopted, would mean that certain items currently eligible for export, reexport or transfer (in-country) to most destinations under the No License Required (NLR) designation would require an EAR authorization (*i.e.,* in accordance with the terms and conditions of an EAR license exception or a license issued by BIS). Adding these items to the CCL, to be controlled under ECCN 1C351, may also change the export clearance requirements under the FTR for certain exports of these items by triggering an EEI filing requirement in AES (note that the requirement generally does not apply to items below a certain value that are classified as EAR99, *i.e.,* subject to the EAR, but not listed under an ECCN on the CCL).

To the extent that compliance with the changes proposed in this rule would impose a burden on persons, including small businesses, BIS believes the burden would be minimal. The reclassification process would need to be done only once per license applicant for exports, reexports or transfers (in-country) of these emerging technology items and, consequently, would constitute a one-time burden for each applicant. Similarly, assessing the availability of license exceptions and/or applying for and using BIS licenses would impose some minimal burden on persons, including small businesses.

However, it should be noted that these EAR requirements would likely have less impact than might otherwise be the case, because of the resources that BIS makes available to all exporters, including small businesses. Specifically, BIS's website has free on-line training explaining export basics, including instructions on how to register for and use BIS's online license application tool, and tips on how to complete a license application for chemical and biological items. BIS also provides free export counseling by telephone and email via both its Washington, DC and Western Regional offices. In addition, BIS accepts requests for commodity classifications and processes them without charge to assist those exporters who need assistance in classifying their items for the purpose of determining whether any CCL-based license requirements would apply.

Significant Alternatives and Underlying Analysis

As noted above, BIS does not believe that the amendments proposed in this rule, if published in a final rule, would have a significant economic impact on small businesses. Nevertheless, consistent with 5 U.S.C. 603(c), BIS considered significant alternatives to these proposed amendments to assess whether the alternatives would: (1) Accomplish the stated objectives of this proposed rule (consistent with the emerging technology requirements in ECRA); and (2) minimize any significant economic impact of this proposed rule on small entities. BIS could have proposed a much broader control on marine toxins controlled under ECCN 1C351 that would have captured a greater number of such toxins. However, that option would have had a greater impact not only on small businesses, but also on research and development laboratories (both academic and corporate), which are involved in advancing biological technology. BIS has determined that proposing focused controls on those marine toxins capable of posing a greater risk to human/animal health and the environment (*i.e.,* the four toxins proposed for control under ECCN 1C351 and corresponding ''development'' and production ''technology'' in ECCN 1E001) is the least disruptive alternative for implementing export controls in a manner consistent with controlling technology that has been determined, through the Section 1758 technology interagency process authorized under ECRA, to be essential to U.S. national security.

BIS is not proposing different compliance or reporting requirements for small businesses. If a small business is subject to a compliance requirement for the export, reexport or transfer (in-country) of this ''software'' and related ''technology,'' then it would submit a license application using the same process as any other company (*i.e.,* electronically via SNAP–R). The license application process is free of charge to all entities, including small businesses. In addition, as noted above, the resources and other compliance tools made available by BIS typically serve to lessen the impact of any EAR license requirements on small businesses.

Lastly, consistent with 5 U.S.C. 603(c), BIS assessed the use of performance standards rather than design standards and also considered whether an exemption for small businesses was practical under the circumstances (*i.e.,* within the context of the changes proposed in this rule).

BIS determined that the use of design standards was the most appropriate approach for regulating exports/reexports of these toxins. Although the marine toxins that warrant control under this proposed rule are naturally occurring, dual-use biological toxins, they can now be more easily isolated and purified due to novel synthesis methods and equipment. For this reason, the absence of export controls on such toxins could be exploited for biological weapons purposes. However, because these toxins and related ''technology'' are dual-use items, they also have legitimate commercial and scientific applications. Consequently, controlling these toxins and the related ''technology'' based on design standards is the most appropriate way to impose export controls in a manner that would enhance U.S. national security, but also consider the legitimate commercial and scientific applications for these toxins.

This proposed rule does not contain an exemption for small businesses from this license requirement because BIS and its interagency partners are assessing whether these controls are essential to U.S. national security. Specifically, these toxins and related ''technology'' could be used for biological weapons purposes and, as such, controlling these items on the CCL may be determined to be essential to U.S. national security pursuant to the interagency process for identifying emerging and foundational technologies that is described in Section 1758(a) of ECRA (50 U.S.C. 4817(a)). An exemption for small businesses would undermine the effectiveness of these proposed controls.

Conclusion

BIS has identified the synthesis and collection of the marine toxins and the related ''technology'' addressed in this proposed rule as a technology suitable for evaluation under Section 1758 of ECRA that warrants public notice and comment. Consequently, consistent with the Regulatory Flexibility Act, BIS has prepared this IRFA addressing the impact that this proposed rule, if adopted, would have on small entities. BIS's assessment indicates that the amendments proposed in this rule would not have a significant economic impact on a substantial number of small entities.

Please submit any comments concerning this IRFA in accordance with the instructions provided in the **ADDRESSES** section of this proposed rule.

List of Subjects

15 CFR Part 740

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements, Terrorism.

For the reasons stated in the preamble, parts 740, 742 and 774 of the Export Administration Regulations (15 CFR parts 730–774) are proposed to be amended as follows:

PART 740—LICENSE EXCEPTIONS

■ 1. The authority citation for part 740 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 7201 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 2. Section 740.20 is amended by revising paragraph (b)(2)(v) and paragraph (b)(2)(vi) introductory text to read as follows:

§ 740.20 License Exception Strategic Trade Authorization (STA).

* * * * *

(b) * * *

(2) * * *

(v) License Exception STA may not be used for any item controlled by ECCN 1C351.a, .b, .c, .d.15, .d.16 or .e, ECCNs 1C353, 1C354, 1E001 (*i.e.,* for technology, as specified in ECCN 1E001, for items controlled by ECCN 1C351.a, .b, .c, .d.15, .d.16 or .e or ECCNs 1C353 or 1C354) or ECCN 1E351.

(vi) Toxins controlled by ECCN 1C351.d.1 through 1C351.d.14 and 1C351.d.17 through 1C351.d.22 are authorized under License Exception STA to destinations indicated in Country Group A:5 (See supplement no. 1 to part 740), subject to the following limits. For purposes of this paragraph (b)(2)(vi), all such toxins that are sent from one exporter, reexporter or transferor to a single end-user, on the same day, constitute one shipment.

* * * * *

PART 742—CONTROL POLICY—CCL BASED CONTROLS

■ 3. The authority citation for part 742 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Notice of November 10, 2021, 86 FR 62891 (November 12, 2021).

■ 4. Section 742.18 is amended by revising paragraph (a)(1), paragraph (b)(1)(i) introductory text, and paragraphs (b)(1)(ii) and (iii) to read as follows:

§ 742.18 Chemical Weapons Convention (CWC or Convention).

* * * * *

(a) * * *

(1) Schedule 1 chemicals and mixtures controlled under ECCN 1C351. A license is required for CW reasons to export or reexport Schedule 1 chemicals controlled under ECCN 1C351.d.15 or .d.16 to all destinations including Canada. CW applies to 1C351.d.15 for ricin in the form of Ricinus Communis AgglutininII (RCA_{II}), which is also known as ricin D or Ricinus Communis LectinIII (RCL_{III}), and Ricinus Communis LectinIV (RCL_{IV}), which is also known as ricin E. CW applies to 1C351.d.16 for saxitoxin identified by C.A.S. #35523–89–8. (Note that the advance notification procedures and annual reporting requirements described in § 745.1 of the EAR also apply to exports of Schedule 1 chemicals.)

* * * * *

(b) * * *

(1) * * *

(i) *Exports to States Parties to the CWC.* Applications to export Schedule 1 Chemicals controlled under ECCN 1C351.d.15 or .d.16 to States Parties to the CWC (destinations listed in supplement no. 2 to part 745 of the EAR) generally will be denied, unless all of the following conditions are met:

* * * * *

(ii) *Exports to States not party to the CWC.* Applications to export Schedule 1 chemicals controlled under ECCN 1C351.d.15 or .d.16 to States not Party to the CWC (destinations not listed in supplement no. 2 to part 745 of the EAR) generally will be denied, consistent with U.S. obligations under the CWC to prohibit exports of these chemicals to States not Party to the CWC.

(iii) *Reexports.* Applications to reexport Schedule 1 chemicals controlled under ECCN 1C351.d.15 or .d.16 generally will be denied to all destinations (including both States Parties to the CWC and States not Party to the CWC).

* * * * *

PART 774—THE COMMERCE CONTROL LIST

■ 5. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 6. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1, revise ECCNs 1C351 and 1C991 to read as follows:

Supplement No. 1 to Part 774—The Commerce Control List

* * * * *

1C351 Human and animal pathogens and "toxins," as follows (see List of Items Controlled).

License Requirements

Reason for Control: CB, CW, AT

Control(s)	*Country chart (see Supp. No. 1 to part 738)*
CB applies to entire entry.	CB Column 1

CW applies to 1C351.d.15 and .d.16 and a license is required for CW reasons for all destinations, including Canada, as follows: CW applies to 1C351.d.15 for ricin in the form of (1) Ricinus communis AgglutininII (RCA_{II}), also known as ricin D or Ricinus Communis LectinIII (RCL_{III}) and (2) Ricinus communis LectinIV (RCL_{IV}), also known as ricin E. CW applies to 1C351.d.16 for saxitoxin identified by C.A.S. #35523–89–8. See § 742.18 of the EAR for licensing information pertaining to chemicals subject to restriction pursuant to the Chemical Weapons Convention (CWC). The Commerce Country Chart is not designed to determine licensing requirements for items controlled for CW reasons.

Control(s)	*Country chart (see Supp. No. 1 to part 738)*
AT applies to entire entry.	AT Column 1.

License Requirement Notes: 1. All vaccines and 'immunotoxins' are excluded from the scope of this entry. Certain medical products and diagnostic and food testing kits that contain biological toxins controlled under 1C351.d, with the exception of toxins controlled for CW reasons under 1C351.d.15 or .d.16, are excluded from the scope of this entry. Vaccines, 'immunotoxins,' certain medical products, and diagnostic and food testing kits excluded from the scope of this entry are controlled under ECCN 1C991.

2. For the purposes of this entry, only saxitoxin is controlled under 1C351.d.16; other members of the paralytic shellfish poison family (e.g., neosaxitoxin) are designated EAR99.

3. Clostridium perfringens strains, other than the epsilon toxin-producing strains of Clostridium perfringens described in 1C351.c.12, are excluded from the scope of this entry, since they may be used as positive control cultures for food testing and quality control.

4. Unless specified elsewhere in this ECCN 1C351 (e.g., in License Requirement Notes 1–3), this ECCN controls all biological agents and ''toxins,'' regardless of quantity or attenuation, that are identified in the List of Items Controlled for this ECCN, including small quantities or attenuated strains of select biological agents or ''toxins'' that are excluded from the lists of select biological agents or ''toxins'' by the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), or the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (HHS), in accordance with their regulations in 9 CFR part 121 and 42 CFR part 73, respectively.

5. Biological agents and pathogens are controlled under this ECCN 1C351 when they are an isolated live culture of a pathogen agent, or a preparation of a toxin agent that has been isolated or extracted from any source or material, including living material that has been deliberately inoculated or contaminated with the agent. Isolated live cultures of a pathogen agent include live cultures in dormant form or in dried preparations, whether the agent is natural, enhanced or modified.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A
GBS: N/A

Special Conditions for STA

STA: (1) Paragraph (c)(1) of License Exception STA (§ 740.20(c)(1)) may be used for items in 1C351.d.1 through 1C351.d.14 and 1C351.d.17 through 1C351.d.22. See § 740.20(b)(2)(vi) for restrictions on the quantity of any one toxin that may be exported in a single shipment and the number of shipments that may be made to any one end user in a single calendar year. Also see the Automated Export System (AES) requirements in § 758.1(b)(4) of the EAR. (2) Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any items in 1C351.

List of Items Controlled

Related Controls: (1) Certain forms of ricin and saxitoxin in 1C351.d.15 and .d.16 are CWC Schedule 1 chemicals (see § 742.18 of the EAR). The U.S. Government must provide advance notification and annual reports to the OPCW of all exports of Schedule 1 chemicals. See § 745.1 of the EAR for notification procedures. See 22 CFR part 121, Category XIV and § 121.7 for CWC Schedule 1 chemicals that are ''subject to the ITAR.'' (2) The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, and the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, maintain controls on the possession, use, and transfer within the United States of certain items controlled by this ECCN (for APHIS, see 7 CFR 331.3(b), 9 CFR 121.3(b), and 9 CFR 121.4(b); for CDC, see 42 CFR 73.3(b) and 42 CFR 73.4(b)). (3) See 22 CFR part 121, Category XIV(b), for modified biological agents and biologically derived substances that are ''subject to the ITAR.''

Related Definitions: For the purposes of this entry, 'immunotoxins' are monoclonal antibodies linked to a toxin with the intention of destroying a specific target cell while leaving adjacent cells intact.

Items:

a. Viruses identified on the Australia Group (AG) ''List of Human and Animal Pathogens and Toxins for Export Control,'' as follows:

a.1. African horse sickness virus;
a.2. African swine fever virus;
a.3. Andes virus;
a.4. Avian influenza (AI) viruses identified as having high pathogenicity (HP), as follows:
a.4.a. AI viruses that have an intravenous pathogenicity index (IVPI) in 6-week-old chickens greater than 1.2; *or*
a.4.b. AI viruses that cause at least 75% mortality in 4- to 8-week-old chickens infected intravenously.

Note: Avian influenza (AI) viruses of the H5 or H7 subtype that do not have either of the characteristics described in 1C351.a.4 (specifically, 1C351.a.4.a or .a.4.b) should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0). If the amino acid motif is similar to that observed for other HPAI isolates, then the isolate being tested should be considered as HPAI and the virus is controlled under 1C351.a.4.

a.5. Bluetongue virus;
a.6. Chapare virus;
a.7. Chikungunya virus;
a.8. Choclo virus;
a.9. Classical swine fever virus (Hog cholera virus);
a.10. Crimean-Congo hemorrhagic fever virus;
a.11. Dobrava-Belgrade virus;
a.12. Eastern equine encephalitis virus;
a.13. Ebolavirus (includes all members of the Ebolavirus genus);
a.14. Foot-and-mouth disease virus;
a.15. Goatpox virus;
a.16. Guanarito virus;
a.17. Hantaan virus;
a.18. Hendra virus (Equine morbillivirus);
a.19. Japanese encephalitis virus;
a.20. Junin virus;
a.21. Kyasanur Forest disease virus;
a.22. Laguna Negra virus;
a.23. Lassa virus;
a.24. Louping ill virus;
a.25. Lujo virus;
a.26. Lumpy skin disease virus;
a.27. Lymphocytic choriomeningitis virus;
a.28. Machupo virus;
a.29. Marburgvirus (includes all members of the Marburgvirus genus);
a.30. Middle East respiratory syndrome-related coronavirus (MERS-related coronavirus);
a.31. Monkeypox virus;
a.32. Murray Valley encephalitis virus;
a.33. Newcastle disease virus;
a.34. Nipah virus;
a.35. Omsk hemorrhagic fever virus;
a.36. Oropouche virus;
a.37. Peste-des-petits ruminants virus;
a.38. Porcine Teschovirus;
a.39. Powassan virus;
a.40. Rabies virus and all other members of the Lyssavirus genus;
a.41. Reconstructed 1918 influenza virus;

Technical Note: 1C351.a.41 includes reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments.

a.42. Rift Valley fever virus;
a.43. Rinderpest virus;
a.44. Rocio virus;
a.45. Sabia virus;
a.46. Seoul virus;
a.47. Severe acute respiratory syndrome-related coronavirus (SARS-related coronavirus);
a.48. Sheeppox virus;
a.49. Sin Nombre virus;
a.50. St. Louis encephalitis virus;
a.51. Suid herpesvirus 1 (Pseudorabies virus; Aujeszky's disease);
a.52. Swine vesicular disease virus;
a.53. Tick-borne encephalitis virus (Far Eastern subtype, formerly known as Russian Spring–Summer encephalitis virus—see 1C351.b.3 for Siberian subtype);
a.54. Variola virus;
a.55. Venezuelan equine encephalitis virus;
a.56. Vesicular stomatitis virus;
a.57. Western equine encephalitis virus; *or*
a.58. Yellow fever virus.

b. Viruses identified on the APHIS/CDC ''select agents'' lists (see Related Controls paragraph #2 for this ECCN), but not identified on the Australia Group (AG) ''List of Human and Animal Pathogens and Toxins for Export Control,'' as follows:

b.1. [Reserved];
b.2. [Reserved]; *or*
b.3. Tick-borne encephalitis virus (Siberian subtype, formerly West Siberian virus—see 1C351.a.53 for Far Eastern subtype).

c. Bacteria identified on the Australia Group (AG) ''List of Human and Animal Pathogens and Toxins for Export Control,'' as follows:

c.1. Bacillus anthracis;
c.2. Brucella abortus;
c.3. Brucella melitensis;
c.4. Brucella suis;
c.5. Burkholderia mallei (Pseudomonas mallei);
c.6. Burkholderia pseudomallei (Pseudomonas pseudomallei);
c.7. Chlamydia psittaci (Chlamydophila psittaci);
c.8. Clostridium argentinense (formerly known as Clostridium botulinum Type G), botulinum neurotoxin producing strains;
c.9. Clostridium baratii, botulinum neurotoxin producing strains;
c.10. Clostridium botulinum;
c.11. Clostridium butyricum, botulinum neurotoxin producing strains;

c.12. Clostridium perfringens, epsilon toxin producing types;
c.13. Coxiella burnetii;
c.14. Francisella tularensis;
c.15. Mycoplasma capricolum subspecies capripneumoniae (''strain F38'');
c.16. Mycoplasma mycoides subspecies mycoides SC (small colony) (a.k.a. contagious bovine pleuropneumonia);
c.17. Rickettsia prowazekii;
c.18. Salmonella enterica subspecies enterica serovar Typhi (Salmonella typhi);
c.19. Shiga toxin producing Escherichia coli (STEC) of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups;
Note: Shiga toxin producing Escherichia coli (STEC) includes, inter alia, enterohaemorrhagic E. coli (EHEC), verotoxin producing E. coli (VTEC) or verocytotoxin producing E. coli (VTEC).
c.20. Shigella dysenteriae;
c.21. Vibrio cholerae; *or*
c.22. Yersinia pestis.
d. ''Toxins,'' as follows, or their subunits:
d.1. Abrin;
d.2. Aflatoxins;
d.3. Botulinum toxins;
d.4. Brevetoxin;
d.5. Cholera toxin;
d.6. Clostridium perfringens alpha, beta 1, beta 2, epsilon and iota toxins;
d.7. Conotoxins;
d.8. Diacetoxyscirpenol;
d.9. Gonyautoxin;
d.10. HT–2 toxin;
d.11. Microcystins (Cyanginosins);
d.12. Modeccin;
d.13. Nodularin;
d.14. Palytoxin;
d.15. Ricin;
d.16. Saxitoxin;
d.17. Shiga toxins (shiga-like toxins, verotoxins, and verocytotoxins);
d.18. Staphylococcus aureus enterotoxins, hemolysin alpha toxin, and toxic shock syndrome toxin (formerly known as Staphylococcus enterotoxin F);
d.19. T–2 toxin;
d.20. Tetrodotoxin;
d.21. Viscumin (Viscum album lectin 1); *or*
d.22. Volkensin.
e. ''Fungi'', as follows:
e.1. Coccidioides immitis; *or*
e.2. Coccidioides posadasii.

* * * * *

1C991 Vaccines, immunotoxins, medical products, diagnostic and food testing kits, as follows (see List of Items Controlled).

License Requirements

Reason for Control: CB, AT

Control(s)	*Country chart (see Supp. No. 1 to part 738)*
CB applies to 1C991.c.	CB Column 3
AT applies to entire entry.	AT Column 1

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A

GBS: N/A

List of Items Controlled

Related Controls: (1) Medical products containing ricin or saxitoxin, as follows, are controlled for CW reasons under ECCN 1C351:
(a) Ricinus communis AgglutininII (RCA_{II}), also known as ricin D, or Ricinus Communis LectinIII (RCL_{III});
(b) Ricinus communis LectinIV (RCL_{IV}), also known as ricin E; *or*
(c) Saxitoxin identified by C.A.S. #35523–89–8.
(2) The export of a ''medical product'' that is an ''Investigational New Drug'' (IND), as defined in 21 CFR 312.3, is subject to certain U.S. Food and Drug Administration (FDA) requirements that are independent of the export requirements specified in this ECCN or elsewhere in the EAR. These FDA requirements are described in 21 CFR 312.110 and must be satisfied in addition to any requirements specified in the EAR.
(3) Also see 21 CFR 314.410 for FDA requirements concerning exports of new drugs and new drug substances.

Related Definitions: For the purpose of this entry, 'immunotoxins' are monoclonal antibodies linked to a toxin with the intention of destroying a specific target cell while leaving adjacent cells intact. For the purpose of this entry, 'medical products' are: (1) Pharmaceutical formulations designed for testing and human (or veterinary) administration in the treatment of medical conditions; (2) prepackaged for distribution as clinical or medical products; and (3) approved by the U.S. Food and Drug Administration either to be marketed as clinical or medical products or for use as an ''Investigational New Drug'' (IND) (see 21 CFR part 312). For the purpose of this entry, 'diagnostic and food testing kits' are specifically developed, packaged and marketed for diagnostic or public health purposes. Biological toxins in any other configuration, including bulk shipments, or for any other end-uses are controlled by ECCN 1C351. For the purpose of this entry, 'vaccine' is defined as a medicinal (or veterinary) product in a pharmaceutical formulation, approved by the U.S. Food and Drug Administration or the U.S. Department of Agriculture to be marketed as a medical (or veterinary) product or for use in clinical trials, that is intended to stimulate a protective immunological response in humans or animals in order to prevent disease in those to whom or to which it is administered.

Items:

Technical Note: For purposes of the controls described in this ECCN, 'toxins' refers to those toxins, or their subunits, controlled under ECCN 1C351.d.
a. Vaccines containing, or designed for use against, items controlled by ECCN 1C351, 1C353 or 1C354.
b. Immunotoxins containing toxins controlled by 1C351.d;
c. Medical products that contain any of the following:
c.1. Toxins controlled by ECCN 1C351.d (except for botulinum toxins controlled by ECCN 1C351.d.3, conotoxins controlled by ECCN 1C351.d.7, or items controlled for CW reasons under ECCN 1C351.d.15 or .d.16); *or*
c.2. Genetically modified organisms or genetic elements controlled by ECCN 1C353.a.3 (except for those that contain, or code for, botulinum toxins controlled by ECCN 1C351.d.3 or conotoxins controlled by ECCN 1C351.d.7);
d. Medical products not controlled by 1C991.c that contain any of the following:
d.1. Botulinum toxins controlled by ECCN 1C351.d.3;
d.2. Conotoxins controlled by ECCN 1C351.d.7; *or*
d.3. Genetically modified organisms or genetic elements controlled by ECCN 1C353.a.3 that contain, or code for, botulinum toxins controlled by ECCN 1C351.d.3 or conotoxins controlled by ECCN 1C351.d.7;
e. Diagnostic and food testing kits containing toxins controlled by ECCN 1C351.d (except for items controlled for CW reasons under ECCN 1C351.d.15 or .d.16).

* * * * *

Thea D. Rozman Kendler,
Assistant Secretary for Export Administration.

[FR Doc. 2022–10907 Filed 5–20–22; 8:45 am]
BILLING CODE 3510–33–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0355]

RIN 1625–AA00

Safety Zone; Lake Erie, Cleveland, OH

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary safety zone for certain waters of Lake Erie. This action is necessary to provide for the safety of life on these navigable waters near Cleveland, OH, during the Tall Ships Cleveland event fireworks display tri-annually in July. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Buffalo 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 June 22, 2022.

ADDRESSES: You may submit comments identified by docket number USCG–2022–0355 using the Federal eRulemaking 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.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email LT Jared Stevens, Waterways Management Division, MSU Cleveland, U.S. Coast Guard; telephone 216–937–0124, email *Jared.M.Stevens@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

On January 28, 2022, Tall Ships America notified the Coast Guard that it will be conducting a Tall Ships fireworks display tri-annually in July. Hazards from the fireworks display may include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The event fireworks are to be launched from the Cleveland Port Authority Terminal adjacent to Lake Erie, Cleveland, Ohio. The Captain of the Port Buffalo (COTP) has determined that potential hazards associated with the fireworks to be used in this display would be a safety concern for anyone within a 420-foot radius of the Cleveland Port Authority during the fireworks display.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within a 420 foot radius of the fireworks, before, during, and after the scheduled event.

The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231).

III. Discussion of Proposed Rule

The COTP is proposing to establish a safety zone tri-annually in July. This safety zone will cover all navigable waters within a 420-foot radius of the fireworks display, before, during, and after the scheduled event. The duration of the zone is intended to ensure the safety of vessels and these navigable waters during the scheduled Tall Ships fireworks display.

No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP 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, and we discuss First Amendment rights of protestors.

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 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 the size, location, and duration of the proposed rule. This safety zone would restrict navigation around the Tall Ships fireworks display triannually with a limited radius from the fireworks launch point for a period not likely to exceed 6 hours. Vessel traffic will be able to safely transit around the safety zone. Moreover, the rule would allow vessels to seek permission to enter the zone.

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 safety 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 a triannual safety zone for a fireworks display that would prohibit vessel navigation within 420 feet of the Cleveland Port Authority before, during and after the display.

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.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

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–2022–0355 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. 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; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.9XX to read as follows:

§ 165.9XX Safety Zone; Lake Erie, Cleveland, OH

(a) *Location.* All navigable waters of Lake Erie adjacent to Cleveland, OH, within a 420-foot radius from the fireworks launch site located near Port of Cleveland Dock 20.

(b) *Definitions. Official Patrol Vessel* 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, or local officer designated by or assisting the Captain of the Port Buffalo (COTP) in the enforcement of the regulations in this section. *Participant* means all persons and vessels attending the event.

(c) *Regulations.* (1) The Coast Guard may patrol the event area under the direction of a designated Coast Guard Patrol Commander. The Patrol Commander may be contacted on Channel 16 VHF–FM (156.8 MHz) by the call sign ''PATCOM.''

(2) All persons and vessels not registered with the sponsor as participants or official patrol vessels are considered spectators. The ''official patrol vessels'' consist of any Coast Guard, state, or local law enforcement and sponsor provided vessels designated or assigned by the Captain of the Port Buffalo to patrol the event.

(3) Spectator vessels desiring to transit the regulated area may do so only with prior approval of the Patrol Commander and when so directed by that officer and will be operated at a no wake speed in a manner which will not endanger participants in the event or any other craft.

(4) No spectator shall anchor, block, loiter, or impede the through transit of official patrol vessels in the regulated area during the effective dates and times, unless cleared for entry by or through an official patrol vessel.

(5) The Patrol Commander may forbid and control the movement of all vessels in the regulated area. When hailed or signaled by an official patrol vessel, a vessel shall come to an immediate stop and comply with the directions given. Failure to do so may result in expulsion from the area, citation for failure to comply, or both.

(6) Any spectator vessel may anchor outside the regulated areas specified in this chapter, but may not anchor in, block, or loiter in a navigable channel.

(7) The Patrol Commander may terminate the event or the operation of any vessel at any time it is deemed necessary for the protection of life or property.

(8) The Patrol Commander will terminate enforcement of the special regulations at the conclusion of the event.

(d) *Enforcement Period.* This section will be enforced tri-annually in July. The Coast Guard will provide advance notice of the enforcement date and time of the safety zone by publishing a Notice of Enforcement in the **Federal Register**, as well as issuing a Broadcast Notice to Mariners.

Dated: May 12, 2022.

M.I. Kuperman,

Captain, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. 2022–10881 Filed 5–20–22; 8:45 am]

BILLING CODE 9110–04–P

Notices

Federal Register
Vol. 87, No. 99
Monday, May 23, 2022

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 AGRICULTURE

Submission for OMB Review; Comment Request

May 17, 2022.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are required regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to 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.

Comments regarding this information collection received by June 22, 2022 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *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.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Farm Service Agency

Title: Agricultural Foreign Investment Disclosure Act Report.

OMB Control Number: 0560–0097.

Summary of Collection: The Agricultural Foreign Investment Disclosure Act of 1978 (AFIDA) requires foreign investors to report in a timely manner all held, acquired, or transferred United States agricultural land under penalty of law to Farm Service Agency (FSA). Authority under the 92 STAT (1263–1267) or 7 U.S.C. 3501–3508 or Public Law 95–460, to cover the collection of the information was delegated by the Secretary of Agriculture to the Farm Service Agency (FSA). Foreign investors may obtain form FSA–153, AFIDA Report, from their local FSA county office or from the FSA internet site.

Need and Use of the Information: The regulation in the 7 CFR part 781.1–5, requires foreign investors who buy, sell, or hold a direct or indirect interest in U.S. agricultural land to report their holdings and transactions to FSA. The information collected from the AFIDA Reports is used to monitor the effect of foreign investment upon family farms and rural communities and in the preparation of a voluntary report to Congress and the President. Congress reviews the report and decides if regulatory action is necessary to limit the amount of foreign investment in U.S. agricultural land. If this information was not collected, FSA could not effectively monitor foreign investment and the impact of such holdings upon family farms and rural communities.

Description of Respondents: Business or other for-profit; Individuals or households; Farms.

Number of Respondents: 7,775.

Frequency of Responses: Reporting: On occasion; Annually.

Total Burden Hours: 3,694.

Farm Service Agency

Title: Measurement Service Record.

OMB Control Number: 0560–0260.

Summary of Collection: The information collection is authorized by 7 CFR part 718 and described in FSA Handbook 2–CP. If a producer requests measurement services, it becomes necessary for the producer to provide certain information which is collected on an FSA–409 or 409 A. The information is necessary to fulfill the producer's request for measurement services. Producers may request acreage or production measurement services.

Need and Use of the Information: The Farm Service Agency (FSA) will collect the following information that the producer is required to provide on the FSA–409 and FSA 409 A: farm serial number, program year, farm location, contact person, and type of service request (acreage or production). The collected information is used to create a record of measurement service requests and cost to the producer.

Description of Respondents: Farms.

Number of Respondents: 135,000.

Frequency of Responses: Reporting: On occasion; Weekly; Monthly.

Total Burden Hours: 33,750.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–10948 Filed 5–20–22; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Office of Partnerships and Public Engagement

New Information Collection: Entities Serving Socially Disadvantaged/ Veteran Farmers and Ranchers

AGENCY: OPPE, USDA.

ACTION: Notice of request for approval—new information collection and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Office of Partnerships and Public Engagement to request approval for a new information collection for survey administration.

DATES: Comments on this notice must be received within 60 days of publication to be assured of consideration.

ADDRESSES: Office of Partnerships and Public Engagement (OPPE) invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods:

Federal eRulemaking Portal: This website provides the ability to type short comments directly into the comment field on this web page or

attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.

Mail, including CD–ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Office of Partnerships and Public Engagement, Docket Clerk, 1400 Independence Ave. SW, Mail Stop 0601, Room 524–A, Washington, DC 20250–3700.

Hand or courier-delivered submittals: Deliver to 1400 Independence Ave. SW, Room 520–A, Washington, DC 20250–3700. You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number [USDA–OPPE]. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

Docket: For access to background documents or comments received, send requests to the OPPE Docket Room at 1400 Independence Ave. SW, Washington, DC 20250, Mail Stop 3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: U.S. Department of Agriculture, Attention: Kenya Nicholas, 1400 Independence Ave. SW, Mail Stop 0601, Washington, DC 20250, Office 202–720–6350 and Fax 202–720–7704 or via email at: *2501grants@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Survey—Entities Serving Socially Disadvantaged/Veteran Farmers and Ranchers.

OMB Number: 0503–New.

Expiration Date of Approval: Three years from approval date.

Type of Request: New information collection.

Abstract: The Office of Partnerships and Public Engagement (OPPE) has established a partnership with the Southern Rural Development Council who will be conducting a survey with USDA's stakeholders including nonprofits, community-based and non-governmental organizations, higher education institutions, and others. Participants and stakeholders of USDA's 2501 Program nationwide will assist OPPE in meeting its stakeholder community needs and to increase the impact of services provided, access to, and participation in USDA's programs and services. The information collected is on a single form, illustrating a short assessment of:

1. The self-identification of partners, collaborators, and stakeholders.

2. Programmatic feedback—a short description of challenges faced during grant administration, outreach, and training efforts.

3. Participants contact information.

4. Evaluation on the effectiveness of program delivery.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .08 hours (15 minutes) per response. [*Note:* To arrive at this estimate = number of burden hours divided by number of responses.]

Type of Respondents: Higher education institutions, nonprofits, and community-based and non-governmental organizations.

Estimated Number of Respondents: 250.

Estimated Number of Responses: 250.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 250.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) 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; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to U.S. Department of Agriculture, Attention: Kenya Nicholas, 1400 Independence Ave. SW, Mail Stop 0601, Washington, DC 20250, Office 202–720–6350 and Fax 202–720–7704 or via email at: *2501grants@usda.gov.*

All comments received will be available for public inspection during regular business hours at the same address.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Lisa Ramirez,

Director, Office of Partnerships and Public Engagement.

[FR Doc. 2022–11000 Filed 5–20–22; 8:45 am]

BILLING CODE 3412–89–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Arkansas Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Arkansas Advisory Committee (Committee) will hold a virtual (online) meeting Friday, May 6, 2022 at 1:00 p.m. Central Time. The purpose of the meeting is for the Committee to discuss testimony received regarding IDEA compliance and implementation in Arkansas schools.

DATES: The meeting will be held on Friday, June 3, 2022 1:00 p.m.–2:00 p.m. Central time.

Web Access (audio/visual): Register at: *https://www.zoomgov.com/meeting/register/vJIscOGoqjooHM1EJsIahW7NqmSgwGbwn6g.*

Phone Access (audio only): provided upon registration.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, Designated Federal Officer, at *mwojnaroski@usccr.gov* or (202) 618–4158.

SUPPLEMENTARY INFORMATION: Members of the public may join online or listen to this discussion through the call-in number provided upon registration. An open comment period will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Melissa Wojnaroski at *mwojnaroski@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Arkansas Advisory Committee link. Persons interested in the work of this

Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Roll Call
II. Discussion: IDEA Compliance and Implementation in Arkansas School
III. Public Comment
IV. Adjournment

Dated: May 17, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–10963 Filed 5–20–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–964, A–201–838]

Seamless Refined Copper Pipe and Tube From the People's Republic of China and Mexico: Continuation of Antidumping Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determinations by the U.S. Department of Commerce (Commerce) and the U.S. International Trade Commission (ITC) that revocation of the antidumping duty (AD) orders on seamless refined copper pipe and tube from the People's Republic of China (China) and Mexico would likely lead to continuation or recurrence of dumping and material injury to an industry in the United States, Commerce is publishing this notice of continuation of the orders.

DATES: Applicable May 23, 2022.

FOR FURTHER INFORMATION CONTACT: Paola Aleman Ordaz or Thomas Martin, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4031 or (202) 482–3936, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 22, 2010, Commerce published in the **Federal Register** the AD orders on seamless refined copper pipe and tube from China and Mexico.[1] On November 1, 2021, Commerce published the notice of initiation of the sunset reviews of the *Orders,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] Commerce conducted expedited sunset reviews of the *Orders,* pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2). As a result of its reviews, Commerce determined, pursuant to sections 751(c)(1) and 752(c) of the Act, that revocation of the *Orders* would likely lead to continuation or recurrence of dumping.[3] Commerce, therefore, notified the ITC of the magnitude of the dumping margins likely to prevail should the *Orders* be revoked.[4] On May 17, 2022, the ITC published its determination, pursuant to section 751(c) of the Act, that revocation of the *Orders* would likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[5]

Scope of the Orders

The merchandise covered by the scope of the *Orders* are all seamless refined copper pipes and tubes, including redraw hollows, greater than or equal to 6 inches (152.4 millimeters (mm)) in length and measuring less than 12.130 inches (308.12 mm) (actual) in outside diameter (OD), regardless of wall thickness, bore (*e.g.,* smooth, enhanced with inner grooves or ridges), manufacturing process (*e.g.,* hot finished, cold-drawn, annealed), outer surface (*e.g.,* plain or enhanced with grooves, ridges, fins, or gills), end finish (*e.g.,* plain end, swaged end, flared end, expanded end, crimped end, threaded), coating (*e.g.,* plastic, paint), insulation, attachments (*e.g.,* plain, capped, plugged, with compression or other fitting), or physical configuration (*e.g.,* straight, coiled, bent, wound on spools).

The scope of the *Orders* covers, but it is not limited to, seamless refined copper pipe and tube produced or comparable to the American Society for Testing and Materials (ASTM) ASTM–B42, ASTM–B68, ASTM–B75, ASTM–B88, ASTM–B88M, ASTM–B188, ASTM–B251, ASTM–B251M, ASTM–B280, ASTM–B302, ASTM–B306, ASTM–B359, ASTM–B743, ASTM–B819, and ASTM–B903 specifications and meeting the physical parameters described therein. Also included within the scope of the *Orders* are all sets of covered products, including ''line sets'' of seamless refined copper tubes (with or without fitting or insulation) suitable for connecting an outdoor air conditioner or heat pump to an indoor evaporator unit. The phrase ''all sets of covered products'' denotes any combination of items put up for sale that is comprised of merchandise subject to the scope.

''Refined copper'' is defined as: (1) Metal containing at least 99.85 percent by weight of copper; or (2) metal containing at least 97.5 percent by weight of copper, provided that the content by weight of any other element does not exceed the following limits:

Element	Limiting content percent by weight
Ag—Silver	0.25
As—Arsenic	0.5
Cd—Cadmium	1.3
Cr—Chromium	1.4
Mg—Magnesium	0.8
Pb—Lead	1.5
S—Sulfur	0.7
Sn—Tin	0.8
Te—Tellurium	0.8
Zn—Zinc	1.0
Zr—Zirconium	0.3
Other elements (each)	0.3

Excluded from the scope of the *Orders* are all seamless circular hollows of refined copper less than 12 inches in length whose OD (actual) exceeds its length. The products subject to the *Orders* are currently classifiable under subheadings 7411.10.1030 and 7411.10.1090 of the Harmonized Tariff Schedule of the United States (HTSUS). Products subject to the *Orders* may also enter under HTSUS subheadings 7407.10.1500, 7419.80.5050, 7419.99.5050, 8415.90.8065, and 8415.90.8085. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the *Orders* is dispositive.

Continuation of the Orders

As a result of the determinations by Commerce and the ITC that revocation of the *Orders* would likely lead to continuation or recurrence of dumping and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act and 19 CFR 351.218(a), Commerce hereby orders the continuation of the *Orders.* U.S. Customs and Border Protection will continue to collect AD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise. The

[1] *See Seamless Refined Copper Pipe and Tube from Mexico and the People's Republic of China: Antidumping Duty Orders and Amended Final Determination of Sales at Less Than Fair Value from Mexico,* 75 FR 71010 (November 22, 2010) (collectively, *Orders*).

[2] *See Initiation of Five-Year (Sunset) Review,* 86 FR 60201 (November 1, 2021).

[3] *See Seamless Refined Copper Pipe and Tube from the People's Republic of China and Mexico: Final Results of the Expediated Sunset Reviews of the Antidumping Duty Orders,* 87 FR 12079 (March 3, 2022).

[4] *Id.*

[5] *See Seamless Refined Copper Pipe and Tube from China and Mexico,* 87 FR 29877 (May 17, 2022).

effective date of the continuation of the orders will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act and 19 CFR 351.218(c)(2), Commerce intends to initiate the next sunset review of the *Orders* not later than 30 days prior to the fifth anniversary of the effective date of continuation.

Notification to Interested Parties

This five-year sunset review and this notice are in accordance with sections 751(c) and 751(d)(2) of the Act and this notice is published pursuant to section 777(i)(1) of the Act and 19 CFR 351.218(f)(4).

Dated: May 17, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–11003 Filed 5–20–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC036]

Marine Mammals; File No. 25754

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that the NMFS Pacific Islands Fisheries Science Center, 1845 Wasp Boulevard, Building 176, Honolulu, HI 96818 (Responsible Party: Erin Oleson, Ph.D.), has applied in due form for a permit to conduct research on cetaceans.

DATES: Written, telefaxed, or email comments must be received on or before June 22, 2022.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 25754 from the list of available applications. These documents are also available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 25754 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Carrie Hubard or Sara Young, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

The applicant proposes to conduct research on 34 cetacean species in U.S. and international waters of the Pacific Islands region, including the Hawaiian archipelago, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, Kingman Reef, Palmyra Atoll, Johnston Atoll, Wake Atoll, Howland Island, Baker Island, and Jarvis Island. The following endangered or threatened species may be taken during research activities: Blue whale (*Balaenoptera musculus*), false killer whale (*Pseudorca crassidens*), fin whale (*B. physalus*), humpback whale (*Megaptera novaeangliae*), North Pacific right whale (*Eubalaena japonica*), sei whale (*B. borealis*), and sperm whale (*Physeter macrocephalus*). The objectives of the research are to determine the abundance, stock structure, distribution, movement patterns, and ecological relationships of cetaceans in the study area. Research activities include aerial surveys using manned and unmanned aircraft systems, vessel surveys, behavioral observations, photo-identification, passive acoustic recordings, underwater photography, biological sample collection (skin and blubber biopsies, exhaled air, feces, and sloughed skin), and tagging (suction-cup and dart/barb). Marine mammal parts would also be imported, exported, salvaged, or received for analysis and curation. See the application for complete numbers of animals requested by species, life stage, and procedure. The permit is requested for five years.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: May 18, 2022.

Amy Sloan,

Acting Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–11016 Filed 5–20–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB875]

Notice of Intent To Prepare a Programmatic Environmental Impact Statement for Identification of One or More Aquaculture Opportunity Area(s) in Southern California

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

ACTION: Notice of intent to prepare a Programmatic Environmental Impact Statement; notice of public scoping.

SUMMARY: The NMFS West Coast Region is publishing this Notice of Intent (NOI) to prepare a Programmatic Environmental Impact Statement (PEIS) under the National Environmental Policy Act (NEPA) for the proposed identification of one or more Aquaculture Opportunity Areas (AOAs) to be located in Federal waters off the coast of Southern California. An AOA is considered to be a defined geographic area that has been evaluated to determine its potential suitability for commercial aquaculture. The proposed action is a planning initiative only and does not propose any aquaculture facilities or permits. The United States Army Corps of Engineers (USACE) Los Angeles District, the United States Coast Guard (USCG) District Eleven, and the Environmental Protection Agency (EPA) Region 9 will act as cooperating agencies for the purposes of the PEIS.

DATES: NMFS requests comments concerning the scope of the proposed action, its potential impacts to the natural and human environment, means for avoiding, minimizing, or mitigating potential impacts, the range of preliminary alternatives proposed in this notification, and any additional reasonable alternatives that should be considered within the Southern

California Bight. All comments must be received by 8:59 p.m. Pacific Standard Time (PST) July 22, 2022. NMFS expects the Draft PEIS is to be available in 2023 and the Final PEIS to be available April of 2024 with a Record of Decision May of 2024. NMFS will host two webinar-based public scoping meetings and will allow for oral comments in English during allotted times in the webinar. The webinar meetings will occur at the following dates and times:

(1) June 27, 2022, 12 p.m. to 2 p.m. PST
(2) July 11, 2022, 5 p.m. to 7 p.m. PST

ADDRESSES: Due to remaining COVID uncertainties, all public comment opportunities will be electronic, either through written comments or through oral comment stated during allotted times in the webinar-based public listening sessions. Please do not send any written comments by hard-copy mail or facsimile to a NMFS office address or fax number. You may submit comments on the NOI by any of the following methods.

Electronic Submission: Submit all written public comments via *https://www.regulations.gov.* Enter NOAA–NMFS–2022–0051 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Webinar links: Provide oral comments during designated times during virtual public scoping meetings, as described under the **DATES** section of this document. To hear audio and provide comments during the public scoping meetings, dial 888–673–9785 and use participant access code 5831012. To view presentations during the public scoping meetings, click on the webinar link. The webinar link for June 27, 2022, is: *https://www.mymeetings.com/nc/join.php?i=PWXW2725139&p=5831012&t=c.* The webinar link for July 11, 2022, is: *https://www.mymeetings.com/nc/join.php?i=PWXW2725143&p=5831012&t=c.* Links and toll-free phone numbers for each webinar can also be found at *https://www.fisheries.noaa.gov/event/southern-california-aquaculture-opportunity-area-scoping-meeting.* Please see the '*Public Scoping Process*' section of this document for more accessibility options.

Instructions: It is important that reviewers provide their comments at such times and in such a manner that they are useful to the agency's preparation of the PEIS. Therefore, comments must be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions. Comments must be submitted by one of the above methods to ensure they are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record. All personal identifying information (*e.g.,* name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Diane Windham, NOAA–NMFS West Coast Region Aquaculture Coordinator, *socalaoa.wcr@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Purpose and Need for the Proposed Action

The Federal action proposed in the PEIS is to identify one or more locations (referred to as AOAs) that may be suitable for multiple future offshore aquaculture projects in Federal waters of the Southern California Bight, and to evaluate the impacts of siting aquaculture in those locations. AOAs identified through this process would be considered potentially suitable for finfish, shellfish, macroalgae, or multi-species aquaculture. The proposed action is a long-term planning effort. It is not a regulatory or permitting action. The analysis may be used to inform such processes for individual projects proposed later in time.

On May 7, 2020, the White House issued an Executive Order on Promoting American Seafood Competitiveness and Economic Growth (E.O. 13921), which requires the Secretary of Commerce to identify geographic areas containing locations suitable for commercial aquaculture. The purpose of the proposed action is to apply a science-based approach to identify AOAs in Federal waters. The goal of identifying AOAs is to promote American seafood competitiveness, food security, economic growth, and to support the facilitation of the development of domestic commercial aquaculture, consistent with sustaining and conserving marine resources and applicable laws, regulations and policies.

The proposed action is needed to meet the directives of E.O. 13921 to address the increasing demand for seafood, facilitate long-term planning for marine aquaculture development, and address interests and concerns regarding offshore marine aquaculture siting.

Background

The National Centers for Coastal Ocean Science (NCCOS) initiated a marine spatial planning process to assist agency decision makers in identifying areas that may be suitable for locating AOAs as mandated by E.O. 13921. This process was based on spatial suitability modeling that included data layers relevant to administrative boundaries, national security (*i.e.,* military), navigation and transportation, energy and industry infrastructure, commercial and recreational fishing, natural and cultural resources, and oceanography (*i.e.,* non-living resources). This spatial modeling approach was specific to the planning goal of identifying discrete areas between 500 and 2,000 acres that met the industry and engineering requirements of depth and distance from shore and are the most suitable for all types of aquaculture development including the cultivation of finfish, macroalgae, shellfish, or a combination of species. This work resulted in an Aquaculture Opportunity Area Atlas for the Southern California Bight (Morris, J.A. Jr, MacKay, J.K., Jossart, J.A., Wickliffe, L.C., Randall, A.L., Bath, G.E., Balling, M.B., Jensen, B.M., and Riley, K.L. 2021. An Aquaculture Opportunity Area Atlas for the Southern California Bight. NOAA Technical Memorandum NOS NCCOS 298. Beaufort, NC. 485 pp. *https://doi.org/10.25923/tmx9-ex26.* Available online at *https://coastalscience.noaa.gov/data_reports/an-aquaculture-opportunity-area-atlas-for-the-southern-california-bight/*) (referred to hereafter as the Atlas).

The Atlas includes peer-reviewed technical information that may be used to assist agency decision makers in identifying areas that may be suitable for locating AOAs in Federal waters of the Southern California Bight. The Southern California Bight is considered as the marine space within the United States Exclusive Economic Zone (U.S. EEZ) associated with the coastline between Point Conception and the U.S./Mexico border, and encompassing the Channel Islands. The Atlas does not reflect a decision by any agency to identify specific AOAs or foreclose the agency's ability to evaluate other reasonable locations for consideration in the Southern California Bight. The Atlas is a technical document providing geospatial planning information that will be used as one source of information to assist NMFS in

identifying AOAs through the NEPA process.

Preliminary Proposed Action and Alternatives

The NMFS West Coast Region proposes to identify geographically discrete areas within Federal waters (outside of State waters within the U.S. EEZ) off the coast of Southern California that would be suitable to site future aquaculture development. The identified area(s) would be known as the Southern California AOA. The information within the Atlas was used as the basis for the locations described in the preliminary alternatives. Alternative 1 is the No Action Alternative, in which no AOA would be identified in Federal waters offshore of Southern California. In Alternative 2, NMFS would identify at least one and up to eight AOAs from within the boundaries of the North Study Areas Selected Site Options (SSOs), depicted as polygons in Figure 3.45 and Figure 3.62 of the Atlas. The North Study Areas SSOs are located between 10.02 and 19.72 kilometers (5.41 and 10.65 nautical miles) offshore of Santa Barbara and Ventura Counties in the Santa Barbara Channel. In Alternative 3, NMFS would identify at least one and up to two AOAs from within the boundaries of the Central North Study Area SSOs, as depicted as polygons in Figure 3.82 of the Atlas. The Central North Study Area SSOs are located between 8.06 and 8.82 kilometers (4.35 and 4.76 nautical miles) offshore of Los Angeles County in Santa Monica Bay. In Alternative 4, NMFS would identify the AOA(s) from within the boundaries of either study area, up to a maximum area to be determined by NMFS with input from the public. The total 10 SSOs are depicted as red dots in Figure 3.44 of the Atlas. The alternative descriptions are preliminary. Based on input received during public scoping, NMFS may analyze more or fewer alternatives in the Draft PEIS or may revise the above preliminary alternatives.

Summary of Expected Impacts

The PEIS will analyze potential impacts to the human environment that may occur should projects be proposed in one or more AOAs, if identified. Potential stressors associated with pre-construction, construction, operations and maintenance, and decommissioning of aquaculture activities that would be analyzed in the PEIS include, but are not limited to, bottom disturbance, vessel traffic, introduction of structures in the water column, introduction of cultivated aquatic organisms into the marine environment, and the introduction of commercial aquaculture products into economic markets and socioeconomic connections (*e.g.,* job opportunities, infrastructure demands, or consumer perspectives).

Based on preliminary evaluation of the potential stressors described above, potential environmental impacts could include modifications to marine habitat, changes in water quality, underwater noise, risk of marine debris, novel interactions of native and/or protected living marine resources with infrastructure and vessels (*e.g.,* injury or mortality due to entanglement, vessel collision, as well as behavioral changes such as aggregating, avoidance, or other disturbance), novel interactions of cultivated aquatic organisms with disease, invasive and/or nuisance species found in the marine environment, and novel interactions among naturally occurring organisms and cultivated species such as food-web dynamics or genetic interactions.

Environmental resources that may be analyzed in the PEIS include, but are not limited to, unique geographic areas such as marine managed areas and bathymetric features, water quality, hydrology and chemistry, air quality, ecosystem functions, wild fish stocks targeted for commercial and recreational fishing, highly migratory species, and protected species and their habitats and movement patterns.

The PEIS may also evaluate the connection between the marine environment and human landscape through the analysis of available socio-economic data. Topics may include, but are not limited to, interactions of offshore aquaculture with historic and cultural resources, working waterfronts, environmental justice, public health and safety, and with other ocean user groups in geographic space and in economic markets. Socio-economic indicators that may be used to analyze potential impacts of the expected interactions include, but are not limited to, employment opportunities and other financial considerations of a commercial aquaculture business, biosecurity, seafood safety and compliance programs, economic patterns of the existing seafood sector, fisheries, shipping, tourism, or other ocean activities within the region, supply chains, planned coastal development and existing coastal infrastructure, demographic data of coastal communities such as income and education, community access to resources, social vulnerability, and social values.

Potentially affected user groups may include commercial and recreational fishers, other recreational and tourism-based offshore ocean activities, the commercial shipping industry, the existing aquaculture industry within State waters, protected resource management and other research cruises, regional port districts, employees and consumers within the regional seafood sector, coastal communities, and Native American tribes and Indigenous communities with cultural traditions, identities, and experiences associated with the ocean.

NMFS encourages comment on the proposed alternatives and the identified stressors, impacts, resources, and other public concerns that should be considered in the PEIS.

Anticipated Permits and Authorizations

The proposed action, identification of one or more AOAs, is a planning action and does not include any activity that would require a permit or authorization as part of planning. The proposed action does not create any new regulatory framework or change any existing statutory authority related to offshore marine aquaculture. Neither the Final PEIS nor the resulting Record of Decision (ROD) would authorize any activities or approve any individual projects. Future proposals for aquaculture projects proposed for siting within an AOA would undergo project level environmental review and permitting. A proposed project would undergo project-specific NEPA review that could tier from the PEIS. In addition, project-specific permits and approvals from the permitting agencies would be required. Additional NEPA analysis may be required as part of permitting and authorization processes. Cooperating agencies may adopt the PEIS and utilize the information in their permitting actions.

Schedule for the Decision-Making Process

This NOI initiates the NEPA compliance process associated with writing a PEIS. During the 60-day comment period, interested parties are invited to provide comments on the proposed action, the preliminary range of alternatives, any additional reasonable alternatives in the Southern California Bight, and potential stressors, impacts, and resources. NMFS expects the Draft PEIS to be available to the public on or around Fall of 2023 and the Final PEIS to be available to the public on or around April of 2024.

Public Scoping Process

This NOI continues the scoping process, which guides the development of the PEIS. NMFS will use the public scoping process to gather input from

individuals, organizations, Native American tribes, and Federal, State, and local agencies on the proposed action. The scoping process will inform the scope and significant issues to be analyzed in the PEIS. Interested parties may submit public comments according to the instructions described in the **DATES** and **ADDRESSES** sections above. Additional information may be found online at *https://www.fisheries.noaa.gov/west-coast/aquaculture/west-coast-region-southern-california-aquaculture-opportunity-area.* Accessible options for the visually or hearing impaired include full recordings and written transcripts of the webinar-based listening sessions. All presentation materials, recordings, and transcripts will be posted to the website within five business days of the webinar. Persons needing reasonable accommodations to attend and participate in the public meetings should contact Diane Windham at *socalaoa.wcr@noaa.gov.* To allow sufficient time to process requests, please notify at least five business days prior to the relevant meeting.

Request for Identification of Potential Alternatives, Information, and Analyses Relevant to the Proposed Action

NMFS requests data, comments, views, information, analysis, alternatives, or suggestions from the public; affected federal, state, tribal, and local governments, agencies, and offices; the scientific community; industry; or any other interested party on the Proposed Action that would help the agency consider both beneficial and adverse impacts. Specifically, for offshore regions in the Southern California Bight, NMFS requests public input on the following:

(1) The scope of the NEPA analysis, including the range of reasonable alternatives described above.

(2) Suitable species and gear for aquaculture.

(3) Suitable reporting requirements for owners and operators of aquaculture facilities.

(4) Types of aquaculture (*e.g.,* finfish, shellfish, seaweed, integrated multi-trophic aquaculture) that could be supported and/or analyzed.

(5) Potential impacts to biological, physical, social, cultural, and economic resources.

(6) Information related to social barriers and/or economic constraints for aquaculture development.

(7) Information related to technologies and strategies that could increase opportunity or mitigate risks of aquaculture development.

(8) Information related to diversity, equity, and inclusion in aquaculture and the seafood sector.

(9) Information related to climate change and climate equity.

(10) Potential interactions with protected species, essential fish habitat, and other sensitive habitats.

(11) Potential interactions with commercial and recreational fishing industries, tourism and recreation, and other offshore ocean users.

(12) Information on other current or planned activities in, or in the vicinity of, the areas described in this NOI and their possible impacts on aquaculture development, or the impact of aquaculture developments on those activities.

(13) Input on the size parameters of a single AOA that would be suitable to support aquaculture development in the Southern California Bight.

(14) Input related to the risks and/or benefits of whether an AOA should be a single, continuous geographic space, or a collection of discrete areas separated from one another.

(15) Input related to how an AOA could simultaneously support aquaculture development along with environmental, economic, and social sustainability—including ways to incorporate mitigation and cost-benefit analyses.

(16) Other information relevant to the Proposed Action and its impacts on the human environment.

Lead and Cooperating Agencies

Consistent with E.O. 13921, NOAA is designated as the lead agency for the proposed action. The NMFS West Coast Region invited the EPA Region 9, the USCG District Eleven, and the USACE Los Angeles District to act as cooperating agencies for the purposes of the PEIS. EPA, USCG, and USACE have agreed to act as cooperating agencies.

Decision Maker

Scott M. Rumsey, Acting Regional Administrator of NOAA Fisheries' West Coast Region.

Nature of Decision To Be Made

If an action alternative is selected, the decision maker would select an alternative that identifies one or more AOAs as part of a planning exercise for offshore marine aquaculture in Southern California. No specific aquaculture projects are being proposed or will be permitted through the PEIS. The analysis presented in the Draft and Final PEIS and the identification of any AOAs in the ROD will serve to guide and inform future decision-making (*e.g.,* environmental review and permitting processes) if and when specific proposals to conduct aquaculture operations are proposed within these areas.

Authority: Executive Order on Promoting American Seafood Competitiveness and Economic Growth (E.O. 13921).

Dated: May 13, 2022.

Danielle Blacklock,

Director, Office of Aquaculture, National Marine Fisheries Service.

[FR Doc. 2022–11010 Filed 5–20–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC040]

Marine Mammals; File No. 26394

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Pangolin Pictures, 1650 Broadway, Suite 1208, New York, NY 10019 (Responsible Party: Kevin Bachar), has applied in due form for a permit to conduct commercial and educational photography on humpback whales (*Megaptera novaeangliae*) and other cetaceans.

DATES: Written, telefaxed, or email comments must be received on or before June 22, 2022.

ADDRESSES: These documents are available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 26394 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Carrie Hubard or Amy Hapeman, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant proposes to film up to 75 humpback whales in the Au'au

channel in Hawai'i. Filming would take place from onboard a boat, using underwater divers, and from an unmanned aircraft system. Other species that would be filmed if encountered are up to 150 bottlenose dolphins (*Tursiops truncatus*), 50 pantropical spotted dolphins (*Stenella attenuata*), 250 spinner dolphins (*S. longirostris*), 50 melon-headed whales (*Peponocephala electra*), 50 pygmy killer whales (*Feresa attenuata*), and 10 minke whales (*Balaenoptera acutorostrata*). Footage would be used for a documentary to air on National Geographic Television. The permit would be valid from December 2022 through May 2023.

It has come to the agency's attention that the 2016 interim final humpback approach rule (50 CFR 216.19; 81 FR 62010, September 8, 2016) does not explicitly exempt permits issued under section 104(c)(6) of the MMPA from its prohibitions. It is not the agency's intent to preclude the issuance of permits or authorizations consistent with the requirements of the MMPA. We interpret the rule to allow issuance of these permits. Consistent with this interpretation, it has been our practice to continue to issue section 104(c)(6) permits that are in compliance with the MMPA's requirements and our review procedures, as evidenced by issuance of four such permits since the rule's effective date. However, to eliminate any potential ambiguity, we intend to revise the rule to explicitly clarify that photography permits issued under section 104(c)(6) of the MMPA are exempt from the prohibitions on approach.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: May 18, 2022.

Amy Sloan,

Acting Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–11015 Filed 5–20–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC006]

Fisheries of the Gulf of Mexico; 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 75 Life History Topical Working Group Recommendations Webinar for Gulf of Mexico Gray Snapper.

SUMMARY: The SEDAR 75 assessment of Gulf of Mexico gray snapper will consist of a series of assessment webinars. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 75 Recommendations Webinar for the Life History Topical Working Group will be held June 16, 2022, from 2 p.m. to 4 p.m., Eastern. 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.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

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 of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries 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 Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries 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:

Participants will make recommendations on life history data available for use in the assessment of Gulf of Mexico gray snapper.

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

The meeting is 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 10 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: May 18, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–11021 Filed 5–20–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC054]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Herring Committee via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Friday, June 10, 2022, at 1 p.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/7663920824181513742*.

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Herring Committee will develop Framework 7 to the Atlantic Herring Fishery Management Plan, an action to protect adult spawning of Atlantic herring on Georges Bank. They will also review and recommend annual herring research priorities. The Committee will receive an update on the Industry Funded Monitoring (IFM) Program for the Atlantic herring fishery and consider recent correspondence about the IFM program since it was fully implemented in July 2021. Other business may be discussed, as necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: May 18, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–11017 Filed 5–20–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC050]

NOAA Fisheries Draft Climate Regional Action Plans (2022–2024)

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

ACTION: Notice, extension of comment period.

SUMMARY: NMFS is extending the comment period for the Notice of Availability of Draft Climate Regional Action Plans. We, NMFS, are soliciting review and comment from the public and all interested parties, and will consider all substantive comments received during the review period before publishing final Climate Regional Action Plans. Comments are invited on: (a) The clarity of the goals and activities in the plans, (b) how to strengthen the proposed Plans and activities; (c) what additional goals and activities need to be addressed. Comments submitted in response to this notice will be provided to the Regional Action Plan Teams for consideration in development of the final plans. To review the draft regional plans, visit: *https://www.fisheries.noaa.gov/national/climate/climate-science-strategy-regional-action-plans*.

DATES: The original NoA issued on 22 April 2022 (87 FR 24099) provided a comment period ending on 02 June 2022. The comment period is now being extended and will close 29 July 2022. Comments received after this date may not be accepted. Comments received prior to this announcement do not need to be resubmitted as a result of the extension of the comment period.

ADDRESSES: Comments may be submitted on the NOAA Fisheries Draft Climate Regional Action Plans by either of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal.

1. Go to *www.regulations.gov* and enter *NOAA-NMFS-2022-0007* in the search box.
2. Click the ''Comment'' icon
3. Enter or attach your comments.

- *Mail:* Submit written comments to Roger Griffis, NMFS/Office of Science and Technology, 1315 East-West Highway, Silver Spring, MD 20910. Include on the envelope the following identifier ''Draft Climate Regional Action Plans Comments.''
- *Instructions:* Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

The NOAA Fisheries Draft Climate Regional Action Plans are available online at *https://www.fisheries.noaa.gov/national/climate/climate-science-strategy-regional-action-plans* or upon request from the NMFS Office of Science and Technology.

FOR FURTHER INFORMATION CONTACT: Roger Griffis, (301)–980–4694, *NMFS.RAPcomments@noaa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The NOAA Fisheries Climate Science Strategy, released in August of 2015 and available at *https://www.fisheries.noaa.gov/topic/climate-change,* responded to the growing demand from fisheries and other decision makers for better information about what's changing, what's at risk and how to respond to changing climate and ocean conditions. The Climate Science Strategy identified seven key objectives to produce and deliver the climate-related information to meet these needs and fulfill NMFS mandates in a changing climate. The Climate Science

Strategy provided a national framework designed to be customized and implemented in each region through Regional Action Plans.

In 2016 NMFS created the first Regional Action Plans in collaboration with Fishery Management Councils and many other partners to identify the strengths, weaknesses, priorities, and specific actions to implement the Climate Science Strategy in the Northeast, Southeast, Pacific Islands, West Coast and Alaska Regions. While some impacts of changing climate and oceans on living marine resources are shared across regions, each region has a unique combination of climate-related challenges, capabilities, and information requirements needed to implement the Strategy.

The Climate Science Regional Action Plans are cross-agency, coordinated efforts to increase implementation of the Climate Science Strategy in each region, and include goals and actions to help track changing marine ecosystem conditions, assess risks, provide early warnings and longer-term projections, and evaluate management strategies under changing conditions.

Development of the Draft Regional Action Plans

In 2021 NMFS conducted an assessment of progress to implement the Climate Science Strategy during 2016–2020 including efforts under the first Regional Action Plans. This 5 year Progress Report (*https://spo.nmfs.noaa.gov/content/tech-memo/noaa-fisheries-climate-science-strategy-five-year-progress-report*) provides useful information for development of updated Regional Action Plans for 2022–2024. The draft 2022–2024 Regional Action Plans were developed by regional teams consisting of NMFS personnel from Science Centers and Regional Offices. The updated plans build upon previous efforts and identify proposed actions over the next 3 years (2022–2024) to address key climate-science needs in each region.

The goal of the draft Regional Action Plans is to continue to increase the production, delivery and use of climate-related information needed for fisheries management and protected species conservation in each region. Each draft Regional Action Plan identifies specific actions to implement the seven objectives of the NOAA Fisheries Climate Science Strategy. The actions address key needs in each region based on input from NMFS scientists, resource managers, stakeholders and other sources. The draft Regional Action Plans include actions to provide decision makers with better information on what's changing, what's at risk and how different management strategies may perform under changing climate and ocean conditions.

Some specific actions and products include:

Tracking change: Monitor and assess key indicators of ecosystem conditions to better track and provide early warnings of changing conditions.

Forecasting conditions: Research and modeling to understand the mechanisms of change and provide near and longer term forecasts of conditions.

Assessing risks: Assess the vulnerability of marine resources, fisheries, fishing communities and other sectors that depend on marine resources.

Evaluating best strategies: Identify alternative management approaches and evaluate how they may perform under changing conditions to identify best approaches for stewardship of the Nation's valuable marine resources.

Public Comments Solicited

NMFS is committed to increasing the production, delivery, and use of climate-related information to fulfill its living marine resource stewardship mandates. NMFS works with and depends on many partners to fulfill its science and information needs, including other government agencies, academia, fisheries, and other organizations. As such, NMFS is providing this opportunity for broad public review and comment on the draft Climate Science Regional Action Plans.

Public comments are invited to help clarify and strengthen the draft Regional Action Plans. Comments are invited on: (a) The clarity of the goals and activities in the plans, (b) how to strengthen the proposed Plans and activities; (c) what additional goals or activities need to be addressed. Comments submitted in response to this notice will be provided to the Regional Action Plan Teams for consideration in development of the final Plans.

Authority: 16 U.S.C. 1881c, Fisheries Research Section 404(a) and Executive Order 14008, Section 216(c).

Dated: May 18, 2022.

Evan Howell,

Director, Office of Science and Technology, National Marine Fisheries Service.

[FR Doc. 2022–11048 Filed 5–20–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC049]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public joint meeting of its Habitat Committee via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Friday, June 10, 2022, at 8:30 a.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/965763058356419085.*

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Committee plans on selecting preferred alternatives for Southern New England Habitat Area of Particular Concern Framework. They also plan to discuss aquaculture updates and consider recommending that the Council initiate a framework related to authorization of Atlantic salmon aquaculture. The Committee will discuss offshore development (wind, cables) including upcoming comment opportunities. Also on the agenda is a brief review of Northeast Regional Habitat Assessment products and next steps. Other business may be discussed as necessary.

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 listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been

notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the date. This meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

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

Dated: May 18, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–11019 Filed 5–20–22; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities Notice of Intent To Renew Collection 3038–0061: Daily Trade and Supporting Data Reports

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (CFTC) is announcing an opportunity for public comment on the proposed renewal of a collection of certain information by the agency. Under the Paperwork Reduction Act (''PRA''), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including proposed extension of an existing collection of information, and to allow 60 days for public comment. This notice solicits comments on the daily trade and supporting data reports that are submitted to CFTC related to reporting requirements on Reporting Markets, including Designated Contract Markets.

DATES: Comments must be submitted on or before July 22, 2022.

ADDRESSES: You may submit comments, identified by ''OMB Control No. 3038–0061'' by any of the following methods:

- The Agency's website, at *https://comments.cftc.gov/.* Follow the instructions for submitting comments through the website.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail above.

Please submit your comments using only one method. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *https://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Owen Kopon, Associate Director, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581; (202) 418–5360; email: *OKopon@cftc.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA, 44 U.S.C. 3501 *et seq.,* Federal agencies must obtain approval from the Office of Management and Budget (''OMB'') for each collection of information they conduct or sponsor. ''Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the Commission is publishing notice of the proposed extension of the existing collection of information listed below. 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.[1]

Title: Regulation 16.02 Daily Trade and Supporting Data Reports (OMB Control No. 3038–0061). This is a request for extension of a currently approved information collection.

Abstract: Commission Rule 16.02 requires Reporting Markets to report transaction-level trade data and related order information for each executed transaction. The Commission uses the transaction-level trade data and related order information to discharge its regulatory responsibilities, including the responsibilities to prevent market manipulations and commodity price distortions and ensure the financial integrity of its jurisdictional markets.

With respect to the collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of 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.

You should submit only information that you wish to make available publicly. If you wish for the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[2]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *https://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the Information Collection Request will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

Burden Statement: The Commission is revising its burden estimate for this collection. The Commission estimates that up to 20 Reporting Markets could provide daily trade and supporting data reports to the Commission in the future. The CFTC believes that Reporting Markets incur an average burden of two hours to compile and submit each report made pursuant to Commission Rule 16.02. Reporting Markets submit an average of 250 reports annually. The estimated total annual time-burden for all Reporting Markets is 10,000 hours. The respondent burden for this collection is estimated to be as follows:

Estimated Number of Respondents: 20.

[1] 44 U.S.C. 3512, 5 CFR 1320.5(b)(2)(i) and 1320.8 (b)(3)(vi).

[2] *See* 17 CFR 145.9.

Estimated Average Burden Hours per Respondent: 500 hours.

Estimated Total Annual Burden Hours: 10,000 hours.

Frequency of Collection: Daily.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: May 18, 2022.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2022–11004 Filed 5–20–22; 8:45 am]

BILLING CODE 6351–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: Wednesday, May 25, 2022, 10–11 a.m.

PLACE: This meeting will be held remotely.

STATUS: Commission Meeting—Open to the Public.

MATTERS TO BE CONSIDERED: Briefing Matter:

Notice of Proposed Rulemaking: Safety Standard for Recreational Off-Highway Vehicle and Utility Task/Terrain Vehicle Debris Penetration Hazards.

All attendees should pre-register for the Commission meeting using the following link: *https://cpsc.webex.com/cpsc/onstage/g.php?MTID=e7b57b48965ca252d4a0572526961419a.*

After registering you will receive a confirmation email containing information about joining the meeting.

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814, 301–504–7479 (Office) or 240–863–8938 (Cell).

Dated: May 18, 2022.

Alberta E. Mills,

Commission Secretary.

[FR Doc. 2022–11098 Filed 5–19–22; 11:15 am]

BILLING CODE 6355–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Comment Request; NCCC Service Project Application

AGENCY: The Corporation for National and Community Service.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Corporation for National and Community Service (operating as AmeriCorps) is proposing to renew an information collection.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by July 22, 2022.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) *By mail sent to:* AmeriCorps, Attention Jacob Sgambati, 250 E Street SW, Washington, DC 20525.

(2) By hand delivery or by courier to the AmeriCorps mailroom at the mail address given in paragraph (1) above, between 9 a.m. and 4 p.m. Eastern Time, Monday through Friday, except Federal holidays.

(3) Electronically through *www.regulations.gov.*

Comments submitted in response to this notice may be made available to the public through regulations.gov. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comment that may be made available to the public, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Jacob Sgambati, 202–246–3131, or by email at *jsgambati@cns.gov.*

SUPPLEMENTARY INFORMATION:

Title of Collection: AmeriCorps NCCC Service Project Application.

OMB Control Number: 3045–0010.

Type of Review: Renewal.

Respondents/Affected Public: Current/prospective AmeriCorps NCCC sponsors.

Total Estimated Number of Annual Responses: 1,800.

Total Estimated Number of Annual Burden Hours: 17,100.

Abstract: The AmeriCorps NCCC Service Project Application is completed by organizations interested in sponsoring an AmeriCorps NCCC team. Each year, AmeriCorps NCCC engages teams of members in service projects in communities across the United States. The service projects, which typically last from six to eight weeks, address critical needs in natural and other disasters, infrastructure improvement, environmental stewardship and conservation, energy conservation, and urban and rural development. Members construct and rehabilitate low-income housing, respond to natural disasters, clean up streams, help communities develop emergency plans, and address other local needs. AmeriCorps also seeks to continue using the currently approved information collection until the revised information collection is approved by OMB. There have been several changes made in an effort to streamline the document for users. Based on feedback from stakeholders, the document now has additional project objective options for users to select and the radio buttons have been changed to check boxes to allow for users to select as many objectives as they would like. The NCCC Service Project Application was simplified by deleting the ''Organizational Capacity'' and ''Needs'' narrative pages. The currently approved information collection is due to expire on 10/31/22.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. 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. All written comments will be available for public inspection on *regulations.gov.*

Dated: May 16, 2022.

Jacob Sgambati,

Deputy Director.

[FR Doc. 2022–11001 Filed 5–20–22; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID USA–2022–HQ–0012]

Proposed Collection; Comment Request

AGENCY: U.S. Army Corps of Engineers, Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the U.S. Army Corps of Engineers announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: 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; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 22, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to U.S. Army Corps of Engineers, 441 G Street NW, Washington, DC 20314–1000, ATTN: Ms. Kathryn Nevins, or call 703–428–6440.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Recreation Area and Visitor Center Visitor Comment Cards; OMB Control Number 0710–0019.

Needs and Uses: The information collection requirement is necessary to understand and determine the satisfaction of recreation visitors to U.S. Army Corps of Engineers managed recreation areas and visitor centers.

Affected Public: Individuals or households.

Annual Burden Hours: 3,750.

Number of Respondents: 45,000.

Responses per Respondent: 1.

Annual Responses: 45,000.

Average Burden per Response: 5 minutes.

Frequency: On occasion.

Respondents to this collection of information via comment cards are public visitors to U.S. Army Corps of Engineers Recreation Areas. Participation is voluntary. Comment cards are distributed via two methods. In a rack, for example at a visitor center or kiosk, resulting in visitor initiated response, or scheduled surveys where visitors are intercepted by a survey clerk. The respondent is selected from exiting visitors where one member of the party is asked to complete the card and return to the survey clerk. Recreation areas where comment cards are used, meet visitation and funding thresholds or a local administrative need. Survey Clerks are staff or U.S. Army Corps of Engineers trained volunteers. Visitors are asked questions in the following categories; previous visits, area information sources, fees charged, facilities used, facility rating, and demographics.

Dated: May 17, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–11033 Filed 5–20–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–HA–0059]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Health Agency announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: 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; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 22, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *https://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments,

please write to the Psychological Health Center of Excellence (PHCoE), 7700 Arlington Blvd., Suite 5101, Box #22 (Silver Spring Office), Falls Church, VA 22041, Dr. Derek Smolenski, or call (253) 968–4153.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Department of Defense Suicide Event Report; DD Form 2996; OMB Control Number 0720–0058.

Needs and Uses: The information collection is necessary for ongoing surveillance of deaths by suicide and other suicide-related behaviors (suicide attempts, non-suicidal self-harm, suicide ideation) that occur among members of the Military Services. The information collected is used in generating an annual report, supporting planning and programmatic activities of the Defense Suicide Prevention Office, and providing information to the Military Services on changes in event frequency or the distribution of potential risk and protective factors.

Affected Public: Federal Government.

Annual Burden Hours: 2,500 hours.

Number of Respondents: 3,000.

Responses per Respondent: 1.

Annual Responses: 3,000.

Average Burden per Response: 50 minutes.

Frequency: As required.

Dated: May 17, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–11025 Filed 5–20–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0057]

Proposed Collection; Comment Request

AGENCY: The Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: 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; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 22, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Human Resources Activity, 4800 Mark Center Drive, Suite 08F05, Alexandria, VA 22350, LaTarsha Yeargins, 571–372–2089.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Post-Election Voting Survey of State Election Officials; OMB Control Number 0704–PEVS.

Needs and Uses: The primary objective of the Post-Election Voting Survey of State Election Officials, conducted on behalf of the Federal Voting Assistance Program (FVAP), is to gather feedback from the state election officials (SEOs) responsible for administering the Uniformed and Overseas Citizens Absentee Voting Act (UOCAVA) on behalf of the military and overseas voters. This customer service focused survey will help FVAP understand how it can best engage election officials and identify areas where its processes can be improved. This ongoing evaluation will help determine the extent to which FVAP is achieving its mission and what actions FVAP might be able to take in the future to improve its products and services. Conducting this research will help FVAP meet its federal and congressional mandates in terms of ensuring that UOCAVA voters are receiving adequate support from state officials in the registration and voting process for federal elections. The data obtained through this study is also intended to provide insights into existing barriers to UOCAVA voting and recommendations for addressing these challenges. To obtain the necessary information, the Post-Election Voting Survey of State Election Officials project will use data collected from the population of SEOs from all 50 U.S. States, the District of Columbia, and the four U.S. territories covered under UOCAVA: Puerto Rico, Guam, American Samoa, and the U.S. Virgin Islands.

Affected Public: Individuals or households.

Annual Burden Hours: 13.75 hours.

Number of Respondents: 55.

Responses per Respondent: 1.

Annual Responses: 55.

Average Burden per Response: 15 minutes.

Frequency: Biennially.

Dated: May 17, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–11046 Filed 5–20–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0008]

Submission for OMB Review; Comment Request

AGENCY: The Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by June 22, 2022.

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: Angela Duncan, 571–372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Exceptional Family Member Program Survey; OMB Control Number 0704–EFMS.

Type of Request: New.

Number of Respondents: 16,500.

Responses per Respondent: 1.

Annual Responses: 16,500.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 4,125 hours.

Needs and Uses: The Quick Compass survey of the Exceptional Family Member Program (EFMP) is a DoD-wide large-scale survey of active duty members that will be used to systematically evaluate active duty service member perceptions of the EFMP. The survey will assess topics such as perceptions of the EFMP enrollment process, family support, and referrals. Data will be aggregated by appropriate demographics, including Service, and paygrade. In order to be able to meet reporting requirements for DoD leadership, the Military Services, and Congress, the survey needs to be completed by December 2022. Results will be used by the Military Services to evaluate their EFMP programs and will be reported to Congress.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: May 17, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–11020 Filed 5–20–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2022–HQ–0015]

Proposed Collection; Comment Request

AGENCY: Department of the Navy (DON), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Department of the Navy announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: 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; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 22, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *https://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Program Executive Officer for Enterprise Information Systems (PEO EIS); Enterprise Systems and Services (PMW 250), 701 South Courthouse Road, Suite 1400, Arlington, VA 22204, Attn: Frank Sowa, 757–541–5850.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Risk Management Information System; OPNAV Form 3750/16, OPNAV Form 5102/10, OPNAV Form 5102/11; OMB Control Number 0703–0065.

Needs and Uses: The information collection requirement is necessary to collect information on injuries/fatalities, occupational illnesses required of Federal government agencies by the Occupational Safety and Health Administration, and pertinent information for property damage occurring during DON operations. The data maintained in this system will be used for analytical purposes to improve the DON's accident prevention policies, procedures, standards and operations, as well as to ensure internal data quality assurance. The collection will also help to ensure that all individuals receive required safety, fire, security, force protection, and emergency management training courses necessary to perform assigned duties and comply with Federal, DoD, and DON related regulations.

Affected Public: Individuals or households.

Annual Burden Hours: 37.5.

Number of Respondents: 25.

Responses per Respondent: 1.

Annual Responses: 25.

Average Burden Per Response: 1.5 hours.

Frequency: On occasion.

Respondents are Federal contractors who are involved in an incident or mishap while performing duties in support of a DON contract, or while in/on a DON base, building, vessel, vehicle, or other facility; Military retirees and foreign nationals who are involved in an incident while in/on a DON base, building, vessel, vehicle, or other facility; Military dependents who are involved in an incident while in/on a DON base, building, vessel, vehicle, or

other facility, or while accompanying their military sponsor.

Dated: May 17, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–11044 Filed 5–20–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: Office of Environment, Health, Safety and Security, U.S. Department of Energy.

ACTION: Notice and request for comments.

SUMMARY: The Department of Energy (DOE), pursuant to the Paperwork Reduction Act of 1995, intends to extend for three years an information collection request with the Office of Management and Budget (OMB). The purpose of this collection is to ensure that individuals who occupy positions affording them access to certain materials, nuclear explosive devices, facilities, and programs meet the highest standards of reliability and physical and mental suitability.

DATES: Comments regarding this proposed information collection must be received on or before July 22, 2022. If you anticipate 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 Mike Hamar, EHSS–1.2/6H–035 Forrestal Building, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585–1290 or by email at *mike.hamar@hq.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Mike Hamar, EHSS–1.2/6H–035 Forrestal Building, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585–1290 or by email at *mike.hamar@hq.doe.gov* or by telephone at (202) 586–2569.

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the extended 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.:* 1910–5122;

(2) *Information Collection Request Title:* Human Reliability Program;

(3) *Type of Review:* Renewal;

(4) *Purpose:* The purpose of this collection is to ensure that individuals who occupy positions affording access to certain materials, nuclear explosive devices, facilities, and programs meet the highest standards of reliability and physical and mental suitability.

This information collection request consists of forms that will certify to DOE that respondents were advised of the requirements for occupying or continuing to occupy a Human Reliability Program (HRP) position. The HRP is a security and safety reliability program for individuals who apply for or occupy certain positions that are critical to the national security. It requires an initial and annual supervisory review, medical assessment, management evaluation, and a DOE personnel security review of all applicants or incumbents. It is also used to ensure that employees assigned to nuclear explosive duties do not have emotional, mental, or physical conditions that could result in an accidental or unauthorized detonation of nuclear explosives. The information collection instructions are forms which include: HRP Certification (DOE F 470.3), Acknowledgement and Agreement to Participate in the HRP (DOE F 470.4), Authorization and Consent to Release HRP Records in Connection with HRP (DOE F 470.5), and HRP Alcohol Testing Form (DOE F 470.7).

(5) *Estimated Number of Respondents:* 41,312;

(6) *Annual Estimated Number of Total Responses:* 41,365;

(7) *Annual Estimated Number of Burden Hours:* 3,587;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $312,069.

Statutory Authority: 42 U.S.C. 2165; 42 U.S.C. 2201; 42 U.S.C. 5814–5815; 42 U.S.C. 7101 *et seq.;* 50 U.S.C. 2401 *et seq.;* E.O. 10450, 3 CFR 1949–1953 Comp., p. 936, as amended; E.O. 10865, 3 CFR 1959–1963 Comp., p. 398, as amended; 3 CFR Chap. IV.

Signing Authority

This document of the Department of Energy was signed on May 17, 2022, by Matthew B. Moury, Director, Office of Environment, Health, Safety and Security, 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 May 18, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–10978 Filed 5–20–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Idaho Cleanup Project

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open in-person/virtual hybrid meeting.

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

DATES: Wednesday, June 15, 2022; 2:00 p.m.–5:30 p.m.

The opportunity for public comment is at 4:15 p.m. MT.

These times are subject to change; please contact the ICP Citizens Advisory Board (CAB) Administrator (below) for confirmation of times prior to the meeting.

ADDRESSES: This meeting will be open to the public in-person at the Residence Inn Idaho Falls (address below) or virtually via Zoom. To attend virtually, please contact Jordan Davies, ICP CAB Administrator, by email *jdavies@northwindgrp.com* or phone (720) 452–7379, no later than 5:00 p.m. MT on Tuesday, June 14, 2022.

Board members, Department of Energy (DOE) representatives, agency liaisons, and Board support staff will participate in-person, strictly following COVID–19 precautionary measures, at: Residence Inn Idaho Falls, 635 West Broadway, Idaho Falls, ID 83402.

FOR FURTHER INFORMATION CONTACT: Jordan Davies, ICP CAB Administrator, by phone (720) 452–7379 or email *jdavies@northwindgrp.com* or visit the Board's internet homepage at *https://energy.gov/em/icpcab.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda (agenda topics may change up to the day of the meeting; please contact Jordan Davies for the most current agenda):

1. Recent Public Outreach
2. Idaho Cleanup Project (ICP) Overview
3. Integrated Waste Treatment Unit (IWTU) Update
4. Recommendation Discussion Regarding ICP Accomplishments

Public Participation: The in-person/online virtual hybrid meeting is open to the public either in-person at the Residence Inn Idaho Falls or via Zoom. To sign-up for public comment, please contact the ICP CAB Administrator (above) no later than 5:00 p.m. MT on Tuesday, June 14, 2022. In addition to participation in the live public comment session identified above, written statements may be filed with the Board either five days before or five days after the meeting by sending them to the ICP CAB Administrator at the aforementioned email address. Written public comment received prior to the meeting will be read into the record. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Jordan Davies, ICP CAB Administrator, phone (720) 452–7379 or email *jdavies@northwindgrp.com.* Minutes will also be available at the following website: *https://www.energy.gov/em/icpcab/listings/cab-meetings.*

Signed in Washington, DC, on May 17, 2022.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2022–10977 Filed 5–20–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collection Extension

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

ACTION: Notice.

SUMMARY: EIA submitted an information collection request for extension as required by the Paperwork Reduction Act of 1995. The information collection requests a three-year extension of its *Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery,* OMB Control Number 1905–0210. This generic clearance enables EIA to collect customer and stakeholder feedback from the public on service delivery in an efficient and timely manner to ensure that EIA's programs effectively meet our customers' needs and to collect feedback on improving service delivery to the public.

DATES: Comments on this information collection must be received no later than June 22, 2022. 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: If you need additional information, contact Gerson Morales, U.S. Energy Information Administration, telephone (202) 586–7077, or by email at *Gerson.Morales@eia.gov.*

SUPPLEMENTARY INFORMATION: This information collection request contains:

(1) *OMB No.:* 1905–0210;

(2) *Information Collection Request Title:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery;

(3) *Type of Request:* Three-year extension without change;

(4) *Purpose:* This information collection activity provides a means to collect qualitative customer and stakeholder feedback in an efficient timely manner, in accordance with the Administration's commitment to improving service delivery. Qualitative feedback means data that provide useful insights on perceptions and opinions but are not statistical surveys that yield quantitative results that can be generalized to the population of the study. This feedback provides insights into customer or stakeholder perceptions, experiences, and expectations. It also provides an early warning of issues with service, or focuses attention on areas where communication, training or changes in operations might improve the accuracy of data report on survey instruments or the delivery of products or services. These collections allow for ongoing, collaborative, and actionable communications between the agency and its customers and stakeholders. It also allows feedback to contribute directly to the improvement of program management. EIA will only submit a collection for approval under this generic clearance if it meets the following conditions:

- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions;
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study;
- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future; and
- With the exception of information needed to provide remuneration for participants of focus groups and cognitive laboratory studies, personally identifiable information (PII) is collected only to the extent necessary and is not retained.

If these conditions are not met, EIA will submit an information collection request to OMB for approval through the normal PRA process. The solicitation of feedback on Agency Service Delivery includes topics such as: Timeliness of publishing, understanding of questions and terminology used in EIA products, perceptions on data confidentiality and security, appropriateness and relevancy of information published, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses

are assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. Advances in technology and service delivery systems in the private sector, have increased the public's expectations of the Government's customer service promise. The Federal Government has a responsibility to streamline and make more efficient its service delivery to better serve the public.

(5) *Annual Estimated Number of Respondents:* 80,600;

(6) *Annual Estimated Number of Total Responses:* 80,600;

(7) *Annual Estimated Number of Burden Hours:* 8,600;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $717,068 (8,600 annual burden hours multiplied by $83.38 per hour). EIA 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.

Statutory Authority: Executive Order 12,862 (1993) and Executive Order 13,571 (2011).

Signed in Washington, DC, on May 18, 2022.

Samson Adeshiyan,

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

[FR Doc. 2022–11032 Filed 5–20–22; 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: EIA invites public comment on the proposed three-year extension, with changes, to the Electric Power & Renewable Electricity Surveys (EPRES) as required under the Paperwork Reduction Act of 1995. EPRES consists of nine surveys, including annual, monthly and one daily survey. These surveys collect data from entities involved in the production, transmission, delivery, and sale of electricity, and in maintaining the reliable operation of the power system. The data collected are the primary source of information on the nation's electric power system. The renewable energy survey collects information on the manufacture, shipment, import, and export of photovoltaic cells and modules, and is the primary national source of information on these topics.

DATES: EIA must receive all comments on this proposed information collection no later than July 22, 2022. 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: Send your comments to Sara Hoff, Office of Energy Production, Conversion & Delivery, U.S. Energy Information Administration, Forrestal Building, U.S. Department of Energy, 1000 Independence Ave. SW, EI–23, Washington, DC 20585. Submission via email to *Electricity2023@eia.gov* is recommended.

FOR FURTHER INFORMATION CONTACT: Sara Hoff, (202) 586–1242 email: *Electricity2023@eia.gov.* The forms and instructions are available on EIA's website at *https://www.eia.gov/survey/.*

SUPPLEMENTARY INFORMATION: Comments are invited on whether or not: (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) EIA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used, is accurate; (c) EIA can improve the quality, utility, and clarity of the information it will collect; and (d) EIA can minimize the burden of the collection of information on respondents, such as automated collection techniques or other forms of information technology.

This information collection request contains:

(1) *OMB No.:* 1905–0129.

(2) *Information Collection Request Title:* Electric Power & Renewable Electricity Surveys.

(3) *Type of Request:* Three-year extension with changes.

(4) *Purpose:* EIA's EPRES consists of the following nine surveys:

Form EIA–63B *Photovoltaic Module Shipments Report* tracks photovoltaic module manufacturing, shipments, technology types, revenue, and related information.

Form EIA–860 *Annual Electric Generator Report* collects data on existing and planned electric generation plants, and associated equipment including generators, boilers, cooling systems, and environmental control systems. Data are collected from all existing units and from planned units scheduled for initial commercial operation within ten years of the specified reporting period (depending on the type of power plant).

Form EIA–860M *Monthly Update to the Annual Electric Generator Report* collects data on the status of proposed new generators scheduled to begin commercial operation within the future 12-month period; and existing generators that have proposed modifications that are scheduled for completion within one month. The information is needed to ensure a complete and accurate inventory of the nation's generating fleet, for such purposes as reliability and environmental analysis.

Form EIA–861 *Annual Electric Power Industry Report* collects annual information on the retail sale, distribution, transmission, and generation of electric energy in the United States and its territories. The data include related activities such as energy efficiency and demand response programs. In combination with Form EIA–861S short form and the monthly Form EIA–861M, this annual survey provides coverage of sales to ultimate customers of electric power and related activities.

Form EIA–861S *Annual Electric Power Industry Report (Short Form)* collects a limited set of information annually from small companies involved in the retail sale of electricity. A complete set of annual data are collected from large companies on Form EIA–861. The small utilities that currently report on Form EIA–861S are required to complete Form EIA–861 once every eight years to provide updated information for the statistical estimation of uncollected data.

Form EIA–861M *Monthly Electric Power Industry Report* collects monthly information from a sample of electric utilities, energy service providers, and distribution companies that sell or deliver electric power to end users. Data included on this form includes sales and revenue for end-use sectors—residential, commercial, industrial, and transportation. This survey is the monthly complement to the annual data collection from the universe of respondents that report on Form EIA–861 and Form EIA–861S.

Form EIA–923 *Power Plant Operations Report* collects information from electric power plants in the United States on electric power generation, energy source consumption, end of reporting period fossil fuel stocks, as well as the quality and cost of fossil fuel receipts.

Form EIA–930 *Balancing Authority Operations Report* collects a

comprehensive set of the current day's system demand data on an hourly basis and the prior day's basic hourly electric system operating data on a daily basis. The data provide a basic measure of the current status of electric systems in the United States and can be used to compare actual system demand with the day-ahead forecast thereby providing a measure of the accuracy of the forecasting used to commit resources. In addition, the data can be used to address smart grid related issues such as integrating wind and solar generation, improving the coordination of natural gas and electric short-term operations and expanding the use of demand response, storage, and electric vehicles in electric systems operations.

(4a) Proposed Changes to Information Collection:

Form EIA–860 Annual Electric Generator Report

EIA proposes to add battery storage questions for proposed applications, including planned design attributes, energy storage capacity, and use case. For energy storage applications that are operationally connected to renewable technologies, EIA proposes to add a question that identifies the related plants and generators.

EIA also proposes to add 'bifacial' as a solar photovoltaic technology option.

Form EIA–861 Annual Electric Power Industry Report

EIA proposes to expand questions about battery storage on the net metering and non net-metered distributed generators schedules. EIA is dropping two questions on net metering 'storage' and adding six questions pertaining to batteries.

For non net-metered EIA is dropping one 'storage' question and adding two questions about batteries. EIA is proposing to add one question about Photovoltaic generators.

Form EIA–861M Monthly Electric Power Industry Report

EIA proposes to expand questions about battery storage on the net metering and non net-metered distributed generators schedules. EIA is dropping two questions on net metering 'storage' and adding six questions pertaining to batteries.

For non net-metered EIA is dropping one 'storage' question and adding two questions about batteries. EIA is proposing to add one question about Photovoltaic generators.

Form EIA–930 Hourly and Daily Balancing Authority Operations Report

EIA proposes to improve the EIA–930 by adding an information technology security requirement and limiting reported values to integers. EIA also proposes adding demand response and energy storage to the list of options for which net generation is to be reported.

Form EIA–930A Annual Balancing Authority Generator Inventory Report

EIA proposes to improve the ability to reconcile Form EIA–930 data with data reported on Form EIA–860 and Form EIA–923 by collecting the plants and generators used by each balancing authority.

(5) *Annual Estimated Number of Respondents:* 21,488:

Form EIA–63B has 57 respondents;

Form EIA–860 has 5,716 respondents;

Form EIA–860M has 478 respondents;

Form EIA–861 has 1,735 respondents;

Form EIA–861S has 1,692 respondents;

Form EIA–861M has 650 respondents;

Form EIA–923 has 10,997 respondents;

Form EIA–930 has 63 respondents;

Pretesting methodology consists of 100 respondents.

(6) *Annual Estimated Number of Total Responses:* 84,881.

(7) *Annual Estimated Number of Burden Hours:* 198,781 hours.

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $16,574,360 (198,781 burden hours times $83.38 per hour). EIA estimates that there are no additional costs to respondents associated with the surveys other than the costs associated with the burden hours since the information is maintained during normal course of business.

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

Signed in Washington, DC, on May 18, 2022.

Samson A. Adeshiyan,

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

[FR Doc. 2022–11012 Filed 5–20–22; 8:45 am]

BILLING CODE 6450–01–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 Instituting Proceedings

Docket Numbers: RP22–926–000.

Applicants: Millennium Pipeline Company, LLC.

Description: § 4(d) Rate Filing: System Map URL Update to be effective 6/16/2022.

Filed Date: 5/16/22.

Accession Number: 20220516–5242.

Comment Date: 5 p.m. ET 5/30/22.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) 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.

Filings in Existing Proceedings

Docket Numbers: RP21–1188–000.

Applicants: Texas Eastern Transmission, LP.

Description: Report Filing: TETLP Test Period Updates—RP21–1188–000 to be effective N/A.

Filed Date: 5/16/22.

Accession Number: 20220516–5200.

Comment Date: 5 p.m. ET 5/30/22.

Any person desiring to protest in any 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: *https://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 17, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–11035 Filed 5–20–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–1870–000]

Vansycle II Wind, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Vansycle II Wind, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is June 6, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*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. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: May 17, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–11043 Filed 5–20–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–1879–000]

South Portland ESS, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of South Portland ESS, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is June 6, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*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. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: May 17, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–11041 Filed 5–20–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC22–8–000]

Commission Information Collection Activities (FERC–1000); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Three-year renewal of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–1000 (Request for a Medical Exception to the COVID–19 Vaccination Requirement). The Commission did not receive any comments on the 60-day notice.

DATES: Comments on the collection of information are due June 22, 2022.

ADDRESSES: Send written comments on FERC Form No. 1000 to OMB through *www.reginfo.gov/public/do/PRAMain,* Attention: Federal Energy Regulatory Commission Desk Officer. Please identify the OMB Control Number: 1902–0320 in the subject line. Your comments should be sent within 30 days of publication of this notice in the **Federal Register**.

Please submit copies of your comments (identified by Docket No. IC22–8–000 and the form(s)) to the Commission as noted below. Electronic filing through *http://www.ferc.gov,* is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery.

○ *Mail via U.S. Postal Service only, addressed to:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

○ *Hand (Including Courier) Delivery to:* Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: OMB submissions must be formatted and filed in accordance with submission guidelines at *www.reginfo.gov/public/do/PRAMain.* Using the search function under the ''Currently Under Review field,'' select Federal Energy Regulatory Commission; click ''submit'' and select ''comment'' to the right of the subject collection.

FERC submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* or telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC–1000, Request for a Medical Exception to the COVID–19 Vaccination Requirement.

OMB Control No.: 1902–0320.

Abstract: The purpose of this three-year renewal of the information collection is to allow the Federal Energy Regulatory Commission to collect information from FERC employees (and their medical providers) applying for a medical exception to the COVID–19 Vaccination Requirement as specified in Part 2 of FERC Form No. 1000.[1]

Consistent with guidance from the Centers for Disease Control and Prevention (CDC), guidance from the Safer Federal Workforce Task Force established pursuant to Executive Order 13991 of January 20, 2021, *Protecting the Federal Workforce and Requiring Mask-Wearing,* and Executive Order 14043 of September 9, 2021, *Requiring Coronavirus Disease 2019 Vaccination for Federal Employees,* the request for this information collection is essential to continue the Commission's health and safety measures regarding the federal employee medical exceptions to the COVID–19 mandatory vaccinations. In addition, the Rehabilitation Act of 1973, as amended, requires Federal Agencies to provide reasonable accommodations to qualified employees with disabilities unless that reasonable accommodation would impose an undue hardship on the employee's Agency. See 29 U.S.C. 791 and 29 CFR part 1614; see also 20 CFR part 1630 and Executive Order 13164 of July 26, 2000, *Requiring Federal Agencies to Establish Procedures to Facilitate the Provision of Reasonable Accommodation.* Section 2 of E.O. 14043 mandates that each agency, ''implement, to the extent consistent with applicable law, a program to require COVID–19 vaccination for all of its Federal employees, with exceptions only as required by law.'' This medical exception form (FERC Form No. 1000) is necessary for the Commission to determine whether to grant medical exceptions to the vaccine requirement under the Rehabilitation Act.

The information being requested helps promote the safety of the Federal workforce, Federal buildings, and others on site at FERC facilities. This collection is consistent with the COVID–19 Workplace Safety Agency Model Safety Principles established by the White House Safer Federal Workforce Task Force and guidance from the Centers for Disease Control and Prevention.

Type of Respondent: Medical Providers.

Estimate of Annual Burden:[2] The Commission estimates the annual public reporting burden for the information collection as:

[1] The vaccination requirement issued pursuant to E.O. 14043, is currently the subject of a nationwide injunction. While that injunction remains in place, the Federal Energy Regulatory Commission (FERC) will not process requests for a medical exception from the COVID–19 vaccination requirement pursuant to E.O. 14043. FERC will also not request the submission of any medical information related to a request for an exception from the vaccination requirement pursuant to E.O. 14043 while the injunction remains in place. But FERC may nevertheless receive information regarding a medical exception. That is because, if FERC were to receive a request for an exception from the COVID–19 vaccination requirement pursuant to E.O. 14043 during the pendency of the injunction, FERC will accept the request, hold it in abeyance, and notify the employee who submitted the request that implementation and enforcement of the COVID–19 vaccination requirement pursuant to E.O. 14043 is currently enjoined and that an exception therefore is not necessary so long as the injunction is in place. In other words, during the pendency of the injunction, any information collection related to requests for medical exception from the COVID–19 vaccination requirement pursuant to E.O. 14043 is not undertaken to implement or enforce the COVID–19 vaccination requirement.

[2] ''Burden'' is the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to Title 5 Code of Federal Regulations 1320.3.

FERC–1000—REQUEST FOR A MEDICAL EXCEPTION TO THE COVID–19 VACCINATION REQUIREMENT

	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden & cost per response [3] (4)	Total annual burden hours & total annual cost (3) * (4) = (5)
Medical Provider	24	1	24	30 minutes (½ hour); $72.	720 minutes (12 hours); $1,728.

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate 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.

Dated: May 17, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–11038 Filed 5–20–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP22–138–000]

Northern Natural Gas Company; Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed Northern Lights 2023 Expansion Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental document, that will discuss the environmental impacts of the Northern Lights 2023 Expansion Project (Project), involving construction and operation of facilities by Northern Natural Gas Company (Northern) in Freeborn, Scott, Sherburne, Stearns, and Washington Counties, Minnesota, and Monroe County, Wisconsin. The Commission will use this environmental document in its decision-making process to determine whether the Project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies regarding the project. As part of the National Environmental Policy Act (NEPA) review process, the Commission takes into account concerns the public may have about proposals and the environmental impacts that could result from its action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. This gathering of public input is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the environmental document on the important environmental issues. Additional information about the Commission's NEPA process is described below in the *NEPA Process and Environmental Document* section of this notice.

By this notice, the Commission requests public comments on the scope of issues to address in the environmental document. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on June 17, 2022. Further details on how to submit comments are provided in the *Public Participation* section of this notice.

Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the environmental document. Commission staff will consider all comments during the preparation of the environmental document.

If you submitted comments about this Project to the Commission before the opening of this docket on March 28, 2022, you will need to file those comments in Docket No. CP22–138–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this Project. State and local government representatives should notify their constituents of this proposed Project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable easement agreement. You are not required to enter into an agreement. However, if the Commission approves the Project, the Natural Gas Act conveys the right of eminent domain to the company. Therefore, if you and the company do not reach an easement agreement, the pipeline company could initiate condemnation proceedings in court. In such instances, compensation would be determined by a judge in accordance with state law. The Commission does not subsequently grant, exercise, or oversee the exercise of that eminent domain authority. The courts have exclusive authority to handle eminent domain cases; the Commission has no jurisdiction over these matters.

Northern provided landowners with a fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' which addresses typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. This fact sheet along with other landowner topics of interest are available for viewing on the FERC website (*www.ferc.gov*) under the Natural Gas Questions or Landowner Topics link.

Public Participation

There are three methods you can use to submit your comments to the Commission. Please carefully follow these instructions so that your comments are properly recorded. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.*

[3] Cost estimates are based on industry costs for general internal medicine physicians (NAICS code 29–1216) defined by the Bureau of Labor Statistics. The cost figure for the general internal medicine physicians in 2021 was an average annual salary plus benefits of $300,076/year or $144/hour.

(1) You can file your comments electronically using the eComment feature, which is located on the Commission's website (*www.ferc.gov*) under the link to FERC Online. Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; a comment on a particular project is considered a ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the Project docket number (CP22–138–000) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Additionally, the Commission offers a free service called eSubscription which makes it easy to stay informed of all issuances and submittals regarding the dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

Summary of the Proposed Project

The Project would provide for incremental winter firm service of 44,222 dekatherms per day (Dth/day) serving residential, commercial and industrial customer market growth in Northern's Market Area and 6,667 Dth/day of additional firm service that would allow a shipper enhanced reliability and flexibility in scheduling their transportation capacity.

The Project consists of the following facilities:

- A 2.8-mile extension of 36-inch-diameter Ventura North E-line, in Freeborn County, Minnesota;
- a 1.07-mile, 30-inch-diameter loop of 20-inch-diameter Elk River 1st and 2nd branch lines, in Washington County, Minnesota;
- a 1.14-mile extension of 24-inch-diameter Willmar D branch line, in Scott County, Minnesota;
- a 2.5-mile extension of 8-inch-diameter Princeton tie over loop, in Sherburne County, Minnesota;
- a 2.0-mile loop of 3-inch-diameter Paynesville branch line, in Stearns County, Minnesota;
- a 0.34-mile extension of 8-inch-diameter Tomah branch line loop, in Monroe County, Wisconsin; and
- aboveground facilities including one new pig launcher, four new valve settings, replacement of valves and piping inside four facilities, removal of three valve settings, and associated piping.

The general location of the Project facilities is shown in appendix 1.[1]

Land Requirements for Construction

Construction of the Project would disturb about 255.4 acres of land. The total acreage required for operation of all Project facilities is about 52.4 acres. About 12.4 percent of the construction footprint would overlap with easements for existing Northern facilities.

NEPA Process and the Environmental Document

Any environmental document issued by the Commission will discuss impacts that could occur as a result of the construction and operation of the proposed Project under the relevant general resource areas:

- Geology and soils;
- water resources and wetlands;
- vegetation and wildlife;
- threatened and endangered species;
- cultural resources;
- land use and recreation;
- environmental justice;
- air quality and noise;
- reliability and safety; and
- cumulative impacts

Commission staff will also evaluate reasonable alternatives to the proposed Project or portions of the Project and make recommendations on how to lessen or avoid impacts on the various resource areas. Your comments will help Commission staff identify and focus on the issues that might have an effect on the human environment and potentially eliminate others from further study and discussion in the environmental document.

Following this scoping period, Commission staff will determine whether to prepare an Environmental Assessment (EA) or an Environmental Impact Statement (EIS). The EA or the EIS will present Commission staff's independent analysis of the issues. If Commission staff prepares an EA, a *Notice of Schedule for the Preparation of an Environmental Assessment* will be issued. The EA may be issued for an allotted public comment period. The Commission would consider timely comments on the EA before making its decision regarding the proposed project. If Commission staff prepares an EIS, a *Notice of Intent to Prepare an EIS/Notice of Schedule* will be issued, which will open up an additional comment period. Staff will then prepare a draft EIS which will be issued for public comment. Commission staff will consider all timely comments received during the comment period on the draft EIS and revise the document, as necessary, before issuing a final EIS. Any EA or draft and final EIS will be available in electronic format in the public record through eLibrary[2] and the Commission's natural gas environmental documents web page (*https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents*). If eSubscribed, you will receive instant email notification when the environmental document is issued.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this Project to formally cooperate in the preparation of the environmental document.[3] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the *Public Participation* section of this notice.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, the Commission is using this notice to initiate consultation with the applicable State Historic

[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary''. For instructions on connecting to eLibrary, refer to the last page of this notice. At this time, the Commission has suspended access to the Commission's Public Reference Room due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll free, (886) 208–3676 or TTY (202) 502–8659.

[2] For instructions on connecting to eLibrary, refer to the last page of this notice.

[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at title 40, Code of Federal Regulations, section 1501.8.

Preservation Offices, and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the Project's potential effects on historic properties.[4] The environmental document for this Project will document findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; potentially interested Indian tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the Project and includes a mailing address with their comments. Commission staff will update the environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed Project.

If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please complete one of the following steps:

(1) Send an email to *GasProjectAddressChange@ferc.gov* stating your request. You must include the docket number CP22–138–000 in your request. If you are requesting a change to your address, please be sure to include your name and the correct address. If you are requesting to delete your address from the mailing list, please include your name and address as it appeared on this notice. This email address is unable to accept comments.

Or

(2) Return the attached ''Mailing List Update Form'' (appendix 2).

Additional Information

Additional information about the Project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number (CP22–138) in the ''Docket Number'' field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings. Public sessions or site visits will be posted on the Commission's calendar located at *https://www.ferc.gov/news-events/events* along with other related information.

Dated: May 17, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–11034 Filed 5–20–22; 8:45 am]

BILLING CODE 6717–01–P

[4] The Advisory Council on Historic Preservation's regulations are at title 36, Code of Federal Regulations, part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

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: EG22–116–000.
Applicants: Ocean State BTM, LLC.
Description: Ocean State BTM, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 5/17/22.
Accession Number: 20220517–5114.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: EG22–117–000.
Applicants: Rumford ESS, LLC.
Description: Rumford ESS, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 5/17/22.
Accession Number: 20220517–5116.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: EG22–118–000.
Applicants: Madison BTM, LLC.
Description: Madison BTM, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 5/17/22.
Accession Number: 20220517–5117.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: EG22–119–000.
Applicants: South Portland ESS, LLC.
Description: South Portland ESS, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 5/17/22.
Accession Number: 20220517–5118.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: EG22–120–000.
Applicants: Sanford ESS, LLC.
Description: Sanford ESS, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 5/17/22.
Accession Number: 20220517–5121.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: EG22–121–000.
Applicants: Madison ESS, LLC.
Description: Madison ESS, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 5/17/22.
Accession Number: 20220517–5129.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: EG22–122–000.
Applicants: AE–ESS NWS 1, LLC.
Description: AE–ESS NWS 1, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 5/17/22.
Accession Number: 20220517–5130.
Comment Date: 5 p.m. ET 6/7/22.

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

Docket Numbers: ER16–2320–011.
Applicants: Pacific Gas and Electric Company.
Description: Compliance filing: TO18 Compliance Filing to be effective 3/1/2017.
Filed Date: 5/16/22.
Accession Number: 20220516–5244.
Comment Date: 5 p.m. ET 6/6/22.

Docket Numbers: ER20–1863–006.
Applicants: Ingenco Wholesale Power, L.L.C.
Description: Compliance filing: Infomrational Filing on Reactive Tariff ER20–1863 to be effective N/A.
Filed Date: 5/17/22.
Accession Number: 20220517–5136.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: ER21–1005–001.
Applicants: Montana-Dakota Utilities Co.
Description: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.19a(b): Refund Report Montana-Dakota Utilities Co. to be effective N/A.
Filed Date: 5/17/22.
Accession Number: 20220517–5152.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: ER21–1339–002.
Applicants: California Ridge Wind Energy LLC.
Description: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.19a(b): Refund Report_California Ridge Wind Energy LLC to be effective N/A.
Filed Date: 5/17/22.

Accession Number: 20220517–5133.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: ER21–1622–001.
Applicants: Otter Tail Power Company.
Description: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.19a(b): Refund Report_Otter Tail Power Company to be effective N/A.
Filed Date: 5/17/22.
Accession Number: 20220517–5160.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: ER21–2179–001.
Applicants: Oliver Wind I, LLC.
Description: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.19a(b): Refund Report_Oliver Wind I, LLC to be effective N/A.
Filed Date: 5/17/22.
Accession Number: 20220517–5167.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: ER21–2401–001.
Applicants: Oliver Wind Energy Center II, LLC.
Description: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.19a(b): Refund Report_Oliver Wind Energy Center II, LLC to be effective N/A.
Filed Date: 5/17/22.
Accession Number: 20220517–5148.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: ER22–682–002.
Applicants: Duke Energy Progress, LLC.
Description: Duke Energy Progress, LLC submits a Petition for Limited Waiver of Rate Schedule Provision.
Filed Date: 5/13/22.
Accession Number: 20220513–5205.
Comment Date: 5 p.m. ET 6/3/22.

Docket Numbers: ER22–1884–000.
Applicants: Sanford ESS, LLC.
Description: Baseline eTariff Filing: Sanford ESS MBR Application Filing to be effective 6/1/2022.
Filed Date: 5/16/22.
Accession Number: 20220517–5001.
Comment Date: 5 p.m. ET 6/6/22.

Docket Numbers: ER22–1885–000.
Applicants: South Portland ESS, LLC.
Description: Baseline eTariff Filing: South Portland ESS MBR Application Filing to be effective 6/1/2022.
Filed Date: 5/17/22.
Accession Number: 20220517–5002.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: ER22–1886–000.
Applicants: NextEra Energy Transmission Southwest, LLC.
Description: Application for Authorization for Abandoned Plant Incentive Rate Treatment of NextEra Energy Transmission Southwest, LLC.
Filed Date: 5/16/22.
Accession Number: 20220516–5279.
Comment Date: 5 p.m. ET 6/6/22.

Docket Numbers: ER22–1887–000.
Applicants: New York Independent System Operator, Inc.
Description: § 205(d) Rate Filing: NYISO 205 filing of LGIA among NYISO, LIPA, and LI Solar for SA2709 to be effective 5/3/2022.
Filed Date: 5/17/22.
Accession Number: 20220517–5073.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: ER22–1888–000.
Applicants: AE–ESS NWS 1, LLC.
Description: Baseline eTariff Filing: AE–ESS NWS 1, LLC MBR Application to be effective 6/1/2022.
Filed Date: 5/17/22.
Accession Number: 20220517–5100.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: ER22–1889–000.
Applicants: Public Service Company of Colorado.
Description: § 205(d) Rate Filing: 2022–05–17 PSCo-BkCoU-Trans Intercon Agrmt—Amnd–433–0.1.0 to be effective 5/18/2022.
Filed Date: 5/17/22.
Accession Number: 20220517–5112.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: ER22–1890–000.
Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.
Description: § 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii): Alligator Creek Solar LGIA Amendment Filing to be effective 4/17/2022.
Filed Date: 5/17/22.
Accession Number: 20220517–5113.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: ER22–1891–000.
Applicants: Ingenco Wholesale Power, L.L.C.
Description: Compliance filing: Informational Filing on Reactive Tariff ER20–1863 to be effective N/A.
Filed Date: 5/17/22.
Accession Number: 20220517–5132.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: ER22–1892–000.
Applicants: Liberty Utilities (Granite State Electric) Corp.
Description: § 205(d) Rate Filing: Borderline Sales Rate Sheet Update May 2022 with Request for Notice Waiver to be effective 5/15/2022.
Filed Date: 5/17/22.
Accession Number: 20220517–5140.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: ER22–1893–000.
Applicants: American Electric Power Service Corporation, Ohio Power Company, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: American Electric Power Service Corporation submits tariff filing per 35.13(a)(2)(iii: AEP submits four Facilities Agreements re: ILDSA, SA No. 1336 to be effective 7/17/2022.
Filed Date: 5/17/22.
Accession Number: 20220517–5142.
Comment Date: 5 p.m. ET 6/7/22.

Docket Numbers: ER22–1894–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: First Revised ISA, SA No. 4835; Queue No. AE2–315 to be effective 4/19/2022.
Filed Date: 5/17/22.
Accession Number: 20220517–5164.
Comment Date: 5 p.m. ET 6/7/22.

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 or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) 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.

Dated: May 17, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–11036 Filed 5–20–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–1878–000]

Sanford ESS, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Sanford ESS, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal

Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is June 6, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*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. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: May 17, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–11042 Filed 5–20–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–1882–000]

VESI 10 LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of VESI 10 LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is June 6, 2022.

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Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*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. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: May 17, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–11040 Filed 5–20–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM93–11–000]

Revisions to Oil Pipeline Regulations Pursuant to the Energy Policy Act of 1992; Notice of Annual Change in the Producer Price Index for Finished Goods

The Commission's regulations include a methodology for oil pipelines to change their rates through use of an index system that establishes ceiling levels for such rates. The Commission bases the index system, found at 18 CFR 342.3, on the annual change in the Producer Price Index for Finished Goods (PPI–FG), minus point two one percent (PPI–FG −0.21%). The Commission determined in the January 2022 Order [1] that PPI–FG −0.21% is the appropriate oil pricing index factor for pipelines to use for this period.

The regulations provide that the Commission will publish annually an index figure reflecting the final change in the PPI–FG after the Bureau of Labor Statistics publishes the final PPI–FG in May of each calendar year. The annual average PPI–FG index figures were 202.9 for 2020 and 221.0 for 2021.[2]

[1] *Five-Year Rev. of the Oil Pipeline Index,* 178 FERC ¶ 61,023, at P 105 (2022) (January 2022 Order).

[2] Bureau of Labor Statistics (BLS) publishes the final figure in mid-May of each year. This figure is publicly available from the Division of Industrial Prices and Price Indexes of the BLS, at 202–691–7705, and in print in August in Table 1 of the annual data supplement to the BLS publication Producer Price Indexes via the internet at *http://www.bls.gov/ppi/home.htm.* To obtain the BLS data, scroll down to ''PPI Databases'' and click on ''Top Picks'' of the Commodity Data including ''headline'' FD–ID indexes (Producer Price Index—PPI). At the next screen, under the heading ''PPI Commodity Data,'' select the box, ''Finished goods—WPUFD49207,'' then scroll to the bottom of this screen and click on Retrieve data.

Thus, the percent change (expressed as a decimal) in the annual average PPI–FG from 2020 to 2021, minus 0.21 percent, is positive 0.087107.[3] Oil pipelines must multiply their July 1, 2021, through June 30, 2022, index ceiling levels[4] by positive 1.087107[5] to compute their index ceiling levels for July 1, 2022, through June 30, 2023, in accordance with 18 CFR 342.3(d). For guidance in calculating the ceiling levels for each 12-month period beginning January 1, 1995,[6] see Explorer Pipeline Company, 71 FERC ¶ 61,416, at n.6 (1995).

In addition to publishing the full text of this Notice in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print this Notice via the internet through FERC's Home Page (*http://www.ferc.gov*) using the eLibrary link. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field and follow other directions on the search page.

User assistance is available for eLibrary and other aspects of FERC's website during normal business hours. For assistance, please contact the Commission's Online Support at 1–866–208–3676 (toll free) or 202–502–6652 (email at *FERCOnlineSupport@ferc.gov*), or the Public Reference Room at 202–502–8371, TTY 202–502–8659. E-Mail the Public Reference Room at *public.referenceroom@ferc.gov*.

Dated: May 17, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–11037 Filed 5–20–22; 8:45 am]

BILLING CODE 6717–01–P

[3] [221.0–202.9]/202.9 = 0.089207 − 0.0021 = 0.087107.

[4] *See* January 2022 Order, 178 FERC ¶ 61,023 at P 106 (directing oil pipelines to recompute their July 1, 2021 through June 30, 2022 index ceiling levels to be effective March 1, 2022), *reh'g denied, Five-Year Rev. of the Oil Pipeline Index,* 179 FERC ¶ 61,100, at P 8 (2022); *see also Revisions to Oil Pipeline Reguls. Pursuant to the Energy Pol'y Act of 1992,* 178 FERC ¶ 61,046 (2022).

[5] 1 + 0.087107 = 1.087107.

[6] For a listing of all prior multipliers issued by the Commission, see the Commission's website, *https://www.ferc.gov/industries-data/oil/general-information/oil-pipeline-index.*

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–1883–000]

Ledyard Windpower, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Ledyard Windpower, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is June 6, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*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. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: May 17, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–11039 Filed 5–20–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2022–0437; FRL–9869–01–OGC]

Proposed Consent Decree, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with the Clean Air Act, as amended (CAA or the Act), notice is given of a proposed consent decree in *Growth Energy* v. *Regan,* No. 1:22–cv–01191 (D. DC). On April 29, 2022, Plaintiff Growth Energy filed a complaint in the United States District Court for the District of Columbia alleging that the Environmental Protection Agency (EPA or the Agency) failed to perform a non-discretionary duty in accordance with the Act to establish volumes under the renewable fuel program for 2023. The proposed consent decree would establish deadlines for EPA to establish the 2023 renewable fuel program volumes: Signature of a proposed rule by September 16, 2022, and signature of a final rule by April 28, 2023.

DATES: Written comments on the proposed consent decree must be received by June 22, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2022–0437, online at *https://www.regulations.gov* (EPA's preferred method). Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID number for this action. Comments received may be posted without change to *https://www.regulations.gov,* including any personal information provided. For

detailed instructions on sending comments and additional information on the rulemaking process, see the ''Additional Information about Commenting on the Proposed Consent Decree'' heading under the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Rosemary Hambright Kaban, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone (202) 564–8829; email address *Kaban.Rosemary@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Obtaining a Copy of the Proposed Consent Decree

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2022–0437) contains a copy of the proposed consent decree. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

The electronic version of the public docket for this action contains a copy of the proposed consent decree and is available through *https://www.regulations.gov*. You may use *https://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search.''

II. Additional Information About the Proposed Consent Decree

The proposed consent decree would establish deadlines for EPA to establish volumes for the renewable fuel program for 2023: September 16, 2022, for EPA to sign a proposed rule, and April 28, 2023, for EPA to sign a final rule. EPA is obligated to establish the 2023 renewable fuel program volumes under 42 U.S.C. 7545(o)(2)(B)(ii). For years after the statutory volumes in 42 U.S.C. 7545(o)(2)(B)(i) cease, the Agency is statutorily obligated to establish the renewable fuel program volumes ''no later than 14 months before the first year for which such applicable volume will apply.'' Under this provision, EPA was required to establish the volumes for 2023 by October 31, 2021. EPA intends to establish applicable percentage standards for obligated parties for 2023 in the same rulemaking that establishes volumes for 2023.

In accordance with section 113(g) of the CAA, for a period of thirty (30) days following the date of publication of this document, the Agency will accept written comments relating to the proposed consent decree. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act.

III. Additional Information About Commenting on the Proposed Consent Decree

Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2022–0437, via *https://www.regulations.gov*. Once submitted, comments cannot be edited or removed from this docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets*. For additional information about submitting information identified as CBI, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *https://www.regulations.gov* website to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment.

Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

Gautam Srinivasan,

Associate General Counsel.

[FR Doc. 2022–10988 Filed 5–20–22; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

[Public Notice: 2022–6010]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the U.S.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (EXIM), as a 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 collection, as required by the Paperwork Reduction Act of 1995. The purpose of this collection is to gather information necessary to make a determination of eligibility of a transaction for EXIM assistance under its medium-term guarantee and insurance program.

DATES: Comments should be received on or before July 22, 2022 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *WWW.REGULATIONS.GOV* (EIB 03–02) or by mail to Office of Information and Regulatory Affairs, 725 17th Street NW, Washington, DC 20038, Ave. NW, Washington, DC. The application tool

can be reviewed at: *https://img.exim.gov/s3fs-public/pub/pending/eib-03-02-mt-application.pdf.*

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Donna Schneider <*donna.schneider@exim.gov*>, 202–565–4223.

SUPPLEMENTARY INFORMATION:

Titles and Form Number: EIB 03–02 Application for Medium Term Insurance, Direct Loan or Guarantee.

OMB Number: 3048–0014.

Type of Review: Update & Renewal.

Need and Use: The purpose of this collection is to gather information necessary to make a determination of eligibility of a transaction for EXIM assistance under its medium-term guarantee and insurance program.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 00.

Estimated Time per Respondent: 2 hours.

Annual Burden Hours: 400 hours.

Frequency of Reporting or Use: As needed.

Government Expenses:

Reviewing Time per Year: 200 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $8,500 (time*wages).

Benefits and Overhead: 20%.

Total Government Cost: $10,200.

Bassam Doughman,

IT Specialist.

[FR Doc. 2022–11030 Filed 5–20–22; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2022–6009]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the U.S.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (EXIM), as a 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 collection, as required by the Paperwork Reduction Act of 1995. The purpose of this collection is to gather information necessary to make a determination of eligibility of a transaction for EXIM assistance under its medium-term guarantee and insurance program.

DATES: Comments should be received on or before July 22, 2022 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *WWW.REGULATIONS.GOV* (EIB 95–10) or by mail to Office of Information and Regulatory Affairs, 725 17th Street NW, Washington, DC 20038, Ave. NW, Washington, DC. The application tool can be reviewed at: *https://img.exim.gov/s3fs-public/pub/pending/eib-95-10-cgf-and-lt-application.pdf.*

FOR FURTHER INFORMATION CONTACT: To request additional information, please Donna Schneider <*donna.schneider@exim.gov*>, 202–565–4223.

SUPPLEMENTARY INFORMATION:

Titles and Form Number: EIB 95–10 Application for Credit Guarantee Facility and Long-term Direct Loan or Guarantee.

OMB Number: 3048–0013.

Type of Review: Update & Renewal.

Need and Use: The information collected will provide information needed to determine compliance and creditworthiness for transaction requests submitted to EXIM under its credit guarantee facility and long-term guarantee and direct loan programs.

Annual Number of Respondents: 85.

Estimated Time per Respondent: 2.5 hours.

Annual Burden Hours: 212.5 hours.

Frequency of Reporting or Use: As needed.

Government Expenses:

Reviewing Time per Year: 148.75 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $6,322 (time * wages).

Benefits and Overhead: 20%.

Total Government Cost: $7,586.

Bassam Doughman,

IT Specialist.

[FR Doc. 2022–10989 Filed 5–20–22; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Thursday, May 26, 2022 at 10 a.m.

PLACE: Hybrid Meeting: 1050 First Street NE, Washington, DC (12th Floor) and virtual.

Note: For those attending the meeting in person, current Covid-19 safety protocols for visitors, which are based on the CDC Covid-19 community level in Washington, DC, will be updated on the commission's contact page by the Monday before the meeting. See the contact page at *https://www.fec.gov/contact/.* If you would like to virtually access the meeting, see the instructions below.

STATUS: This meeting will be open to the public, subject to the above-referenced guidance regarding the Covid-19 community level and corresponding health and safety procedures. To access the meeting virtually, go to the commission's website *www.fec.gov* and click on the banner to be taken to the meeting page.

MATTERS TO BE CONSIDERED:

Interim Final Rule: Independent Expenditure Reporting

Interim Final Rule: Repayment of Candidate Loans

Draft Advisory Opinion 2022–05: DSCC

Draft Advisory Opinion 2022–03: Democracy Engine, LLC

Proposed Final Audit Report on Mike Braun for Indiana (A19–02)

Initial Determination on Eligibility to Receive Primary Election Public Funds—Howie Hawkins, Howie Hawkins 2020 (LRA 1132)

Management and Administrative Matters

CONTACT PERSON FOR MORE INFORMATION:

Judith Ingram, Press Officer

Telephone: (202) 694–1220

Authority: Government in the Sunshine Act, 5 U.S.C. 552b.

Individuals who plan to attend in person and who require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Laura E. Sinram, Acting Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

Vicktoria J. Allen,

Acting Deputy Secretary of the Commission.

[FR Doc. 2022–11176 Filed 5–19–22; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend, with revision, the Application to Become a Savings and Loan Holding Company or to Acquire a Savings Association or Savings and Loan Holding Company (FR LL–10(e); OMB No. 7100–0336).

DATES: The revisions are applicable as of June 22, 2022.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of

the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, With Revision, of the Following Information Collection

Collection title: Application to Become a Savings and Loan Holding Company or to Acquire a Savings Association or Savings and Loan Holding Company.

Collection identifier: FR LL–10(e).

OMB control number: 7100–0336.

Effective Date: June 22, 2022.

Frequency: Event generated.

Respondents: Entities seeking prior approval to become or acquire a savings and loan holding company (SLHC).

Estimated number of respondents: 15.

Estimated average hours per response: Reporting, 60; Disclosure, 1.

Estimated annual burden hours: Reporting, 900; Disclosure, 15.

General description of collection: The form collects information concerning certain proposed SLHC formations, acquisitions, and mergers. Specifically, the form collects financial and managerial information and information about the proposed transaction, the competitive effects of the proposal, and the impact of the transaction on the convenience and needs of the communities to be served. Applicants that file the FR LL–10(e) are also required to publish a notice in a newspaper of general circulation in the community(ies) in which the head office(s) of the applicant; its largest subsidiary savings association, if any; and each savings association to be directly or indirectly acquired are located.

Legal authorization and confidentiality: The FR LL–10(e) is authorized by section 10(b)(2) of the Home Owners' Loan Act (HOLA).[1] The FR LL–10(e) is required to obtain a benefit.

Information submitted on the FR LL–10(e) may be protected from disclosure pursuant to exemption 8 of the Freedom of Information Act (FOIA)[2] if it is contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions. An applicant may also request confidential treatment for information provided on the FR LL–10(e) in accordance with the Board's Rules Regarding Availability of Information,[3] and such requests will be reviewed on a case-by-case basis. To the extent information provided on the FR LL–10(e) is nonpublic commercial or financial information, which is both customarily and actually treated as private by the respondent, or to the extent the information reflects personnel and medical files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, the information may be protected from disclosure pursuant to FOIA exemption 4 or 6, respectively.[4]

Current actions: On January 28, 2022, the Board published a notice in the **Federal Register** (87 FR 4593) requesting public comment for 60 days on the extension, with revision, of the FR LL–10(e). The Board proposed to revise the FR LL–10(e) by adding a two-page standardized application and certification form; adding instructions on what information a filer must include in a notice regarding the reorganization of a newly-formed holding company pursuant to 12 CFR 238.12(a)(2); providing that applicants that have elected to utilize the Community Bank Leverage Ratio framework would not be required to submit information related to risk-weighted assets or risk-based capital ratios; and explicitly listing filings under section 238.11(f) of Regulation LL on the instructions. The Board also proposed a minor change that would correct a cross-reference to the Board's rules regarding the availability of information and to clarify that the informational requirements of the FR LL–10(e) are mandatory for all filers. The comment period for this notice expired on March 29, 2022. The Board did not receive any comments. The revisions will be implemented as proposed.

Board of Governors of the Federal Reserve System, May 17, 2022.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–10966 Filed 5–20–22; 8:45 am]

BILLING CODE 6210–01–P

[1] 12 U.S.C. 1467a(b) (requiring SLHCs to register with the Board on such forms as it may prescribe and authorizing the Board to require reports from SLHCs containing such information concerning the operations of SLHCs and their subsidiaries as the Board may require).

[2] 5 U.S.C. 552(b)(8).

[3] 12 CFR 261.17.

[4] 5 U.S.C. 552(b)(4); (b)(6).

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

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 standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these 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 June 22, 2022.

A. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE,

Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Heart of Georgia Bancshares, Inc., Vidalia, Georgia;* to acquire Bank of Lumber, Lumber City, Georgia.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–11008 Filed 5–20–22; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

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 standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843), and interested persons may express their views in writing on the standards enumerated in section 4. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Comments regarding each of these 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 June 22, 2022.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Fidelity Federal Bancorp, Evansville, Indiana;* to become a bank holding company by acquiring Community Banks of Shelby County, Cowden, Illinois, and also to retain United Fidelity Bank, F.S.B., Evansville, Indiana, and thereby engage in operating a savings association pursuant to section 225.28(b)(4)(ii) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–11011 Filed 5–20–22; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Home Owners' Loan Act (12 U.S.C. 1461 *et seq.*) (HOLA), Regulation LL (12 CFR part 238), and Regulation MM (12 CFR part 239), and all other applicable statutes and regulations to become a savings and loan holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a savings association.

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 whether the proposed transaction complies with the standards enumerated in the HOLA (12 U.S.C. 1467a(e)).

Comments regarding each of these 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 June 22, 2022.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Fidelity Federal Bancorp, Evansville, Indiana;* to become a savings and loan company, following its conversion to a bank holding company for a moment in time in connection with its acquisition of Community Banks of Shelby County, Cowden, Illinois.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–11009 Filed 5–20–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–22–0009; Docket No. CDC–2022–0069]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National Disease Surveillance Program. This collection covers the surveillance activities for four rare disease conditions; Creutzfeldt-Jakob Disease (CJD), Reye Syndrome, Kawasaki Syndrome, and Acute Flaccid Myelitis (AFM).

DATES: CDC must receive written comments on or before July 22, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0069 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without

change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. 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;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. 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 submissions of responses; and
5. Assess information collection costs.

Proposed Project

National Disease Surveillance Program (OMB Control No. 0920–0009, Exp. 8/31/2022)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Surveillance of the incidence and distribution of disease has been an important function of the U.S. Public Health Service (PHS) since an 1878 Act of Congress authorized the PHS to collect morbidity reports. After the Malaria Control in War Areas Program had fulfilled its original 1942 objective of reducing malaria transmission, its basic tenets were carried forward and broadened by the formation of the Communicable Disease Center (CDC) in 1946. CDC was conceived of as a well-equipped, broadly staffed agency used to translate facts about analysis of morbidity and mortality statistics on communicable diseases and through field investigations. It was soon recognized that control measures (such as the DDT spraying for malaria) did not alleviate the threat of disease reintroduction. In 1950, the Malaria Surveillance Program began and in 1952, the National Surveillance Program started. Both programs were based on the premise that diseases cannot be diagnosed, prevented, or controlled until existing knowledge is expanded and new ideas developed and implemented. The original scope of the National Surveillance Program included the study of malaria, murine typhus, smallpox, psittacosis, diphtheria, leprosy, and sylvatic plague. Over the years, the mandate of CDC has broadened in preventive health activities and the surveillance systems maintained have expanded.

The National Disease Surveillance Program is authorized under the Public Health Service Act, Section 301 and 306 (42 U.S.C. 241 and 242K). This information collection activity covers surveillance activities for four, rare diseases: (1) Creutzfeldt-Jakob Disease (CJD), (2) Reye Syndrome, (3) Kawasaki Syndrome, and (4) Acute Flaccid Myelitis. Since the previous approval of 0920–0009, changes are being requested only to the Acute Flaccid Myelitis form. The total estimated burden requested by CDC has been reduced to 98, down 69 hours from the previous total of 167, and is adjusted to match actual, experienced burden more closely. There is no cost to respondents other than the time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Epidemiologist	CJD	10	2	20/60	7
	Kawasaki Syndrome	20	2	15/60	10
	Reye Syndrome1	1	1	20/60	1
	Acute Flaccid Myelitis	100	4	12/60	80
Total					98

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–10991 Filed 5–20–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–22–1233; Docket No. CDC–2022–0067]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Paul Coverdell National Acute Stroke Program (PCNASP) (DP21–2102) Evaluation. This project will collect information from funded PCNASP recipients to gain insight into the effectiveness of implementation approaches, including linking and using data, using team-based approaches to coordinate stroke care, and providing community resources in order to reach the general population and those at highest risk of stroke events, and reduce disparities in access to quality care for high burden populations.

DATES: CDC must receive written comments on or before July 22, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0067 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. 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;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. 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 submissions of responses; and
5. Assess information collection costs.

Proposed Project

Paul Coverdell National Acute Stroke Program (PCNASP) (DP21–2102) Evaluation (OMB Control No. 0920–1233)—Reinstatement—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC is the primary federal agency for protecting health and promoting quality of life through the prevention and control of disease, injury, and disability. CDC is committed to programs that reduce the health and economic consequences of the leading causes of death and disability, thereby ensuring a long, productive, healthy life for all people.

Stroke remains a leading cause of serious, long-term disability and is the fifth leading cause of death in the United States after heart disease, cancer, chronic lower respiratory diseases, and accidents. Estimates indicate that approximately 795,000 people suffer a first-ever or recurrent stroke each year with more than 146,000 deaths annually. Although there have been significant advances in preventing and treating stroke, the rising prevalence of heart disease, diabetes, and obesity has increased the relative risk for stroke, especially in African American populations. Moreover, stroke's lifetime direct cost of health care and indirect cost of lost productivity is staggering and imposes a substantial societal economic burden.

State programs funded through the Paul Coverdell National Acute Stroke Program (PCNASP) are in the forefront of developing and implementing system-change efforts to improve stroke systems of care by using strategies like linking and using data, using team-based approaches to coordinate stroke care, and providing community resources to reach the general populations and specifically those at highest risk of stroke events, and reduce disparities in access to quality care for high burden populations.

When Congress directed the CDC to establish PCNASP in 2001, CDC intended to monitor trends in stroke and stroke care, with the ultimate mission of improving the quality of care for stroke patients in the United States. Since 2021, CDC has funded and provided technical assistance to thirteen recipients to develop comprehensive stroke systems of care. A comprehensive system of care improves quality of care by creating seamless transitions for individuals experiencing stroke. In such a system, pre-hospital providers, in-hospital providers, and early post-hospital providers coordinate patient hand-offs and ensure continuity of care.

While PCNASP has existed since 2001, the goal and mission of the program has evolved with each funding cycle. The 2021–2024 funding cycle is the first such initiative to focus on addressing health equity specifically and understanding efforts to impact stroke outcomes for those at highest risk of stroke. CDC contracted with RTI International to conduct a national evaluation to assess program

implementation as well as short term and intermediate outcomes of the thirteen funded recipients.

CDC and RTI International propose to collect information from all thirteen funded PCNASP recipients to gain insight into the effectiveness of implementation approaches, including linking and using data, using team based approaches to coordinate stroke care, and providing community resources in order to reach the general population and those at highest risk of stroke events, and reduce disparities in access to quality care for high burden populations.

The information collection will focus on describing PCNASP specific contributions to effective state-based stroke systems of care and the costs associated with this work. Two components of the information collection include: (1) Program implementation cost data collection from program recipients using a cost collection tool; and (2) interviews with key program and partner staff. Cost data collection will focus on recipients' cumulative spending to support PCNASP activities, spending by reporting period, and spending associated with specific PCNASP strategies related to building comprehensive state-wide stroke systems of care and strategies focusing on high-risk populations. Interview questions will focus on how each recipient implemented its strategies to increase access to and quality of healthcare overall, as well as for patients at highest risk of stroke events. It will identify challenges encountered and how they were overcome, factors that facilitated implementation, lessons learned along the way, and observed outcomes and improvements. The information to be collected does not currently exist for large scale, statewide programs that employ multiple combinations of strategies to build comprehensive stroke systems of care.

The insights to be gained from this data collection will be critical to improving immediate efforts and achieving the goals of spreading and replicating state-level strategies that are proven programmatically and are cost-effective in contributing to a higher quality of care for stroke patients. OMB approval is requested for three years. CDC requests OMB approval for an estimated 104 annual burden hours. Participation is voluntary and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Program Manager	Cost Collection Tool	13	1	2	26
Program Director	Interview	13	1	1	13
Quality Improvement Specialist	Interview	13	1	1	13
Partner Support Staff	Interview	52	1	1	52
Total					104

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–10992 Filed 5–20–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Injury Prevention and Control

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC). This meeting is closed to the public.

DATES: The meeting will be held on June 8, 2022, from 1 p.m. to 4 p.m., EDT (CLOSED).

ADDRESSES: Zoom Virtual Meeting.

FOR FURTHER INFORMATION CONTACT: Arlene Greenspan, DrPH, MPH, PT, Associate Director for Science, NCIPC, CDC, 4770 Buford Highway NE, Mailstop S–1069, Atlanta, Georgia 30341, Telephone: (770) 488–1279, Email: *ncipcbsc@cdc.gov*.

SUPPLEMENTARY INFORMATION: The meeting designated above will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463 (5 U.S.C. App. 2).

Purpose: The Board will: (1) Conduct, encourage, cooperate with, and assist other appropriate public health authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases, and other impairments; (2) assist States and their political subdivisions in preventing and suppressing communicable and non-communicable diseases and other preventable conditions and in promoting health and well-being; and (3) conduct and assist in research and control activities related to injury. The Board of Scientific Counselors makes recommendations regarding policies, strategies, objectives, and priorities; and reviews progress toward injury prevention goals and provides evidence in injury prevention-related research and programs. The Board also provides advice on the appropriate balance of intramural and extramural research, as well as the structure, progress and performance of intramural programs. The Board is designed to provide guidance on extramural scientific program matters, including the: (1) Review of extramural research concepts for funding opportunity announcements; (2) conduct of Secondary Peer Review of extramural research grant, cooperative agreement, and contract applications received in response to funding opportunity announcements as they relate to the Center's programmatic balance and mission; (3) submission of secondary review recommendations to the Center Director of applications to be considered for funding support; (4) review of

research portfolios, and (5) review of program proposals.

Matters to be Considered: The closed meeting will focus on the Secondary Peer Review of extramural research grant applications received in response to two (2) Notice of Funding Opportunities (NOFOs): (1) RFA–CE–22–002—''Grants to Support New Investigators in Conducting Research Related to Preventing Interpersonal Violence Impacting Children and Youth''; (2) RFA–CE–22–004—''Research Grants to Prevent Firearm-Related Violence and Injuries (R01)''; as well as PA–21–259—PHS 2021–2 Omnibus Solicitation of the NIH, CDC and FDA for Small Business Innovation Research (SBIR) Grant Applications (Parent SBIR [R43/R44] Clinical Trial Not Allowed) and PA–21–260—PHS 2021–2 Omnibus Solicitation of the NIH and CDC for SBIR Grant Applications (Parent SBIR [R43/R44] Clinical Trial Required). Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–10944 Filed 5–20–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3428–PN]

Medicare and Medicaid Programs: Application From the National Dialysis Accreditation Commission (NDAC) for Continued Approval of Its End Stage Renal Disease (ESRD) Facility Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Notice with request for comment.

SUMMARY: This notice acknowledges the receipt of an application from the National Dialysis Accreditation Commission for continued recognition as a national accrediting organization for End Stage Renal Disease facilities that wish to participate in the Medicare or Medicaid programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 22, 2022.

ADDRESSES: In commenting, refer to file code CMS–3428–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3428–PN, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3428–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Caecilia Blondiaux, (410) 786–2190.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from an end-stage renal disease (ESRD) facility provided certain requirements are met. Section 1881(b) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a Medicare-certified ESRD facility. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 494 subparts A through D specify the conditions that an ESRD must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for ESRD facilities.

Generally, to enter into an agreement, an ESRD facility must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 494 subparts A through D of our Medicare regulations. Thereafter, the ESRD facility is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we may deem those provider entities as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services (the Secretary) as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at § 488.4 and 488.5. The regulations at § 488.5(e)(2)(i) require AOs to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

The National Dialysis Accreditation Commission's (NDAC's) current term of approval for their ESRD facility accreditation program expires January 4, 2023.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and regulations at § 488.5 require that our findings concerning review and approval of an AO's requirements consider, among other factors, the

applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this notice is to inform the public of NDAC's request for continued CMS-approval of its ESRD facility accreditation program. This notice also solicits public comment on whether NDAC's requirements meet or exceed the Medicare conditions for coverage (CfCs) for ESRDs.

III. Evaluation of Deeming Authority Request

NDAC submitted all the necessary materials to enable us to make a determination concerning its request for continued CMS-approval of its ESRD facility accreditation program. This application was determined to be complete on March 14, 2022. Under section 1865(a)(2) of the Act and our regulations at § 488.5 (Application and re-application procedures for national accrediting organizations), our review and evaluation of NDAC will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of NDAC's standards for ESRD facilities as compared with CMS' ESRD facility CfCs.
- NDAC's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of NDAC's processes to those of state agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ NDAC's processes and procedures for monitoring an ESRD facility out of compliance with NDAC's program requirements. These monitoring procedures are used only when NDAC's identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the state agency (SA) monitors corrections as specified at § 488.9.

++ NDAC's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ NDAC's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of NDAC's staff and other resources, and its financial viability.

++ NDAC's capacity to adequately fund required surveys.

++ NDAC's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ NDAC's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest involving individuals who conduct surveys or participate in accreditation decisions.

++ NDAC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

V. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: May 18, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–10999 Filed 5–20–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10398 #7]

Medicaid and Children's Health Insurance Program (CHIP) Generic Information Collection Activities: Proposed Collection; Comment Request

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

ACTION: Notice.

SUMMARY: On May 28, 2010, the Office of Management and Budget (OMB) issued Paperwork Reduction Act (PRA) guidance related to the ''generic'' clearance process. Generally, this is an expedited process by which agencies may obtain OMB's approval of collection of information requests that are ''usually voluntary, low-burden, and uncontroversial collections,'' do not raise any substantive or policy issues, and do not require policy or methodological review. The process requires the submission of an overarching plan that defines the scope of the individual collections that would fall under its umbrella. On October 23, 2011, OMB approved our initial request to use the generic clearance process under control number 0938–1148 (CMS–10398). It was last approved on April 26, 2021, via the standard PRA process which included the publication of 60- and 30-day **Federal Register** notices. The scope of the April 2021 umbrella accounts for Medicaid and CHIP State plan amendments, waivers, demonstrations, and reporting. This **Federal Register** notice seeks public comment on one or more of our collection of information requests that we believe are generic and fall within the scope of the umbrella. Interested persons are invited to submit comments regarding our burden estimates or any other aspect of this collection of information, including: The necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility and clarity of the information to be collected, and the use

of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by June 6, 2022.

ADDRESSES: When commenting, please reference the applicable form number (see below) and the OMB control number (0938–1148). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS–10398 (#7)/OMB control number: 0938–1148, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may access CMS' website at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Following is a summary of the use and burden associated with the subject information collection(s). More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**).

Generic Information Collections

1. *Title of Information Collection:* CHIPRA Connecting Kids to Coverage Outreach and Enrollment Grants; *Type of Information Collection Request:* Revision of a currently approved collection; *Use:* In this April 2022 iteration of GenIC#7, regarding MACRA Cycle Vb. Round III, the Cycle Vb. Connecting Kids to Coverage Final Report Template for the Round III AI/AN cooperative agreement is being removed because the data collection is completed. This April 2022 iteration of GenIC#7 also sets out to revise the currently approved templates for the Semi-Annual Report and Final Report Templates and the Monthly Progress Report Templates. The revision changes the template format from a Microsoft Excel spreadsheet to an Adobe pdf. This revision makes the reporting templates user-friendly for the grantees and easier to complete than with the Excel spreadsheet format. The content of the reporting information continues without change as collected through the Semi-Annual Report, Final Report and Monthly Progress Report Templates of this current package. *Form Number:* CMS–10398 (#7) (OMB control number: 0938–1148); *Frequency:* Yearly, quarterly, once, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 47; *Total Annual Responses:* 1,973; *Total Annual Hours:* 10,102. (For policy questions regarding this collection contact Joyce Jordan at 410–786–.)

Dated: May 17, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–10954 Filed 5–20–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; The National Adult Maltreatment Reporting System; OMB #0985–0054

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed revision of information collection requirements for the National Maltreatment Reporting System (NAMRS) OMB Control Number 0985–0054.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by July 22, 2022.

ADDRESSES: Submit electronic comments on the collection of information to Stephanie Whittier Eliason, Administration for Community Living, Washington, DC 20201, at *Stephanie.WhittierEliason@acl.hhs.gov.* Submit written comments on the collection of information to Administration for Community Living, Washington, DC 20201, Attention: to Stephanie Whittier Eliason.

FOR FURTHER INFORMATION CONTACT: Stephanie Whittier Eliason, Administration for Community Living, Washington, DC 20201, at 202.795.7467 and *Stephanie.WhittierEliason@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

This data collection effort is in response to the Elder Justice Act of 2009, which amended Title XX of the Social Security Act [42.U.S.C. 13976 *et seq.*]. These provisions require that the Secretary of HHS ''collects and disseminates data annually relating to the abuse, exploitation, and neglect of elders in coordination with the Department of Justice'' [Sec.

2041(a)(1)(B)], and ''conducts research related to the provision of adult protective services'' [Sec. 2041(a)(1)(D)]. Furthermore, development of a national adult protective services (APS) system based upon standardized data collection and a core set of service provision standards and best practices was recommended by the Elder Justice Coordinating Council to increase federal involvement in addressing elder abuse, neglect and exploitation. Since federal fiscal year 2016, NAMRS has collected descriptive and summary or de-identified case-level data on APS investigations. The purpose of NAMRS is to better understand adult maltreatment as investigated by APS programs. Respondents are state APS agencies and APS agencies in the District of Columbia, Puerto Rico, Guam, Northern Mariana Islands, Virgin Islands, and American Samoa (states, hereafter). Two agencies provide No personally identifiable client or perpetrator information is collected. Data submission is voluntary.

NAMRS consists of three components:

(1) *Agency Component:* Descriptive data on APS program agency information and key program policies; and

(2) *Case Component:* De-identified case-level data on key aspects of APS investigations (*e.g.,* clients, maltreatment types, perpetrators); or

(3) *Key Indicator:* Summary level data on a smaller set of core items about APS investigations States unable to submit a case-level file through the Case Component submit.

ACL provides technical assistance to states to assist in the preparation of their data submissions and reviews and approves submissions. NAMRS was granted a three-year extension through March of 2023. To prepare for the 2023 OMB reauthorization, ACL routinely collects potential changes to NAMRS and held 11 public listening sessions during the summer of 2021 to obtain feedback from stakeholders on potential improvements to NAMRS.

ACL then conducted four focus groups with state APS agencies to discuss potential changes to NAMRS identified in the 11 listening sessions. With input of the technical assistance team, ACL determined the proposed revisions to the information collection.

In summary, the proposed revisions clarify definitions and instructions throughout, add new policy questions to the Agency Component to assist data users with interpreting data, add new code values to various Case Component and Key Indicator data elements in response to stakeholder input, and add one new data element to the Case Component. The annual recurring burden for states will increase slightly, and there will be one-time burden to make changes in APS program information systems. ACL intends to make state-specific NAMRS data available to researchers and other potential users through a request and approval process. The process will include safeguards for APS program confidentiality concerns.

The proposed data collection tools may be reviewed on the ACL website at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden

The proposed revisions add only one new data element, make minor additions to the code values for a number of Key Indicator and Case Component data elements, and include a number of new policy questions in the Agency Component. For the new data element and additional code values, state APS programs may choose to modify their information management systems to collect the data and extract it for reporting. This will be a one-time burden. In addition, states will have an ongoing annual burden of preparing and submitting the data collection.

Since initial establishment of the data collection, NAMRS reporting has become more efficient through state familiarity with the system and improvements such as a ''copy forward'' feature for Case Mapping and Agency Component items. For the new policy questions in the revision, ACL assumes it will pre-load responses for many of the questions for many of the states, requiring only state validation of the accuracy of the information and a very minimal increase in ongoing burden.

Based on current submission and anticipated changes, ACL estimates 59 APS programs will respond every year to the Agency Component, with 50 states providing Case Component data and 9 states providing Key Indicator data. (*Note:* In three states,

Based on the previous estimates of annual submission burden from data gathered during the pilot project, the recurring annual burden to submit the data consists of:

- Hours by administrative staff to respond to the Agency Component, and
- Hours by data staff and administrative staff to respond to the Key Indicator Component, or
- Hours by data staff and administrative to respond and jointly complete the Case Component.

The one-time burden for the revisions will take:

- Hours for administrative to review or add additional information for the new policy questions.
- Hours for programming for the new Key Indicator and Case Component code values.
- Hours for programming for the new Case Component data element.

Recurring and one-time burden estimates are shown in the following table.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden estimate
Agency One-Time	59	1	6.20	365.80
Key Indicator One-Time	9	1	30.00	270.00
Case Component One-Time	50	1	83	4,150.00
One-Time Subtotal			119.20	4,785.80
Agency Component	59	1	4	236.00
Key Indicators Component	9	1	20	180.00
Case Component	50	1	100	5,000.00
Recurring Sub-total			124	5,416.00

Dated: May 17, 2022.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2022–10987 Filed 5–20–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0619]

Advisory Committee; Gastrointestinal Drugs Advisory Committee; Renewal; Correction

AGENCY: Food and Drug Administration, HHS

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice entitled ''Advisory Committee; Gastrointestinal Drugs Advisory Committee; Renewal'' that appeared in the **Federal Register** of May 11, 2022. The document announced the renewal of the Gastrointestinal Drugs Advisory Committee. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Rhea Bhatt, Division of Advisory Committee and Consultant Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2434, Silver Spring, MD 20993–0002, 301–796–9001, email: *GIDAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Wednesday, May 11, 2022 (87 FR 28834), in FR Doc. 2022–10040, on page 28834, the following correction is made:

1. On page 28834, in the first column of the header of the document, ''Docket No. FDA–2021–N–0619'' is corrected to read ''Docket No. FDA–2022–N–0619''.

Dated: May 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–10941 Filed 5–20–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB). The meeting will be open to the public; a pre-registered public comment session will be held during the meeting. Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or send in their public comment via email should send an email to *CARB@hhs.gov.* Registration information is available on the website *http://www.hhs.gov/paccarb* and must be completed by September 5, 2022; all in-person attendees must pre-register by this date and will be given priority over unregistered attendees. Additional information about any updates to COVID–19 safety precautions or requirements, including how to register for the meeting and provide public comment, can be obtained at *http://www.hhs.gov/paccarb* on the Meetings page. Please visit the page for frequent updates.

DATES: The meeting is tentatively scheduled to be held on September 12, from 9:00 a.m. to 5:00 p.m., and September 13, 2022, from 9:00 a.m. to 5:00 p.m. ET (all times are subject to change). The confirmed times and agenda items for the meeting will be posted on the website for the PACCARB at *http://www.hhs.gov/paccarb* when this information becomes available. Pre-registration for attending the meeting in person is required to be completed no later than September 5, 2022; public attendance at the meeting is limited to the available space.

ADDRESSES: Tysons Corner Marriott, 8028 Leesburg Pike, Tysons Corner, Virginia 22182. The meeting can also be accessed through a live webcast and via teleconference on the day of the meeting. For more information, visit *http://www.hhs.gov/paccarb.*

FOR FURTHER INFORMATION CONTACT: Jomana Musmar, M.S., Ph.D., Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Room L616, Switzer Building, 330 C St. SW, Washington, DC 20201. Email: *CARB@hhs.gov.* Telephone: (202) 746–1512.

SUPPLEMENTARY INFORMATION: The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), established by Executive Order 13676, is continued by Section 505 of Public Law 116–22, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA). Activities and duties of the Advisory Council are governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The PACCARB shall advise and provide information and recommendations to the Secretary regarding programs and policies intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. The PACCARB shall function solely for advisory purposes.

Such advice, information, and recommendations may be related to improving: The effectiveness of antibiotics; research and advanced research on, and the development of, improved and innovative methods for combating or reducing antibiotic resistance, including new treatments, rapid point-of-care diagnostics, alternatives to antibiotics, including alternatives to animal antibiotics, and antimicrobial stewardship activities; surveillance of antibiotic-resistant bacterial infections, including publicly available and up-to-date information on resistance to antibiotics; education for health care providers and the public with respect to up-to-date information on antibiotic resistance and ways to reduce or combat such resistance to antibiotics related to humans and animals; methods to prevent or reduce the transmission of antibiotic-resistant bacterial infections; including stewardship programs; and coordination with respect to international efforts in order to inform and advance the United States capabilities to combat antibiotic resistance.

The September 12–13, 2022 public meeting will be dedicated to a One Health AMR and Pandemic Preparedness Policy Workshop with the goal of identifying key issues and critical policy gaps through a series of facilitated discussions examining a hypothetical large-scale disease outbreak scenario based on historic examples and estimates of future AMR

outbreaks. The meeting agenda will be posted on the PACCARB website at *http://www.hhs.gov/paccarb* when it has been finalized. All agenda items are tentative and subject to change.

Public attendance at the meeting is limited to the available space. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the PACCARB by emailing *CARB@hhs.gov* at least one week prior to the meeting. For those unable to attend in person, a live webcast will be available. More information on registration and accessing the webcast can be found at *http://www.hhs.gov/paccarb.*

Members of the public will have the opportunity to provide comments during and prior to the PACCARB meeting by indicating their preference in their registration available on the PACCARB website at *http://www.hhs.gov/paccarb* and/or by emailing *CARB@hhs.gov.* Public comments can also be sent in by mail, and if so, correspondence should be sent in by midnight September 5, 2022, and should be limited to no more than one page. All public comments received prior to September 5, 2022, will be provided to PACCARB members. Additionally, companies and/or organizations involved in combating antibiotic resistance have an opportunity to present their work to members of the PACCARB during an Innovation Spotlight. Pre-registration is required for participation, with limited spots available. All information regarding this session can also be found online at *http://www.hhs.gov/paccarb.*

Dated: May 13, 2022.

Jomana F. Musmar,

Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health.

[FR Doc. 2022–10990 Filed 5–20–22; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Drug Discovery for Aging, Neuropsychiatric and Neurologic Disorders.

Date: June 23–24, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joseph G. Rudolph, Ph.D., Chief and Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7844, Bethesda, MD 20892, 301–408–9098, *josephru@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cancer Diagnostics and Treatments (CDT).

Date: June 23–24, 2022.

Time: 9:30 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Victor A. Panchenko, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 802B2, Bethesda, MD 20892, (301) 867–5309, *victor.panchenko@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Aging and Development, Auditory Vision and Low Vision Technologies.

Date: June 23–24, 2022.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge, Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Barbara Susanne Mallon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1042, *mallonb@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Drug Discovery and Development.

Date: June 27, 2022.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sergei Ruvinov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301–435–1180, *ruvinser@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cardiovascular and Surgical Devices.

Date: June 28–29, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Willard Wilson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, 301–867–5309, *willard.wilson@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Medical Imaging.

Date: June 28–29, 2022.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Krystyna H. Szymczyk, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–4198, *szymczykk@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Biomaterials, Delivery, and Nanotechnology.

Date: June 30–July 1, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: David Filpula, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6181, MSC 7892, Bethesda, MD 20892, 301–435–2902, *filpuladr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 17, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–10950 Filed 5–20–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Library of Medicine Special Emphasis Panel; RFA–R25.
Date: July 28, 2022.
Time: 11:00 a.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Video Assisted Meeting.
Contact Person: Zoe E. Huang, MD, Chief Scientific Review Officer, Scientific Review Office, Extramural Programs, National Library of Medicine, NIH, 6705 Rockledge Drive, Suite 500, Bethesda, MD 20892–7968, 301–594–4937, *huangz@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: May 17, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–10949 Filed 5–20–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; F99/K00 Review October 2022 Council.
Date: June 16, 2022.
Time: 9:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Anita H. Undale, Ph.D., MD, Scientific Review Branch, National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 827–7428, *anita.undale@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: May 17, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–10951 Filed 5–20–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; FORWARD Urology P20 Applications.
Date: June 22, 2022.
Time: 10:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, NIDDK, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7015, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, 301–594–4721, *ryan.morris@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: May 17, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–10956 Filed 5–20–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Dementia Care.
Date: June 22, 2022.
Time: 10:30 a.m. to 2:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Dario Dieguez, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institutes of Health, National Institute on Aging, Bethesda, MD 20814, (301) 827–3101, *dario.dieguez@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: May 17, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–10955 Filed 5–20–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention's (CSAP) Drug Testing Advisory Board (DTAB) will convene via web conference on June 21st, 2022, from 10:00 a.m. EDT to 4:30 p.m. EDT, and June 22nd, 2022, from 10:00 a.m. EDT to 1:00 p.m. EDT.

The board will meet in open-session June 21st, 2022, from 10:00 a.m. EDT to 2:15 p.m. EDT to discuss the Mandatory Guidelines for Federal Workplace Drug Testing Programs, updates on the Drug Free Workplace Program as well as updates from the Department of Transportation, the Nuclear Regulatory Commission, a presentation by Dr. Barry Sample on Workforce Drug Testing for Marijuana in 2021, and a presentation by Dr. Svante Vikingsson on Hydroxy Cocaine and Cocaine Ratios in Hair.

The board will meet in closed-session on June 21, 2022, from 2:45 p.m. EDT to 4:30 p.m. EDT and June 22, 2022, from 10:00 a.m. EDT to 1:00 p.m. EDT, to discuss confidential issues surrounding the proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs (hair), preliminary and unpublished studies on hydroxy cocaine and cocaine ratios in hair, studies on quantitative agreement in hair labs, and oral fluid topical solution data from the Johns Hopkins University Behavioral Pharmacology Research Unit (BPRU). Therefore, the June 21, 2022, from 2:45 to 4:30 and June 22, 2022, from 10:00 a.m. EDT to 1:00 p.m. EDT meetings are closed to the public, as determined by the Assistant Secretary for Mental Health and Substance Use, SAMHSA, in accordance with 5 U.S.C. 552b(c)(4) and (9)(B), and 5 U.S.C. App. 2, Section 10(d).

Meeting registration information can be completed at *https://snacregister.samhsa.gov/.* Web conference and call information will be sent after completing registration. Meeting information and a roster of DTAB members may be obtained by accessing the SAMHSA Advisory Committees website, *https://www.samhsa.gov/about-us/advisory-councils/meetings* or by contacting the Designated Federal Officer, Lisa Davis.

Committee Name: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention, Drug Testing Advisory Board.

Dates/Time/Type: June 21, 2022, from 10:00 a.m. EDT to 2:15 p.m. EDT: OPEN, June 21, 2022, from 2:45 p.m. EDT to 4:30 p.m. EDT: CLOSED, June 22, 2022, from 10:00 a.m. EDT to 1:00 p.m. EDT: CLOSED.

Place: Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857.

Contact: Lisa S. Davis, M.S., Social Science Analyst, Center for Substance Abuse Prevention, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (240) 276–1440, Email: *Lisa.Davis@samhsa.hhs.gov.*

Anastasia Marie Donovan,

Public Health Advisor, Division of Workplace Programs.

[FR Doc. 2022–10998 Filed 5–20–22; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0106]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number 1625–0047

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0047, Plan Approval and Records for Vital System Automation; without change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: You may submit comments to the Coast Guard and OIRA on or before June 22, 2022.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at *https://www.regulations.gov.* Search for docket number [USCG–2022–0106]. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to *https://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.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG–2022–0106], and must be received by June 22, 2022.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments to the Coast Guard will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions to the Coast Guard in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). For more about privacy and submissions to OIRA in response to this document, see the *https://www.reginfo.gov,* comment-submission web page. OIRA posts its decisions on ICRs online at *https://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0047.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (87 FR 12469, March 4, 2022) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Plan Approval and Records for Vital System Automation.

OMB Control Number: 1625–0047.

Summary: This collection pertains to the vital system automation on commercial vessels that is necessary to protect personnel and property on board U.S.-flag vessels.

Need: 46 U.S. Code 3306 authorizes the Coast Guard to promulgate regulations for the safety of personnel and property on board vessels. Various sections within parts 61 and 62 of Title 46 of the Code of Federal Regulations contain these rules.

Forms: None.

Respondents: Owners, operators, shipyards, designers, and manufacturers of certain vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 68,475 hours to 67,275 hours a year, due to a decrease in the estimated annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. *et seq.,* chapter 35, as amended.

Dated: May 17, 2022.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2022–10980 Filed 5–20–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0153]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number 1625–0101

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0101, Periodic Gauging and Engineering Analyses for Certain Tank Vessels Over 30 Years Old; without change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: You may submit comments to the Coast Guard and OIRA on or before June 22, 2022.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at *https://www.regulations.gov.* Search for docket number [USCG–2022–0153]. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to *https://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.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. COAST GUARD, 2703 Martin Luther King Jr. Ave SE, STOP 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG–2022–0153], and must be received by June 22, 2022.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person

in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments to the Coast Guard will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions to the Coast Guard in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). For more about privacy and submissions to OIRA in response to this document, see the *https://www.reginfo.gov,* comment-submission web page. OIRA posts its decisions on ICRs online at *https://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0101.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (87 FR 13741, March 10, 2022) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Periodic Gauging and Engineering Analyses for Certain Tank Vessels Over 30 Years Old.

OMB Control Number: 1625–0101.

Summary: The Oil Pollution Act of 1990 required the issuance of regulations related to the structural integrity of tank vessels, including periodic gauging of the plating thickness of tank vessels over 30 years old. This collection of information is used to verify the structural integrity of older tank vessels.

Need: 46 U.S.C. 3703 authorizes the Coast Guard to prescribe regulations related to tank vessels, including design, construction, alteration, repair, and maintenance. 46 CFR 31.10–21a prescribes the regulations related to periodic gauging and engineering analyses of certain tank vessels over 30 years old.

Forms: None.

Respondents: Owners and operators of certain tank vessels.

Frequency: Every 5 years.

Hour Burden Estimate: The estimated burden has increased from 2,784 hours to 2,842 hours a year, due to an increase in the estimated annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. *et seq.,* chapter 35, as amended.

Dated: May 17, 2022.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2022–10983 Filed 5–20–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0109]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number 1625–0074

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0074, Direct User Fees for Inspection or Examination of U.S. and Foreign Commercial Vessels; without change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: You may submit comments to the Coast Guard and OIRA on or before June 22, 2022.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at *https://www.regulations.gov.* Search for docket number [USCG–2022–0109]. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to *https://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.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG–2022–0109], and must be received by June 22, 2022.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents

mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments to the Coast Guard will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions to the Coast Guard in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). For more about privacy and submissions to OIRA in response to this document, see the *https://www.reginfo.gov,* comment-submission web page. OIRA posts its decisions on ICRs online at *https://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0074.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (87 FR 12471, March 4, 2022) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Direct User Fees for Inspection or Examination of U.S. and Foreign Commercial Vessels.

OMB Control Number: 1625–0074.

Summary: This collection requires the submission of identifying information such as a vessel's name and identification number, and of the owner's choice whether or not to pay fees for future years. A written request to the Coast Guard is necessary.

Need: The Omnibus Budget Reconciliation Act of 1990 [Pub. L. 101–508, 104 Stat. 1388], which amended 46 U.S. C. 2110, requires the Coast Guard to collect user fees from inspected vessels. To properly collect and manage these fees, the Coast Guard must have current information on identification. This collection helps to ensure that we get that information and manage it efficiently.

Forms: None.

Respondents: Owners of vessels.

Frequency: Annually.

Hour Burden Estimate: The estimated burden has increased from 2,999 hours to 3,086 hours a year, due to an increase in the estimated annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. *et seq.,* chapter 35, as amended.

Dated: May 17, 2022.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2022–10981 Filed 5–20–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0151]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number 1625–0096

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0096, Report of Oil or Hazardous Substance Discharge; and Report of Suspicious Maritime Activity; without change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: You may submit comments to the Coast Guard and OIRA on or before June 22, 2022.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at *https://www.regulations.gov.* Search for docket number [USCG–2022–0151]. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to *https://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.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG–2022–0151], and must be received by June 22, 2022.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at

https://www.regulations.gov and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments to the Coast Guard will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions to the Coast Guard in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). For more about privacy and submissions to OIRA in response to this document, see the *https://www.reginfo.gov,* comment-submission web page. OIRA posts its decisions on ICRs online at *https://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0096.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (87 FR 13740, March 10, 2022) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Report of Oil or Hazardous Substance Discharge; and Report of Suspicious Maritime Activity.

OMB Control Number: 1625–0096.

Summary: Any discharge of oil or a hazardous substance must be reported to the National Response Center (NRC) so that the pre-designated on-scene coordinator can be informed and appropriate spill mitigation action carried out. The NRC also receives suspicious activity reports from the public and disseminates this information to appropriate entities.

Need: 33 CFR 153.203, 40 CFR 263.30 and 264.56, and 49 CFR 171.15 mandate that the NRC be the central place for the public to report all pollution spills. 33 CFR 101.305 mandates that owners or operators of those vessels or facilities required to have security plans, report activities that may result in a Transportation Security Incident (TSI) or breaches of security to the NRC. Voluntary reports are also accepted.

Forms: None.

Respondents: Persons-in-charge of a vessel or onshore/offshore facility; owners or operators of vessels or facilities required to have security plans; and the public.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 1,980 hours to 3,683 hours a year, due primarily to an increase in the estimated hour burden per response. The Coast Guard revised the hour burden per response from 5 minutes to 8.5 minutes per response. Based on recent NRC data, the change more accurately reflect the time per response.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. *et seq.,* chapter 35, as amended.

Dated: May 17, 2022.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2022–10982 Filed 5–20–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0005]

Application-Permit-Special License Unlading-Lading-Overtime Services

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day notice and request for comments; revision of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection 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 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than July 22, 2022) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0005 in the subject line and the agency name. Please use the following method to submit comments:

Email. Submit comments to: *CBP_PRA@cbp.dhs.gov.*

Due to COVID–19-related restrictions, CBP has temporarily suspended its ability to receive public comments by mail.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) 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; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to 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. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Application-Permit-Special License Unlading-Lading-Overtime Services.

OMB Number: 1651–0005.

Form Number: CBP Form 3171.

Current Actions: Revision.

Type of Review: Revision.

Affected Public: Businesses.

Abstract: The Application-Permit-Special License Unlading-Lading-Overtime Services (U.S. Customs and Border Protection (CBP) Form 3171) is used by commercial carriers and importers as a request for permission to

unlade imported merchandise, baggage, or passengers. It is also used to request overtime services from CBP officers in connection with lading or unlading of merchandise, or the entry or clearance of a vessel, including the boarding of a vessel for preliminary supplies, ship's stores, sea stores, or equipment not to be re-laden. CBP Form 3171 is provided for by 19 CFR 4.10, 4.30, 4.39, 4.91, 10.60, 24.16, 122.38, 123.8, 146.32 and 146.34.

This form is accessible at: *http://www.cbp.gov/newsroom/publications/forms?title=3171.*

This form is anticipated to be submitted electronically as part of the maritime forms automation project through the Vessel Entrance and Clearance System (VECS), which will eliminate the need for any paper submission of any vessel entrance or clearance requirements under the above referenced statutes and regulations. VECS will still collect and maintain the same data but will automate the capture of data to reduce or eliminate redundancy with other data collected by CBP.

Type of Information Collection: Form 3171.

Estimated Number of Respondents: 2,624.

Estimated Number of Annual Responses per Respondent: 72.

Estimated Number of Total Annual Responses: 188,928.

Estimated Time per Response: 8 minutes.

Estimated Total Annual Burden Hours: 25,190 hours.

Dated: May 18, 2022.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2022–10997 Filed 5–20–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2022–0015; OMB No. 1660–0117]

Agency Information Collection Activities: Proposed Collection; Comment Request; FEMA's Grants Reporting Tool (GRT)

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 60-Day notice of reinstatement and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on a reinstatement, without change, of a previously approved collection for which approval has expired. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the collection of information necessary for the Grants Reporting Tool (GRT).

DATES: Comments must be submitted on or before July 22, 2022.

ADDRESSES: Submit comments at *www.regulations.gov* under Docket ID FEMA–2022–0015. Follow the instructions for submitting comments.

All submissions received must include the agency name and Docket ID, and will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy and Security Notice that is available via a link on the homepage of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jennifer Garza, Acting Senior Advisor, *jennifer.garza@fema.dhs.gov* or (202) 786–9602. You may contact the Information Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: The Grants Reporting Tool (GRT) is a web-based reporting system designed to help State Administrative Agencies (SAAs) meet all reporting requirements as identified in the grant guidance of FEMA's portfolio of preparedness grants managed by the FEMA's Grant Programs Directorate (GPD).

Title 2 CFR, part 200 (Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards), establishes uniform administrative rules for assistance awards and subawards to State, local and Indian Tribal governments. FEMA determined that it is necessary to automate the grant reporting process to have consistent implementation of FEMA grant administration policies, to reduce duplicative and tedious data entry, to measure preparedness gains more effectively, and to streamline application submission and management for recipients and subrecipients.

Title XX of the Homeland Security Act of 2002 authorizes the Secretary of Homeland Security, acting through the FEMA Administrator, to provide grants to assist State, local, and Tribal governments in preventing, preparing for, protecting against, and responding to acts of terrorism. Recipients use the GRT to submit annual investment justifications and biannual progress reports. Further, section 2022 of the Homeland Security Act of 2002 (6 U.S.C. 612) mandates that FEMA review grants awarded to states and high-risk urban areas at least every two years and requires that recipients submit annual reports on the use of funds awarded under sections 2003 or 2004 of the Homeland Security Act of 2002 (6 U.S.C. 604, 605, respectively). Section 2022 also provides DHS the authority to have full access to information regarding activities carried out under any grant DHS administers.

Additionally, Section 662 of the Post-Katrina Emergency Management Reform Act of 2006 (PKEMRA), as amended, (Pub. L. 109–295) (6 U.S.C. 762); the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended (Pub. L. 93–288) (42 U.S.C. 5121 *et seq.*); the Earthquake Hazards Reduction Act of 1977, as amended (Pub. L. 95–124) (42 U.S.C. 7701 *et seq.*); and the National Flood Insurance Act of 1968, as amended (Pub. L. 90448) (42 U.S.C. 4001 *et seq.*) authorize FEMA to administer the Emergency Management Performance Grant (EMPG) Program. The primary purpose of the EMPG program is to provide grants to assist State, local, Tribal and territorial emergency management agencies to implement the National Preparedness System (NPS) and to support the National Preparedness Goal of a secure and resilient nation. Recipients funding under this authorization use the GRT to submit biannual progress reports.

Collection of Information

Title: FEMA's Grants Reporting Tool (GRT).

Type of Information Collection: Reinstatement, without change, of a previously approved collection for which approval has expired.

OMB Number: 1660–0117.

FEMA Forms: FEMA Form FF–207–FY–22–121, Biannual Strategy Implementation Report (BSIR).

Abstract: The GRT is a web-based reporting system designed to help State Administrative Agencies (SAAs) and directly eligible tribes meet all reporting requirements as identified in the grant guidance of FEMA's portfolio of preparedness grants sponsored by FEMA's Grant Programs Directorate (GPD). The information enables FEMA to evaluate applications and make award decisions, monitor ongoing performance, and manage the flow of

Federal funds, and to appropriately close out grants. GRT supports the information collection needs of each grant program processed in the system.

Affected Public: State, Local or Tribal government.

Estimated Number of Respondents: 81.

Estimated Number of Responses: 162.

Estimated Total Annual Burden Hours: 2,471.

Estimated Total Annual Respondent Cost: $111,442.

Estimated Respondents' Operation and Maintenance Costs: $0.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $1,259,210.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) 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; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) 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.

Millicent Brown Wilson,

Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2022–10975 Filed 5–20–22; 8:45 am]

BILLING CODE 9111–78–P

DEPARTMENT OF HOMELAND SECURITY

[Docket Number DHS–2022–0032]

Agency Information Collection Activities: Migrant Protection Protocols (MPP) Disenrollment Request System

AGENCY: Department of Homeland Security (DHS).

ACTION: 60-Day notice and request for comments.

SUMMARY: The Department of Homeland Security, will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted until July 22, 2022. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: You may submit comments, identified by docket number Docket #DHS–2022–0032, at:

○ *Federal eRulemaking Portal: http://www.regulations.gov.* Please follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number Docket #DHS–2022–0032. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

SUPPLEMENTARY INFORMATION: The Department of Homeland Security (DHS) Headquarters (HQ) Migrant Protection Protocols (MPP) program is a U.S. Government program, initiated in January 2019 pursuant to Section 235(b)(2)(C) of the Immigration and Nationality Act (INA). Under MPP, the United States returns to Mexico certain citizens and nationals of countries in the Western Hemisphere other than Mexico while their U.S. removal proceedings are pending.

On June 1, 2021, the Secretary of Homeland Security determined that MPP should be terminated and issued a memorandum to that effect. On August 13, 2021, however, the U.S. District Court for the Northern District of Texas determined in *Texas* v. *Biden* that the June 1, 2021 memo was not issued in compliance with the Administrative Procedure Act and INA and ordered DHS to ''enforce and implement MPP in good faith.'' See *Texas* v. *Biden,* No. 2:21–cv–067, 2021 WL 3603341 (N.D. Tex. Aug. 13, 2021).

On October 29, 2021, after an extensive and comprehensive review, the Secretary of Homeland Security issued a new memorandum terminating MPP, which DHS will implement as soon as practicable after issuance of a final judicial decision to vacate the Texas injunction. Until that time, the Department continues to comply with the Texas injunction requiring good-faith implementation and enforcement of MPP. To carry out the court order requiring good-faith implementation and enforcement of MPP, the Department is proposing a new data collection. To achieve efficiencies and ensure consistency with MPP guidance, DHS seeks to create a public-facing MPP Disenrollment Request website.

All information entered by individuals into the MPP Disenrollment Request System will be used by DHS employees and staff to determine whether, consistent with DHS MPP guidance, an individual should be disenrolled from MPP. Decisions whether to enroll or disenroll individuals from MPP are at DHS's discretion, and the disenrollment request process does not create any obligation or private right of action enforceable in administrative or judicial proceedings. Information submitted will be used to ensure that enrollments are consistent with DHS MPP guidance.

DHS anticipates individual review requests will primarily fall into the following categories:

1. An MPP enrollee believes they meet one of the criteria that should counsel in favor of their exemption and therefore should not have been placed in the program.

2. An MPP enrollee was not given access to a *non-refoulement* interview and wished to have one.

3. An MPP enrollee has experienced a materially changed circumstance such that they now may meet one of the criteria that should counsel in favor of their exception from MPP or may now be able to establish a reasonable possibility of persecution or torture if they were to receive a non-*refoulement* interview.

The purpose of the public facing MPP Disenrollment Request website is to provide an avenue for individuals to initiate a request for disenrollment from MPP should they believe they should not be included in the MPP program. The website will also provide additional information to the users as well. Once an individual has provided information, the government will have the ability to determine whether an individual is incorrectly placed in MPP processing. The information to be collected for self-disclosure is listed below.

Submission Information:

Attorney or Representative Email

Attorney or Representative Name

Attorney or Representative Phone Number

Attorney or Representative Country Code

A #Number

Best Phone Number

Email Address

First, Middle, and Last Name

Date of Birth

Country of Birth

County of Citizen Citizenship

Where are you (MPP enrolled person) located now? (Country, City, State)

Preferred Language

Reason for MPP review

Preparer Name

Preparer Phone Number

Preparer Email

Preparer Relationship to Enrollee

DHS will launch a public-facing website on *DHS.gov* for MPP enrollees or representatives acting on their behalf to submit requests. The information on the application will include instructions for submission. Information about the portal will be made available via a tear sheet given to enrollees at the time they are enrolled in MPP. The MPP Disenrollment Request system URL (*engage.dhs.gov/mpp*) will also be searchable on the *DHS.gov* website.

The public-facing website, which is being developed with assistance from the Department of Homeland Security Office of the Chief Information Officer (OCIO), will employ various cloud-based services (*e.g.,* ServiceNow15 and Akamai16 for cloud security and content delivery) to effectively and efficiently manage the receipt, creation, assignment, tracking, and storage of the self-disclosure of the necessary information to start the MPP Disenrollment Request process. The website is hosted in the Federal Risk and Authorization Management Program (FedRAMP)-certified cloud and provides accessibility and functionality restrictions to define specific user roles through its ServiceNow infrastructure. Each user role has defined and limited access authority to view and edit data sets by Office of the Chief Information Officer master administrators.

While the MPP Disenrollment Request system is under development, enrollees may submit their request for review via email at *MPPRequest@hq.dhs*. With the roll out of the MPP Disenrollment Request application, the email request process will be closed.

This information collection does not have an impact on small businesses or other small entities.

The lack of a public-facing platform to initiate requests for disenrollment from MPP could adversely impact DHS's ability to ensure that enrollments in MPP are consistent with DHS guidance and to timely respond to individual requests for disenrollment from MPP. In addition, the lack of a public-facing platform would reduce DHS's ability to systematically track and monitor these requests.

A new Privacy Impact Assessment is in process titled ''Migrant Protection Protocols (MPP) Case Request System.'' Upon submission of the full 3-year approval, the PIA will be completed. The system is covered by an existing SORN: DHS/USCIS/ICE/CBP–001 Alien File, Index, and National File Tracking System of Records; and DHS/USCIS–007 Benefits Information System.

This is a new information collection.

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. 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;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. 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 submissions of responses.

Analysis

Agency: Department of Homeland Security (DHS).

Title: Migrant Protection Protocols (MPP) Disenrollment Request System.

OMB Number: 1601–0034.

Frequency: Annual.

Affected Public: Public.

Number of Respondents: 5,000

Estimated Time per Respondent: 20 Minutes.

Total Burden Hours: 1,667 Hours.

Robert Dorr,

Acting Executive Director, Business Management Directorate.

[FR Doc. 2022–11022 Filed 5–20–22; 8:45 am]

BILLING CODE 9112–FL–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0114]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Application for Civil Surgeon Designation

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until June 22, 2022.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2013–0002. All submissions received must include the OMB Control Number 1615–0114 in the

body of the letter, the agency name and Docket ID USCIS–2013–0002.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, Telephone number (240) 721–3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on February 15, 2022, at 87 FR 8598, allowing for a 60-day public comment period. USCIS did not receive any comment(s) in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2013–0002 in the search box. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov*.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) 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;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) 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.

Overview of This Information Collection:

(1) *Type of Information Collection Request:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application for Civil Surgeon Designation.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–910; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Business or other for-profit. This information collection is required to determine whether a physician meets the statutory and regulatory requirement for civil surgeon designation. For example, all documents are reviewed to determine whether the physician has a currently valid medical license and whether the physician has had any action taken against him or her by the medical licensing authority of the U.S. state(s) or U.S. territories in which he or she practices. If the Application for Civil Surgeon Designation (Form I–910) is approved, the physician is included in USCIS's public Civil Surgeon locator and is authorized to complete Form I–693 (OMB Control Number 1615–0033) for an applicant's adjustment of status.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–910 is 470 and the estimated hour burden per response is 2 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 940 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $24,205.00.

Dated: May 17, 2022

Samantha L Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2022–10971 Filed 5–20–22; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0056]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Application To Preserve Residence for Naturalization

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until June 22, 2022.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2006–0030. All submissions received must include the OMB Control Number 1615–0056 in the body of the letter, the agency name and Docket ID USCIS–2006–0030.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, Telephone number (240) 721–3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://*

www.uscis.gov, or call the USCIS Contact Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on February 15, 2022, at 87 FR 8602, allowing for a 60-day public comment period. USCIS did receive one comment in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2006–0030 in the search box. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) 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;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) 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.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application to Preserve Residence for Naturalization.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* N–470; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. The information collected on Form N–470 will be used to determine whether an alien who intends to be absent from the United States for a period of one year or more is eligible to preserve residence for naturalization purposes.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection N–470 is 120 and the estimated hour burden per response is 0.6 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 72 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $14,700.

Dated: May 17, 2022.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2022–10970 Filed 5–20–22; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0009]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Petition for Nonimmigrant Worker

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until July 22, 2022.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0009 in the body of the letter, the agency name and Docket ID USCIS–2005–0030. Submit comments via the Federal eRulemaking Portal website at *https://www.regulations.gov* under e-Docket ID number USCIS–2005–0030.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number (240) 721–3000 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *https://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

USCIS is proposing to extend the currently approved USCIS Form I–129 due to the closely approaching Office of Management and Budget (OMB) expiration date of the form. USCIS has separately proposed creating three new OMB-controlled collections of information to replace the currently approved single collection approved (OMB Control Number 1615–0009). 60-day **Federal Register** Notices for the proposed information collections can be found at 86 FR 46260, 86 FR 46261, and 86 FR 46263 which all published on 08/18/2021. The 30-day **Federal Register** Notices can be found at 87 FR 2891 which published on 01/19/2022, and at 87 FR 8599 and 87 FR 8601 which both published on 02/15/2022. USCIS is currently holding on submission of

those three actions due to needing additional time for the systems work required to support the release of these new versions. USCIS will republish a Notice in the **Federal Register** when it is proposing to recommence these actions.

You may access the information collection instrument with instructions or additional information by visiting the Federal eRulemaking Portal site at: *https://www.regulations.gov* and entering USCIS–2005–0030 in the search box. All submissions will be posted, without change, to the Federal eRulemaking Portal at *https://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) 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;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) 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.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Petition for Nonimmigrant Worker.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–129; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Business or other for-profit. USCIS uses the data collected on this form to determine eligibility for the requested nonimmigrant petition and/or requests to extend or change nonimmigrant status. (See USCIS response to Question 1 of this supporting statement, above). An employer (or agent, where applicable) uses this form to petition USCIS for an alien to temporarily enter as a nonimmigrant. An employer (or agent, where applicable) also uses this form to request an extension of stay or change of status on behalf of the alien worker. The form serves the purpose of standardizing requests for nonimmigrant workers and ensuring that basic information required for assessing eligibility is provided by the petitioner while requesting that beneficiaries be classified under certain nonimmigrant employment categories. It also assists USCIS in compiling information required by Congress annually to assess effectiveness and utilization of certain nonimmigrant classifications.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–129 is 294,751 and the estimated hour burden per response is 2.34 hours; the estimated total number of respondents for the information collection E–1/E–2 Classification Supplement to Form I–129 is 4,760 and the estimated hour burden per response is 0.67 hours; the estimated total number of respondents for the information collection Trade Agreement Supplement to Form I–129 is 3,057 and the estimated hour burden per response is 0.67 hours; the estimated total number of respondents for the information collection H Classification Supplement to Form I–129 is 96,291 and the estimated hour burden per response is 2 hours; the estimated total number of respondents for the information collection H–1B and H–1B1 Data Collection and Filing Fee Exemption Supplement is 96,291 and the estimated hour burden per response is 1 hour; the estimated total number of respondents for the information collection L Classification Supplement to Form I–129 is 37,831 and the estimated hour burden per response is 1.34 hours; the estimated total number of respondents for the information collection O and P Classifications Supplement to Form I–129 is 22,710 and the estimated hour burden per response is 1 hour; the estimated total number of respondents for the information collection Q–1 Classification Supplement to Form I–129 is 155 and the estimated hour burden per response is 0.34 hours; and the estimated total number of respondents for the information collection R–1 Classification Supplement to Form I–129 is 6,635 and the estimated hour burden per response is 2.34 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 1,072,810 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $70,681,290.

Dated: May 17, 2022.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2022–10968 Filed 5–20–22; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7054–C–02]

60-Day Notice of Proposed Information Collection: Promise Zones Preference Point Certification Form 50153: Correction; OMB Control No.: 2501–0033

AGENCY: Office of Field Policy and Management, HUD.

ACTION: Notice; correction.

SUMMARY: HUD published a document in the **Federal Register** of May 17, 2022, concerning an information collection. The document contained an incorrect comment due date.

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Anna P. Guido at *Anna.P.Guido@hud.gov* or telephone 202–402–5535. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of May 17, 2022, in FR #2022–10522, on page 29870, in the second column, correct the **DATES** caption to read:

DATES: *Comments Due Date:* July 18, 2022.

Nacheshia Foxx,

Federal Register Liaison for HUD, Office of Regulations, Office of the General Counsel.

[FR Doc. 2022–10946 Filed 5–20–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–963]

Bulk Manufacturer of Controlled Substances Application: Scottsdale Research Institute

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Scottsdale Research Institute, has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 22, 2022. Such persons may also file a written request for a hearing on the application on or before July 22, 2022.

ADDRESSES: The DEA requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.''

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on January 5, 2022, 5436 East Tapekim Road, Cave Creek, Arizona 85331, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

The company plans to bulk manufacture the listed controlled substances for the internal research use and for distribution to customers for research purposes. No other activities for these drug codes are authorized for this registration.

Matthew J. Strait,

Deputy Assistant Administrator.

[FR Doc. 2022–10973 Filed 5–20–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; H–2B Application for Temporary Employment Certification

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 June 22, 2022.

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.

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) if the information will be processed and used in a timely manner; (3) 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; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) 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.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202–693–8538, or by email at *DOL_PRA_PUBLIC@dol.gov*.

SUPPLEMENTARY INFORMATION: This information collection is required by Sections 101(a)(15)(H)(ii)(b) and 214(c) of the Immigration and Nationality Act (INA) (8 U.S.C. 1011(a)(15)(H)(ii)(b) and 1184(c)), as well as 8 CFR 214.2(h)(6), 20 CFR part 655, subpart A, and 29 CFR part 503. This ICR supports Department of Labor and Department of Homeland Security regulations that contain information collections under the H–2B labor certification program. The H–2B program enables employers to bring nonimmigrant foreign workers to the United States to perform non-agricultural work of a temporary nature. The information contained in the Form ETA–9142B, H–2B Application for Temporary Employment Certification, and corresponding appendices serve as the basis for the Secretary's determination that qualified U.S. workers are not available to perform the services or labor needed by the employer and that the wages and working conditions of similarly employed U.S. workers will not be adversely affected by the employment of H–2B workers. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on January 12, 2022 (87 FR 1787).

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: H–2B Application for Temporary Employment Certification.

OMB Control Number: 1205–0509.

Affected Public: Private Sector—Businesses or other for-profits, not-for-profit institutions, and farms.

Total Estimated Number of Respondents: 88,193.

Total Estimated Number of Responses: 299,551.

Total Estimated Annual Time Burden: 86,586 hours.

Total Estimated Annual Other Costs Burden: $994,413.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Dated: May 17, 2022.

Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2022–10985 Filed 5–20–22; 8:45 am]

BILLING CODE 4510–FP–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; H–2A Sheepherder Recordkeeping Requirement

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 June 22, 2022.

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 information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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) if the information will be processed and used in a timely manner; (3) 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; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) 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.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202–693–8538, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This information collection is required by Sections 101(a)(15)(H)(ii)(a), 214(c), and 218 of the Immigration and Nationality Act (INA) and regulations under 20 CFR 655.210. The H–2A temporary labor certification program enables employers to bring nonimmigrant foreign workers to the U.S. to perform agricultural work of a temporary or seasonal nature, as defined in the INA. The INA requires the Secretary of Labor to certify that the temporary employment of foreign workers in job opportunities in herding and production of livestock on the range will not adversely affect the wages and working conditions of workers in the U.S. similarly employed. The Department must request information from employers seeking to hire foreign labor in order to meet its statutory responsibilities under the INA. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on November 15, 2021 (86 FR 63069).

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: H–2A Sheepherder Recordkeeping Requirement.

OMB Control Number: 1205–0519.

Affected Public: Private Sector—Farms.

Total Estimated Number of Respondents: 983.

Total Estimated Number of Responses: 51,116.

Total Estimated Annual Time Burden: 5,112 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Dated: May 17, 2022.

Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2022–10986 Filed 5–20–22; 8:45 am]

BILLING CODE 4510–FP–P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Technical Advisory Committee; Notice of Meeting and Agenda

The Bureau of Labor Statistics Technical Advisory Committee will meet on Friday, June 17, 2022. This meeting will be held virtually from 10:00 a.m. to 4:00 p.m. EST.

The Committee presents advice and makes recommendations to the Bureau of Labor Statistics (BLS) on technical aspects of data collection and the formulation of economic measures and makes recommendations on areas of research. The BLS presents issues and then draws on the expertise of Committee members representing specialized fields within the academic disciplines of economics, statistics, data science, and survey design.

The schedule and agenda for the meeting are as follows:

10:00 a.m. Commissioner's Welcome and Review of Agency Developments

10:30 a.m. Why are estimates of hours worked by the self-employed so volatile?

1:00 p.m. A Methodology to Incorporate Alternative Data in Import and Export Price Indexes

2:30 p.m. Chain-Link Employment Cost Index

4:00 p.m. Approximate Conclusion

The meeting is open to the public. Any questions concerning the meeting should be directed to Sarah Dale, Bureau of Labor Statistics Technical Advisory Committee, at *BLSTAC@bls.gov.* Individuals planning to attend the meeting should register at *https://blstac.eventbrite.com.* Individuals who require special accommodations should contact Ms. Dale at least two days prior to the meeting date.

Signed at Washington, DC, this 17th day of May 2022.

Eric Molina,

Acting Chief, Division of Management Systems, Bureau of Labor Statistics.

[FR Doc. 2022–10984 Filed 5–20–22; 8:45 am]

BILLING CODE 4510–24–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[OMB Control No. 1219–0011]

Extension of a Currently Approved Collection; Respirable Coal Mine Dust Sampling

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps to assure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection for Respirable Coal Mine Dust Sampling.

DATES: All comments must be received on or before July 22, 2022.

ADDRESSES: Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below.

- *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments for docket number MSHA–2022–0025.
- *Mail/Hand Delivery:* Mail or visit DOL–MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452. Before visiting MSHA in person, call 202–693–9455 to make an appointment, in keeping with the Department of Labor's COVID–19 policy. Special health precautions may be required.
- MSHA will post your comment as well as any attachments, except for information submitted and marked as confidential, in the docket at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: S. Aromie Noe, Director, Office of Standards, Regulations, and Variances, MSHA, at *MSHA.information.collections@dol.gov* (email); 202–693–9440 (voice); or 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Chronic exposure to respirable coal mine dust causes various lung diseases, including coal workers' pneumoconiosis (CWP), emphysema, silicosis, and chronic bronchitis, that are known collectively as ''black lung.'' These diseases are debilitating and can result in disability and premature death. While considerable progress has been made in lowering dust levels since the 1970s and, consequently, in lowering the prevalence rate of black lung among coal miners, severe cases of black lung continue to be identified. Information from the federally funded Coal Workers' Health Surveillance Programs administered by the National Institute for Occupational Safety and Health (NIOSH) indicates that black lung remains a key occupational health risk among our nation's coal miners. According to NIOSH, 402 (or 2.7 percent) of the 14,775 underground coal miners who participated in the Coal Workers Health Surveillance Program and were x-rayed between January 2010 and December 2014 were found to have CWP (NIOSH 2019).

Section 103(h) of the Federal Mine Safety and Health Act of 1977 (Mine Act), 30 U.S.C. 813(h), authorizes MSHA to collect information necessary to carry out its duty to protect the safety and health of miners. Further, section 101(a) of the Mine Act, 30 U.S.C. 811(a), authorizes the Secretary of Labor (Secretary) to develop, promulgate, and revise, as may be appropriate, improved mandatory health or safety standards for the protection of life and prevention of injuries in coal and other mines. This Information Collection, OMB No. 1219–0011, concerns requirements for respirable coal mine dust sampling that took effect on February 1, 2016, and respirable dust standards that took effect on August 1, 2016, under MSHA's final rule, *Lowering Miners' Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors* (79 FR 24814; May 1, 2014).

MSHA's standards in 30 CFR parts 70, 71, and 90 require each mine operator of an underground coal mine, surface coal mine, or surface work area of an underground coal mine, and each coal mine operator who employs a part 90 miner, to protect miners from exposure to excessive levels of respirable coal mine dust. Parts 70 and 71 require each coal mine operator to continuously maintain the average concentration of respirable coal mine dust in the mine atmosphere where miners normally work or travel at or below 1.5 milligrams per cubic meter (mg/m^3). When the respirable dust contains more than 5 percent quartz, this standard is reduced to an amount equivalent to 10 divided by the percentage of quartz in the dust sample. In addition, each coal mine operator is required to continuously maintain the average concentration of respirable dust in intake airways at underground mines at or below 0.5 mg/m^3.

If a part 90 miner is employed at the mine, the coal mine operator is required to continuously maintain the average concentration of respirable dust in the mine atmosphere during each shift to which the part 90 miner in the active workings of the mine is exposed at or below 0.5 mg/m^3. This standard is also reduced if more than 5 percent quartz is found in the mine atmosphere during each shift to which the part 90 miner is exposed.

MSHA's standards require that coal mine operators sample respirable coal mine dust on a quarterly basis and submit these samples to MSHA for analysis to determine if the mine is complying with the applicable dust standards. Underground coal mine operators must sample: The Designated Occupation (DO) and Other Designated Occupation (ODO) in each Mechanized Mining Unit (MMU) under 30 CFR 70.208; and each Designated Area (DA) at locations specified in the operator's approved mine ventilation plan under 30 CFR 70.209. In addition, Designated Work Positions (DWPs) at surface coal mines and surface work areas of underground coal mines must be sampled under 30 CFR 71.206. Furthermore, each part 90 miner must be sampled quarterly under 30 CFR 90.207.

The following sections provide a description of the information collection requirements for *Respirable Coal Mine Dust Sampling* conducted under 30 CFR parts 70, 71, and 90. The requirements include general and technical requirements for sampling, sampling device flowrate, operator transmission of respirable dust samples, quarterly sampling, posting or providing respirable dust sampling reports and dust data cards, status changes, respirable dust control plans, and mine ventilation plans.

A. Information Collections Related to Sampling

Table 1 summarizes the information collections related to general and technical requirements for sampling conducted under parts 70, 71, and 90, such as the use of continuous personal dust monitors (CPDMs) instead of coal mine dust personal sampling units (CMDPSUs), shift length, and sampling start date and time.

TABLE 1—GENERAL AND TECHNICAL REQUIREMENTS FOR SAMPLING

30 CFR provision	Topic	General description of collection requirements
70.201(b)(2) 71.201(a)	Use of CMDPSU or CPDM.	Samples taken quarterly using an approved CMDPSU, unless the operator notifies the District Manager (DM) 90 days before use that an approved CPDM will be used.
70.201(e), 71.201(d), 90.201(f).	Shift length	Length of each shift recorded; retained for 6 months; made available for inspection; submitted to the DM when requested.
70.201(f), 71.201(e), 90.201(g).	Sampling start date and time.	Upon request from the DM, submission of the date and time of sampling start, at least 48 hours prior to start.
71.201(f)	Rain restriction	Upon written request by the operator, the DM may waive the rain restriction.
70.201(g)	Run-of-mine material produced.	Recording the amount of run-of-mine material produced by each MMU during each shift to determine the average production for the most recent 30 production shifts; retained for 6 months; made available for inspection.
70.201(j), 90.201(j)	Use of CPDM in anthracite mining.	When choosing not to use a CPDM in anthracite mining that uses full box, open breast, or slant breast mining, provide written notification to the DM.

Use of CMDPSU or CPDM: Section 70.201(b)(2) requires that DAs identified by the underground coal mine operator be sampled quarterly with an approved CMDPSU unless the operator notifies the District Manager in writing that an approved CPDM will be used for all DA sampling at the mine. With respect to DWP sampling, section 71.201(a) requires each mine operator of a surface coal mine and each mine operator of an underground coal mine with surface work areas who is sampling on the surface to sample with an approved CMDPSU. However, the operator may use an approved CPDM if the operator notifies the District Manager in writing that an approved CPDM will be used for all DWP sampling at the mine. MSHA does not expect underground coal mine operators to use the CPDM to conduct DA sampling underground or DWP sampling on the surface area of the underground mine. Also, MSHA does not expect surface coal mine operators to use the CPDM to conduct DWP sampling. Thus, there are no notifications to the MSHA District Manager and therefore no burdens to operators for sections 70.201(b)(2) and 71.201(a).

Shift length: Sections 70.201(e), 71.201(d), and 90.201(f) require that coal mine operators make records showing the length of: Each production shift for each MMU; each normal work shift for each DWP; and each shift for each part 90 miner, respectively. These provisions also require that the records be retained for at least 6 months, made available for inspection by authorized representatives of the Secretary and, except in the case of part 90 miners, by the miners' representative. The records also must be submitted to the District Manager when requested in writing.

There are no separate burdens shown for recording shift lengths for sections 70.201(e) for underground coal mines and 90.201(f) related to part 90 miners when sampling is conducted because records of shift length are accounted for under sections 70.211(c) and 90.209(c) when a CPDM Dust Data Card is printed and signed. However, burdens for recording shift lengths when sampling is not conducted are shown under sections 70.201(e) and 90.201(f).

For surface work areas of underground coal mines and surface coal mines, there is no burden shown for section 71.201(d) when DWP sampling is conducted because records of shift length are accounted for under section 71.207(c) when a CMDPSU Dust Data Card is completed. However, the burden for recording shift length when sampling is not conducted is shown under section 71.201(d).

Sampling start date and time: Sections 70.201(f), 71.201(e), and 90.201(g) require that upon request from the District Manager, the operator must submit the date and time any respirable dust sampling required by parts 70, 71, or 90 will begin. The mine operator must submit this information to MSHA at least 48 hours prior to scheduled sampling.

Rain restriction: Under section 71.201(f), a mine operator may request, in writing, that the rain restriction for a ''normal work shift'' as defined in section 71.2 be waived by the District Manager.

Run-of-mine material produced: Section 70.201(g) requires that to establish a normal production shift, the operator must record the amount of run-of-mine material produced by each MMU during each shift to determine the average production for the most recent 30 production shifts, or for all production shifts if fewer than 30 shifts of production data are available. It also requires that the production records must be retained for at least 6 months and be made available for inspection by authorized representatives of the Secretary and the miners' representative.

Use of CPDM in anthracite mining: Sections 70.201(j) and 90.201(j) allow the mine operator of an anthracite mine that uses the full box, open breast, or slant breast mining method to use either a CPDM or a CMDPSU for respirable coal mine dust sampling required under part 70 or part 90. However, if the mine operator chooses not to use a CPDM, the operator must notify the District Manager in writing of this decision. To estimate the full cost impact upon coal mine operators, MSHA assumed that these operators will use the CPDM for the required sampling. Therefore, no burden was estimated at this time for these operators to notify the District Manager of their choice not to use the CPDM. Operators may reevaluate whether to use the CPDM. Therefore, future updates to this package may result in a burden for these provisions.

B. Information Collections Related to Improper Sampling Device Flowrate

Table 2 summarizes information collections related to sampling device flowrate requirements conducted under parts 70, 71, and 90.

TABLE 2—SAMPLING DEVICE FLOWRATE

30 CFR provision	Topic	General description of collection requirements
70.205(b)(2), 71.205(b)(2), 90.205(b)(2).	Proper flowrate	When using a CMDPSU, each sampling device must be examined by a person certified in sampling, and when the proper flowrate is not maintained, the certified person must note this on the Dust Data Card and transmit to MSHA.

Proper flowrate: Sections 70.205(b)(2), 71.205(b)(2), and 90.205(b)(2) require that if a CMDPSU is used to sample respirable coal mine dust, each approved sampling device must be examined each shift by a person certified in sampling during the last hour of operation to ensure that the sampling device is operating properly and at the proper flowrate. If the proper flowrate is not maintained, the certified person must note that the proper flowrate was not maintained on the back of the Dust Data Card, and the card must accompany the sample which must be transmitted to MSHA. Other events occurring during the collection of respirable coal mine dust samples that may affect the validity of the sample, such as dropping of the sampling head assembly onto the mine floor, must also be noted on the back of the Dust Data Card. The burdens for these requirements are included in the burdens estimated to complete the Dust Data Cards under sections 70.210(c), 71.207(c) and 90.208(c).

C. Information Collections Related to Operator Transmission of Respirable Dust Samples

Table 3 summarizes information collections related to transmission of respirable coal mine dust samples by the operator under parts 70, 71, and 90, such as operator transmission of samples to MSHA, completing the Dust Data Card, and notification of samples taken for other purposes.

TABLE 3—OPERATOR TRANSMISSION OF RESPIRABLE DUST SAMPLES

30 CFR provision	Topic	General description of collection requirements
70.210(a), 71.207(a), 90.208(a).	Transmitting samples to MSHA.	When using a CMDPSU, transmit all samples collected within 24 hours after the sampling shift to MSHA.
70.210(c), 71.207(c), 90.208(c).	Completing the Dust Data Card.	The person certified in sampling must complete the Dust Data Card for each filter cassette and must provide a signature.
70.210(d), 71.207(d), 90.208(d).	Samples for other purposes.	All operator samples must be included to fulfill the sampling requirements, unless the sample has been identified in writing to the DM prior to the intended shift as a sample to be used for another purpose.
70.210(f), 71.207(f), 90.208(f).	CPDM data file information.	When using a CPDM, the certified person must validate, certify, and transmit to MSHA within 24 hours after the end of each shift all sample data file information collected and stored in the CPDM and maintained for at least 12 months.

Transmitting samples to MSHA: Sections 70.210(a), 71.207(a), and 90.208(a) require that if a CMDPSU is used to sample, the operator must transmit within 24 hours after the end of the sampling shift all samples collected to fulfill the requirements of parts 70, 71, or 90, including control filters, in containers provided by the manufacturer of the filter cassette to: Respirable Dust Processing Laboratory, Pittsburgh Safety and Health Technology Center, Cochrans Mill Road, Building 38, P.O. Box 18179, Pittsburgh, Pennsylvania 15236–0179, or to any other address designated by the District Manager.

Completing the Dust Data Card: Sections 70.210(c), 71.207(c), and 90.208(c) require that a person certified in sampling properly complete the Dust Data Card that is provided by the manufacturer for each filter cassette. The card must have an identification number identical to that on the cassette used to take the sample and must be submitted to MSHA with the sample. Each card must be signed by the certified person who performed the required examinations during the sampling shift and include that person's MSHA Individual Identification Number (MIIN). Respirable dust samples with Dust Data Cards not properly completed may be voided by MSHA.

Samples for other purposes: Sections 70.210(d), 71.207(d), and 90.208(d) require all operator samples be included as samples taken to fulfill the sampling requirements of parts 70, 71, and 90, respectively, unless the operator identified the sample in writing to the District Manager and prior to the intended sampling shift as a sample to be used for another purpose.

CPDM data file information: Sections 70.210(f), 71.207(f), and 90.208(f) require that if a CPDM is used to sample, the person certified in sampling must validate, certify, and transmit electronically to MSHA within 24 hours after the end of each sampling shift all sample data file information collected and stored in the CPDM, including the sampling status conditions encountered when sampling. All CPDM data files transmitted electronically to MSHA must be maintained by the operator for at least 12 months.

The burdens for sections 70.210(a), (c), and (f), 71.207(a) and (c), and 90.208(f) are included in the burdens for sections 70.210, 71.207, and 90.208, respectively. Section 71.207(f) pertains only to using the CPDM. However, operators of surface coal mines and operators of surface work areas of underground coal mines are only required to use the CPDM for part 90 miner sampling, and MSHA does not expect them to use the CPDM to conduct DWP sampling. Thus, the burden for section 71.207(f) is accounted for in the burden for section 90.208(f).

D. Information Collections Related to Quarterly Sampling

Table 4 summarizes information collections related to quarterly sampling conducted under parts 70, 71, and 90, such as recording corrective actions when samples exceed the excessive concentration value (ECV) or following a citation.

TABLE 4—QUARTERLY SAMPLING

30 CFR provision	Topic	General description of collection requirements
70.208(e)(3), 70.209(c)(3), 90.207(c)(3).	Record of corrective actions taken when sample exceeds the ECV.	When a valid sample meets or exceeds the ECV, the operator must, upon implementation of corrective actions, make a record of the actions taken. The record must be certified by the mine official; made in a secure book; retained for at least 1 year; and made available for inspection (except for part 90 miners).
70.208(h)(3), 70.209(f)(3), 90.207(f)(3).	Record of corrective actions taken following a citation.	Upon issuance of a citation, the operator must, upon implementation of corrective actions, make a record of the actions taken. The record must be certified by the mine official; made in a secure book; retained for at least 1 year; and made available for inspection (except for part 90 miners).
70.208(i)(2), 70.209(g)(2).	Revised dust control parameters following a citation.	A citation will be terminated when the operator has submitted to the DM revised dust control parameters and the changes are approved by the DM.
71.206(d)	Identifying specific work positions where DWP samples will be collected.	Each operator must provide the DM with a list identifying the specific work positions where DWP samples will be collected for: Active mines; new mines; and DWPs with a change in operational status that increases or reduces the number of active DWPs.
71.206(e)	Notifying MSHA that sample was not taken on a normal work shift.	If a normal work shift is not achieved, the respirable dust sample must be transmitted to MSHA with a notation by the person certified in sampling on the back of the Dust Data Card stating that the sample was not taken on a normal work shift.
71.206(h)(3)	Record of corrective actions taken when sample exceeds the ECV.	When a valid sample meets or exceeds the ECV, the operator must, upon implementation of corrective actions, make a record of the actions taken. The record must be certified by the mine official; made in a secure book; retained for at least 1 year; and made available for inspection.
71.206(k)(3)	Record of corrective actions taken following a citation.	Upon issuance of a citation, the operator must, upon implementation of corrective actions, make a record of the actions taken. The record must be certified by the mine official; made in a secure book; retained for at least 1 year; and made available for inspection.

Record of corrective actions taken when sample exceeds the ECV: Quarterly sampling requirements are in section 70.208 for MMUs, section 70.209 for DAs, and section 90.207 for part 90 miners. Sections 70.208(e)(3), 70.209(c)(3), and 90.207(c)(3) require that when a valid representative sample meets or exceeds the ECV that corresponds to the applicable standard and particular sampling device used for either an MMU or DA, respectively, or that corresponds to the applicable standard and particular sampling device used for part 90 miner sampling, the operator must make, upon implementation of corrective actions, a record of the actions taken. The record must be certified by the mine foreman or equivalent mine official no later than the end of the mine foreman's or equivalent official's next regularly scheduled working shift. The record must be made in a secure book that is not susceptible to alteration or electronically in a computer system so as to be secure and not susceptible to alteration. Such records must be retained at a surface location at the mine for at least 1 year and be made available for inspection by authorized representatives of the Secretary and, except for part 90 miners, the miners' representative. Also, the records must be made available for inspection by the affected part 90 miner who was sampled.

Record of corrective actions taken following a citation: Sections 70.208(h)(3), 70.209(f)(3), and 90.207(f)(3) require that mine operators, upon issuance of a citation for violation of the applicable standard for either an MMU, DA, or part 90 miner, respectively, must make, upon implementation of corrective actions, a record of the actions taken. The record must be certified by the mine foreman or equivalent mine official no later than the end of the mine foreman's or equivalent official's next regularly scheduled working shift. The record must be made in a secure book that is not susceptible to alteration or electronically in a computer system so as to be secure and not susceptible to alteration. Such records must be retained at a surface location at the mine for at least 1 year and be made available for inspection by authorized representatives of the Secretary and, except for part 90 miners, the miners' representative. Also, the records must be made available for inspection by the affected part 90 miner who was sampled.

Revised dust control parameters following a citation: Sections 70.208(i)(2) and 70.209(g)(2) provide that a citation for violation of the applicable standard shall be terminated by MSHA when the operator has submitted to the District Manager revised dust control parameters as part of the mine ventilation plan applicable to the MMU or the DA, respectively, in the citation and such changes have been approved by the District Manager. The revised parameters must reflect the control measures used by the operator to abate the violation.

Identifying specific work positions where DWP samples will be collected: DWPs at surface coal mines and surface work areas of underground coal mines must be sampled quarterly under section 71.206. Under section 71.206(d), operators with multiple work positions that are specified in section 71.206(c)(2) and (c)(3) must sample the DWP exposed to the greatest respirable dust concentration in each work position performing the same activity or task at the same location at the mine and exposed to the same dust generation source. Each operator must provide the District Manager with a list identifying the specific work positions where DWP samples will be collected for: Active mines; new mines; and DWPs with a change in operational status that increases or reduces the number of active DWPs.

Notifying MSHA that sample was not taken on a normal work shift: Section 71.206(e) requires that each DWP sample must be taken on a normal work shift. If a normal work shift is not achieved, the respirable dust sample must be transmitted to MSHA with a notation by the person certified in sampling on the back of the Dust Data Card stating that the sample was not taken on a normal work shift. Section 71.207(c) requires that a person certified in sampling properly complete the Dust Data Card that is provided by the

manufacturer for each filter cassette. The card must have an identification number identical to that on the cassette used to take the sample and must be submitted to MSHA with the sample. Each card must be signed by the certified person who performed the required examinations during the sampling shift and include that person's MIIN. A separate burden has not been included for section 71.206(e) since MSHA assumed that any notations can be made at the same time that the Dust Data Card is completed under section 71.207(c).

Record of corrective actions taken when sample exceeds the ECV: Section 71.206(h)(3) requires that when a valid representative sample taken in accordance with this section meets or exceeds the ECV that corresponds to the applicable standard and particular sampling device used, the operator must make, upon implementation of the corrective actions, a record of the actions taken. The record must be certified by the mine foreman or equivalent mine official no later than the end of the mine foreman's or equivalent official's next regularly scheduled working shift. The record must be made in a secure book that is not susceptible to alteration or electronically in a computer system so as to be secure and not susceptible to alteration. Such records must be retained at a surface location at the mine for at least 1 year and be made available for inspection by authorized representatives of the Secretary and the miners' representative. There are no separate burden estimates projected for section 71.206(h)(3). MSHA assumed that surface samples that meet or exceed the applicable ECV will result in a citation, and this burden appears under section 71.206(k)(3).

Record of corrective actions taken following a citation: Section 71.206(k)(3) requires that upon issuance of a citation for violation of the applicable standard, the operator must make, upon implementation of corrective actions, a record of the actions taken. The record must be certified by the mine foreman or equivalent mine official no later than the end of the mine foreman's or equivalent official's next regularly scheduled working shift. The record must be made in a secure book that is not susceptible to alteration or electronically in a computer system so as to be secure and not susceptible to alteration. Such records must be retained at a surface location at the mine for at least 1 year and be made available for inspection by authorized representatives of the Secretary and the miners' representative.

E. Information Collections Related to Posting or Providing Respirable Dust Sampling Reports or Dust Data Cards

Table 5 summarizes information collections related to reporting respirable dust samples to the operator and posting or providing results conducted under parts 70, 71, and 90, such as posting such reports on the mine bulletin board or providing such reports to part 90 miners.

TABLE 5—POSTING OR PROVIDING RESPIRABLE DUST SAMPLING REPORTS AND DUST DATA CARDS

30 CFR provision	Topic	General description of collection requirements
70.211(b), 71.208(b)	Posting sampling report on the mine bulletin board.	Upon receipt of the sampling report that contains sampling results from MSHA, the operator must post the data for at least 31 days on the mine bulletin board.
70.211(c), 71.208(c)	Posting the Dust Data Card on the mine bulletin board.	When using a CPDM, the person certified in sampling must print, sign, and post the Dust Data Card on the mine bulletin board within 12 hours after the end of each shift.
70.211(c)(5), 71.207(c)	Shift length	When using a CPDM, the person certified in sampling must print, sign, and post the Dust Data Card on the mine bulletin board within 12 hours after the end of each shift, including shift length.
90.209(c)(5)	Shift length	When using a CPDM, the person certified in sampling must print, sign, and provide to each part 90 miner, a paper record (Dust Data Card) of the sample run within 1 hour after the start of the part 90 miner's next work shift, including shift length.
90.209(b)	Sampling report for part 90 miners.	Upon receipt of the sampling report from MSHA, the operator must provide a copy to the part 90 miner only.
90.209(c)	Dust Data Card for part 90 miners.	When using a CPDM, the person certified in sampling must print, sign, and provide to each part 90 miner, a paper record (Dust Data Card) of the sample run within 1 hour after the start of the part 90 miner's next work shift.

Posting sampling report on the mine bulletin board: Sections 70.211(b) and 71.208(b) require that upon receipt of the sampling report that contains sampling results from MSHA, the operator must post the data for at least 31 days on the mine bulletin board.

Posting the Dust Data Card on the mine bulletin board: Sections 70.211(c) and 71.208(c) require, if using a CPDM, the person certified in sampling to print, sign, and post on the mine bulletin board a paper record (Dust Data Card) of each sample run within 12 hours after the end of each sampling shift. This hard-copy record must include the data entered when the sample run was first programmed and the following: The mine identification number; the locations within the mine or the DWP at the mine from which the samples were taken; the concentration of respirable dust, expressed as an equivalent concentration, reported and stored for each sample; the sampling status conditions encountered for each sample; and the shift length. Section 71.208(c) requires that when CPDMs are used for DWP sampling, underground coal mine operators that have surface work areas and surface coal mine operators print, sign, and post a paper record (Dust Data Card) with the shift length and other information regarding sampling for each location sampled under Part 71. MSHA does not expect that the CPDM will be used for DWP sampling by underground coal mine operators on the surface area of the underground mine or by surface coal mine operators. Therefore, no burden was estimated at this time for Section 71.208(c).

Shift length: Section 70.211(c)(5) requires that, when CPDMs are used for sampling, underground coal mine operators print, sign, and post a paper record (Dust Data Card) that must include sample results, including the shift length. Under section 90.209(c)(5), when CPDMs are used for sampling, coal mine operators must print, sign, and provide to each part 90 miner a Dust Data Card that details the sample results, including shift length. Under sections 70.210(c) and 71.207(c), if using a CMDPSU, the operator must

complete a Dust Data Card, which includes reporting the sampling shift start time and sampling time in minutes.

Sampling report for part 90 miners: For part 90 miners, section 90.209(b) requires that upon receipt of the sampling report from MSHA, the operator must provide a copy to the part 90 miner only.

Dust Data Card for part 90 miners: Section 90.209(c) requires that if using a CPDM, the person certified in sampling must print, sign, and provide to each part 90 miner, a paper record (Dust Data Card) of the sample run within 1 hour after the start of the part 90 miner's next work shift. This hard copy record must include the data entered when the sample run was first programmed and the following: The mine identification number; the location within the mine from which the sample was taken; the concentration of respirable dust, expressed as an equivalent concentration reported and stored for each sample; the sampling status conditions encountered for each sample; the shift length; and the part 90 miner's MIIN.

F. Information Collections Related to Status Changes

Table 6 summarizes information collections related to operational status changes conducted under parts 70, 71, and 90.

TABLE 6—STATUS CHANGE REPORTS

30 CFR provision	Topic	General description of collection requirements
70.212(a), 71.209(a), 90.210.	Status changes	For any change in operational status that affects the respirable dust sampling requirements, the operator must report the change to MSHA. Status changes must be reported in writing or electronically, within 3 working days after the status change has occurred.

Status changes: Sections 70.212(a), 71.209(a), and 90.210 require that if there is a change in operational status that affects the respirable dust sampling requirements of parts 70, 71, or 90, respectively, the operator must report the change in operational status of the mine, MMU, DA, DWP, or part 90 miner (such as the part 90 miner entering a terminated, injured, or ill status, or returning to work) to the MSHA District Office or to any other MSHA office designated by the District Manager. Status changes must be reported in writing or electronically, within 3 working days after the status change has occurred.

G. Information Collections Related to Respirable Dust Control Plans

Table 7 summarizes information collections related to dust control plans under parts 71 and 90, such as submission of dust control plans following a citation, posting the plan on the mine bulletin board, or providing the plan to part 90 miners.

TABLE 7—RESPIRABLE DUST CONTROL PLANS

30 CFR provision	Topic	General description of collection requirements
71.300(a)	Dust control plan following a citation.	The mine operator must submit for approval a written respirable dust control plan applicable to the DWP identified in the citation within 15 calendar days after the termination date of a citation.
71.300(a)(1)	Notification of the miners' representatives of dust control plan.	The mine operator must notify the miners' representative at least 5 days prior to submission to MSHA of a respirable dust control plan and any revision to a dust control plan.
71.300(a)(3)	Posting the dust control plan on the mine bulletin board.	A copy of the proposed respirable dust control plan, and a copy of any proposed revision, submitted for Agency approval must be posted on the mine bulletin board at the time of submittal.
90.300(a)	Dust control plan for part 90 miners following a citation.	If an operator abates a violation of the applicable standard by reducing the respirable dust level in the position of the part 90 miner, the operator must submit, for the DM's approval, a written respirable dust control plan for the part 90 miner in the position identified in the citation within 15 calendar days after the citation is terminated.
71.301(d)(1)	Notification of miners' representatives following dust control plan approval.	The approved respirable dust control plan and any revisions must be provided upon request to the miners' representative by the operator following notification of approval.
71.301(d)(3)	Posting the dust control plan on the mine bulletin board following approval.	The plan or revisions must be posted on the mine bulletin board within 1 working day following notification of approval and remain posted for the period that the plan is in effect.
71.301(e)	Review of dust control plans and revisions.	The operator may review respirable dust control plans and submit proposed revisions to such plans to the DM for approval.
90.301(d)	Dust control plan for part 90 miners.	The mine operator must provide a copy of the current respirable dust control plan to the part 90 miner.
90.301(e)	Review of dust control plans and revisions for part 90 miners.	The operator may review respirable dust control plans and submit proposed revisions to such plans to the DM for approval.

Dust control plan following a citation: Section 71.300(a) requires that the operator submit to the District Manager for approval a written respirable dust control plan applicable to the DWP identified in the citation within 15 calendar days after the termination date of a citation for violation of the applicable standard. The respirable dust control plan and revisions must be suitable to the conditions and the mining system of the coal mine and be adequate to continuously maintain respirable dust within the applicable

standard at the DWP identified in the citation.

Notification of the miners' representatives of dust control plan: Section 71.300(a)(1) requires that the mine operator must notify the miners' representative at least 5 days prior to submission to MSHA of a respirable dust control plan and any revision to a dust control plan. If requested, the mine operator must provide a copy to the miners' representative at the time of notification.

Posting the dust control plan on the mine bulletin board: Section 71.300(a)(3) requires that a copy of the proposed respirable dust control plan and a copy of any proposed revision submitted for Agency approval must be posted on the mine bulletin board at the time of submittal. The proposed plan or proposed revision must remain posted until it is approved, withdrawn, or denied.

Dust control plan for part 90 miners following a citation: Section 90.300(a) requires that if an operator abates a violation of the applicable standard by reducing the respirable dust level in the position of the part 90 miner, the operator must submit, for the District Manager's approval, a written respirable dust control plan for the part 90 miner in the position identified in the citation within 15 calendar days after the citation is terminated. The respirable dust control plan and revisions thereof must be suitable to the conditions and the mining system of the coal mine and be adequate to continuously maintain respirable dust within the applicable standard for that part 90 miner.

Notification of miners' representative following dust control plan approval: Under section 71.301(d)(1), the approved respirable dust control plan and any revisions must be provided upon request to the miners' representative by the operator following notification of approval.

Posting the dust control plan on the mine bulletin board following approval: Under section 71.301(d)(3), the plan or revisions must be posted on the mine bulletin board within 1 working day following notification of approval and remain posted for the period that the plan is in effect.

Review of dust control plans and revisions: Under section 71.301(e), the operator may review respirable dust control plans and submit proposed revisions to such plans to the District Manager for approval.

Dust control plan for part 90 miners: Section 90.301(d) requires the operator to provide a copy of the current respirable dust control plan to the part 90 miner.

Review of dust control plans and revisions for part 90 miners: Under section 90.301(e), the operator may review respirable dust control plans and submit proposed revisions to such plans to the District Manager for approval.

H. Information Collections Related to Mine Ventilation Plans

Table 8 summarizes information collections related to mine ventilation plans under part 75, such as notifying miners' representatives of the mine ventilation plan, posting the approved plan on the mine bulletin board, and providing the approved plan to miners' representatives.

TABLE 8—MINE VENTILATION PLANS

30 CFR provision	Topic	General description of collection requirements
75.370(a)(3)(i)	Notification of miners' representatives of mine ventilation plan.	Notify the miners' representative at least 5 days prior to submission of mine ventilation plan and any revision and, if requested, provide a copy to the miners' representative at the time of notification.
75.370(a)(3)(iii), 75.370(f)(3).	Posting the mine ventilation plan and approval on the mine bulletin board.	Posting a copy of the proposed plan and any proposed revision, and the MSHA-approved plan and any revisions, respectively, on the mine bulletin board.
75.370(f)(1)	Providing approved plan to miners' representatives.	Providing a copy of the MSHA-approved plan and any revisions to the miners' representative, if requested.

Notification of the miners' representative of mine ventilation plan: Section 75.370(a)(3)(i) requires underground coal mine operators to notify the miners' representative at least 5 days prior to submission of the mine ventilation plan and any revision and, if requested, provide a copy to the miners' representative at the time of notification.

Posting the mine ventilation plan and approval on the mine bulletin board: Sections 75.370(a)(3)(iii) and (f)(3) require the operator to post a copy of the proposed plan and any proposed revision, and the MSHA-approved plan and any revisions, respectively, on the mine bulletin board.

Providing approved plan to miners' representatives: In addition, Section 75.370(f)(1) requires the operator to provide a copy of the MSHA-approved plan and any revisions to the miners' representative, if requested.

II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection related to *Respirable Coal Mine Dust Sampling.* MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information has practical utility;
- Evaluate the accuracy of MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to enhance the quality, utility, and clarity of the information to be collected; 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.

The information collection request will be available on *http://www.regulations.gov.* MSHA cautions the commenter against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on *www.regulations.gov* and *www.reginfo.gov.*

The public may also examine publicly available documents at USDOL-Mine Safety and Health Administration, 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452. Sign in at the receptionist's desk on the 4th Floor via the East elevator. Before visiting MSHA in person, call 202–693–9455 to make an appointment, in keeping with

the Department of Labor's COVID–19 policy. Special health precautions may be required.

Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION** section of this notice.

III. Current Actions

This request for collection of information contains provisions for *Respirable Coal Mine Dust Sampling.* MSHA has updated the data with respect to the number of respondents, responses, burden hours, and burden costs supporting this information collection request.

Type of Review: Extension of a currently approved collection.

Agency: Mine Safety and Health Administration.

OMB Number: 1219–0011.

Affected Public: Business or other for-profit.

Number of Respondents: 676.

Frequency: On occasion.

Number of Responses: 1,158,062.

Annual Burden Hours: 81,858 hours.

Annual Respondent or Recordkeeper Cost: $42,057.

MSHA Forms: Miner Operator Dust Data Card

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Song-ae Aromie Noe,

Certifying Officer.

[FR Doc. 2022–10897 Filed 5–20–22; 8:45 am]

BILLING CODE 4510–43–P

NATIONAL SCIENCE FOUNDATION

Notice of Intent To Seek Approval To Renew an Information Collection

AGENCY: National Science Foundation.

ACTION: Notice and request for comments.

SUMMARY: NSF is announcing plans to request renewed clearance of this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting OMB clearance of this collection for no longer than 3 years.

DATES: Written comments on this notice must be received by July 22, 2022, to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314; telephone (703) 292–7556; or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

SUPPLEMENTARY INFORMATION:

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Foundation, including whether the information will have practical utility; (b) the accuracy of the Foundation's estimate of the burden of the proposed collection of information; (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 those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Title of Collection: Research Performance Progress Report.

OMB Approval Number: 3145–0221.

Expiration Date of Approval: July 30, 2022.

Type of Request: Intent to seek approval to extend an information collection for three years.

Use of the Information:

NSF developed the RPPR as a service within *Research.gov.* The service provides a common portal for the research community to manage and submit annual project reports to the National Science Foundation (NSF) and to partner agencies. This service replaced NSF's annual and interim project reporting capabilities which resided in the FastLane System.

Complete information about NSF's implementation of the Research Performance Progress Report (RPPR) may be found at the following website: *http://www.nsf.gov/bfa/dias/policy/rppr/index.jsp.*

Burden on the Public: The Foundation estimates that an average of 6.6 hours is expended for each report submitted. An estimated 120,000 reports are expected during the course of one year for a total of 30,000 public burden hours annually.

Dated: May 18, 2022.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2022–11045 Filed 5–20–22; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of May 23, 30, June 6, 13, 20, 27, 2022. The schedule for Commission meetings is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

PLACE: The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

STATUS: Public.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Wendy.Moore@nrc.gov* or *Betty.Thweatt@nrc.gov.*

MATTERS TO BE CONSIDERED:

Week of May 23, 2022

There are no meetings scheduled for the week of May 23, 2022.

Week of May 30, 2022—Tentative

Wednesday, June 1, 2022

10 a.m. Transformation at the NRC—Sustaining Progress as Modern, Risk-Informed Regulator (Contact: Aida Rivera-Varona: 301–415–4001)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

Friday, June 3, 2022

10 a.m. Meeting with Advisory Committee on Reactor Safeguards (Contact: Larry Burkhart: 301–287–3775)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

Week of June 6, 2022—Tentative

There are no meetings scheduled for the week of June 6, 2022.

Week of June 13, 2022

Tuesday, June 14, 2022

10 a.m. Briefing on Human Capital and Equal Employment Opportunity (Contact: Nicole Newton: 301–415–8316)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

Thursday, June 16, 2022

10 a.m. Briefing on Results of the Agency Action Review Meeting (Contact: Nicole Fields: 630–829–9570)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

Week of June 20, 2022—Tentative

There are no meetings scheduled for the week of June 20, 2022.

Week of June 27, 2022—Tentative

There are no meetings scheduled for the week of June 27, 2022.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: May 19, 2022.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2022–11129 Filed 5–19–22; 4:15 pm]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94929; File No. SR–PEARL–2022–21]

Self-Regulatory Organizations: MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Pearl Equities Fee Schedule

May 17, 2022.

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 May 12, 2022, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III 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

The Exchange is filing a proposal to amend the fee schedule (the ''Fee Schedule'') applicable to MIAX Pearl Equities, an equities trading facility of the Exchange.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/pearl* at MIAX Pearl's principal office, 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 Exchange 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 Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's Fee Schedule to adopt a new tiered pricing structure, ''Market Quality Tiers'' or ''MQ Tiers,'' designed to improve market quality on the Exchange in certain specific securities, the ''Market Quality Securities'' or ''MQ Securities,'' and more generally in the form of an enhanced rebate for executions of displayed orders in securities priced at or above $1.00 per share that add liquidity to the Exchange (such orders, ''Added Displayed Volume'') for Members that meet certain minimum quoting requirements across a specified number of securities, as further described below. The Exchange originally filed this proposal on April 29, 2022 (SR–PEARL–2022–17). On May 12, 2022, the Exchange withdrew SR–PEARL–2022–17 and resubmitted this proposal.

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues, to which market participants may direct their order flow. Based on publicly available information, no single registered equities exchange currently has more than approximately 17% of the total market share of executed volume of equities trading, and the Exchange currently represents approximately 1% of the overall market share.[3]

Additionally, in response to the competitive environment, the Exchange also offers tiered pricing, which provides Equity Members [4] (''Members'') with opportunities to qualify for higher rebates or lower fees when certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts

[3] *See* MIAX's ''The Market at a Glance'', available at *https://www.miaxoptions.com/* (last visited April 27, 2022).

[4] The term ''Equity Member'' is a Member authorized by the Exchange to transact business on MIAX Pearl Equities. *See* Exchange Rule 1901.

for satisfying increasingly more stringent criteria.

Adoption of Market Quality Tiers

The Exchange proposes to adopt a new tiered pricing incentive, referred to by the Exchange as the ''Market Quality Tiers'' (or ''MQ Tiers''), in the form of an enhanced rebate for executions of Added Displayed Volume for Members that qualify for the incentive by meeting certain minimum quoting requirements across a specified number of securities, as further described below. The proposed MQ Tiers are designed to encourage Members to improve market quality by quoting at the NBBO [5] for a significant portion of the day (as defined below) on the Exchange in certain specific securities, referred to by the Exchange as MQ Securities and in all securities more generally.[6] By analyzing volume statistics and time at the NBBO the Exchange has identified a number of securities for which it intends to improve these metrics (the MQ Securities). The list of MQ Securities is published on the Exchange's website. The Exchange believes the MQ Tiers will benefit the Exchange and investors by providing improved trading conditions for all market participants through narrower bid-ask spreads and increased depth of liquidity available at the NBBO in a broad base of securities, including the MQ Securities.

The Exchange currently provides a standard rebate of $0.0029 per share for executions of Added Displayed Volume.[7] The Exchange now proposes to introduce a tiered pricing structure in which it will provide an enhanced rebate for executions of Added Displayed Volume to Members that meet certain quoting requirements. Specifically, the Exchange proposes to provide an enhanced rebate of $0.0032 in Tier 1 of the Market Quality Tiers for executions of Added Displayed Volume [8] if the Member's Percent Time at NBBO [9] is at least 25% in an average of at least 250 securities, at least 50 of which must be MQ Securities, per trading day during the month. Similarly, the Exchange proposes to provide an enhanced rebate of $0.0034 in Tier 2 of the Market Quality Tiers for executions of Added Displayed Volume if the Member's Percent Time at NBBO is at least 25% in an average of at least 1,000 securities, at least 100 of which must be MQ Securities, per trading day during the month.

As noted above, to qualify for the incentive provided for in Tier 1 of the Market Quality Tiers, a Member must meet the quoting requirement in an average of at least 250 securities traded on the Exchange (the ''Tier 1 Securities Requirement''), at least 50 of which must be MQ Securities (the ''Tier 1 MQ Securities Requirement''), per trading day during the month. To qualify for the incentive provided for in Tier 2 of the Market Quality Tiers, a Member must meet the quoting requirement in an average of at least 1,000 securities traded on the Exchange (the ''Tier 2 Securities Requirement''), at least 100 of which must be MQ Securities (the ''Tier 2 MQ Securities Requirement''), per trading day during the month. The Tier 1 Securities Requirement and the Tier 2 Securities Requirement, collectively the ''Securities Requirement'' and the Tier 1 MQ Securities Requirement and Tier 2 MQ Securities Requirement, collectively the ''MQ Securities Requirement'' is referred to under this proposal as the ''Incentive Criteria.'' The proposed MQ Tiers are designed to enhance market quality both in a broad manner with respect to all securities traded on the Exchange, through the Securities Requirement, and in a targeted manner with respect to certain designated securities in which the Exchange specifically seeks to inject additional quoting competition (*i.e.,* the MQ Securities), through the MQ Securities Requirement. The number of MQ Securities in which a Member meets the quoting requirement will be counted toward both the Securities Requirement and the MQ Securities Requirement. In order to determine whether a Member meets the applicable Securities Requirements during a month, the average number of securities in which such a Member meets the quoting requirement per trading day during the month will be calculated by summing the number of securities in which the Member met the quoting requirement for each trading day during the month then dividing the resulting sum by the total number of trading days in the month.[10]

In addition, for the purposes of determining qualification for the MQ Tiers, the Exchange will exclude: (1) Any trading day that the Exchange's system experiences a disruption that lasts for more than 60 minutes during Regular Trading Hours; (2) any day with a scheduled early market close; and (3) the ''Russell Reconstitution Day'' (typically the last Friday in June). The Exchange will exclude any trading day that the Exchange's system experiences a disruption that lasts for more than 60 minutes during Regular Trading Hours, any day with a scheduled early market close, and the Russell Reconstitution Day when determining both the numerator (*i.e.,* the number of securities in which a Member has met the quoting requirement for each trading day during the month) and the denominator (*i.e.,* the total number of trading days in the month) for purposes of calculating the average number of securities in which such Member meets the quoting requirement per trading day during the month.

As further detail regarding such proposed exclusions, an Exchange system disruption may occur, for example, where a certain group of securities traded on the Exchange is unavailable for trading due to an Exchange system issue. Similarly, the Exchange may be able to perform certain functions with respect to accepting and processing orders, but may have a failure to another significant process, such as routing to other market centers, that would lead Members that rely on such process to avoid utilizing the Exchange until the Exchange's entire system was operational. The Exchange believes that these types of Exchange system disruptions could preclude Members from participating on the Exchange to the extent that they might have otherwise participated on such days, and thus, the Exchange believes it

[5] With respect to the trading of equity securities, the term ''NBB'' shall mean the national best bid, the term ''NBO'' shall mean the national best offer, and the term ''NBBO'' shall mean the national best bid and offer. *See* Exchange Rule 1901.

[6] The Exchange notes that it will aggregate each Member's MPIDs and view quotes by Member Firm to determine the number of securities in which the Member meets the quoting requirements for that day.

[7] The Exchange notes that the standard rebate of $0.0029 per share for executions of Added Displayed Volume in securities priced at or above $1.00, applicable to Liquidity Indicator Codes AA, AB, and AC, is not changing under this proposal.

[8] The incentives provided for in the Market Quality Tiers will be applicable to the following Liquidity Indicator Codes: AA, AB, and AC. *See* section 1(b) Liquidity Indicator Codes and Associated Fees of the Exchange's Fee Schedule available on its public website (available at *https://www.miaxoptions.com/sites/default/files/fee_schedule-files/MIAX_Pearl_Equities_Fee_Schedule_04012022_b.pdf*).

[9] As proposed, the term ''Percent Time at NBBO'' means the aggregate of the percentage of time during regular trading hours where a Member has a displayed order of at least one round lot at the national best bid (''NBB'') or the national best offer (''NBO'').

[10] As an example, in a month with 20 trading days, if a Member satisfied the quoting requirement in 125 securities (of which 25 were MQ Securities) for ten of the trading days in the month, and satisfied the quoting requirement in 375 securities (of which 75 were MQ Securities) for the other ten trading days in the month, such Member would meet the quoting requirement in an average of 250 securities (*i.e.,* $((125 \times 10) + (375 \times 10))/20$), inclusive of an average of 50 MQ Securities (*i.e.,* $((25 \times 10) + (75 \times 10))/20$), per trading day during the month. Therefore, such Member would meet the applicable Securities Requirements during the month and would qualify for the Tier 1 incentive for that month under this proposal.

is appropriate to exclude such days when determining whether a Member meets the applicable Securities Requirements during a month to avoid penalizing Members that might otherwise have met such requirements. Additionally, the Exchange believes that scheduled early market closures, which typically are the day before, or the day after, a holiday, may preclude some Members from participating on the Exchange at the same level that they might otherwise. For similar reasons, the Exchange believes it is appropriate to exclude the Russell Reconstitution Day in the same manner, as the Exchange believes that the Russell Reconstitution Day typically has extraordinarily high, and abnormally distributed, trading volumes and the Exchange believes this change to normal activity may affect a Member's ability to meet the quoting requirement across various securities on that day. The Exchange notes that the exclusion of any day during which the Exchange's system experiences a disruption that lasts for more than 60 minutes during Regular Trading Hours, any day with a scheduled early market close, and the Russell Reconstitution Day is consistent with the methodologies used by other exchanges when calculating certain Member trading and other volume metrics for purposes of determining whether Members qualify for certain pricing incentives, and the Exchange believes application of this methodology is similarly appropriate for the proposed MQ Tiers pricing incentive.[11]

A Member that qualifies for the enhanced rebate under MQ Tier 1 by meeting the requirements described above during a particular month will receive an enhanced rebate of $0.0032 per share for all executions of Added Displayed Volume (unless a higher rebate applies)[12] during that month. This proposed rebate is $0.0003 higher than the standard rebate ($0.0029) that would otherwise be applicable to such executions. Similarly, a Member that qualifies for the enhanced rebate under MQ Tier 2 by meeting the requirements described above during a particular month will receive an enhanced rebate of $0.0034 per share for all executions of Added Displayed Volume (unless a higher rebate applies) during that month. This proposed rebate is $0.0005 higher than the standard rebate ($0.0029) that would otherwise be applicable to such executions. The Exchange notes that the proposed enhanced rebate will only apply to executions in securities priced at or above $1.00 per share; executions of a qualifying Member's displayed orders that add liquidity to the Exchange in securities priced below $1.00 per share will continue to receive the standard rebate applicable to executions of such orders on the Exchange (*i.e.,* 0.05% of the total value of the transaction).

The Exchange is proposing to provide the enhanced rebate for executions of Added Displayed Volume for qualifying Members as a means of recognizing the value of market participants that consistently quote at the NBBO in a large number of securities generally, and in the MQ Securities in particular. Given the proposed Incentive Criteria for the Market Quality Tiers a Member must make a significant contribution to market quality by providing liquidity at the NBBO in a large number of securities, including certain designated securities in which the Exchange specifically seeks to inject additional quoting competition (*i.e.,* the MQ Securities), for a significant portion of the day. Through the proposed enhanced rebate for qualifying Members, the Exchange hopes to provide improved trading conditions for all market participants through narrower bid-ask spreads and increased depth of liquidity available at the NBBO for a large number of securities generally, including the MQ Securities in particular.

The Exchange notes that the proposed MQ Tiers are similar in structure and purpose to pricing programs at other exchanges that are designed to enhance market quality by incentivizing Members to achieve minimum quoting standards, including minimum quoting at the NBBO in a large number of securities generally, or certain designated securities in particular.[13] The Exchange further notes that, like the proposed MQ Tiers, these programs include as an incentive the provision of an enhanced rebate for executions of liquidity-adding displayed orders for Members that meet the quoting and other requirements of those programs.[14]

In addition to the foregoing changes, the Exchange proposes to add to the Fee Schedule definitions of the terms, ''Market Quality Securities,'' and ''Percent Time at NBBO,'' that are consistent with the descriptions of those terms as set forth above, as such terms are used above describing the calculation methodology and criteria for determining whether a Members qualifies for a rebate under the MQ Tiers that the Exchange is proposing to add to the Fee Schedule, as described above. The Exchange also proposes to make a minor non-substantive edit to the definition of ADAV to remove the parenthetical ''Exchange System Disruption'' to avoid confusion as the Exchange has a pre-existing definition of Exchange System Disruption. The Exchange also proposes to adopt a new paragraph to the General Notes section

[11] *See e.g.,* the CBOE BZX Exchange, Inc. (''Cboe BZX'') equities trading fee schedule on its public website (available at *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/*); the Cboe EDGX Exchange, Inc. (''Cboe EDGX'') equities trading fee schedule available on its public website (available at *https://www.cboe.com/us/equities/membership/fee_schedule/edgx/*); and the MEMX LLC, (''MEMX'') equities trading fee schedule on its public website (available at *https://info.memxtrading.com/fee-schedule/*).

[12] The Exchange currently provides on its Fee Schedule that, ''to the extent a Pearl Equity Member qualifies for higher rebates and/or lower fees than those provided by a tier for which such a Member qualifies, the higher rebate and/or lower fees shall apply.'' *See* the Exchange's Fee Schedule, General Notes section, on its public website (available at *https://www.miaxoptions.com/sites/default/files/fee_schedule-files/MIAX_Pearl_Equities_Fee_Schedule_04012022_b.pdf*).

[13] *See e.g.,* the Nasdaq equities trading fee schedule on its public website, (available at *http://www.nasdaqtrader.com/trader.aspx?id=pricelisttrading2*) and Nasdaq Rule Equity 7, Section 114(d) describing Nasdaq's Qualified Market Maker Program, which provides for an additional rebate (ranging from $0.0001 to $0.0002 per share) for executions of liquidity-providing displayed orders (other than designated retail orders) in securities across all tapes priced at or above $1.00 per share for members that, in addition to executing transactions that represent a specified percentage of consolidated volume and avoiding inefficient order entry practices that place excessive burdens on Nasdaq's systems, quote at the NBBO at least 25% of the time during regular market hours in an average of at least 1,000 securities per day during the month; *see also* the Cboe BZX equities trading fee schedule on its public website, (available at *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/*), which provides for an additional rebate (ranging from $0.0001 to $0.0002 per share) under Cboe BZX's Liquidity Management Program for executions of liquidity-providing displayed orders in Tape B securities priced at or above $1.00 per share for members that, in addition to adding a specified percentage of total consolidated volume in Tape B securities and meeting certain other quoting requirements with respect to a specified number of securities designated as ''LMP Securities'' on a list determined by Cboe BZX, quote at the NBBO at least 15% of the time during regular trading hours in a specified number of such designated LMP Securities (or achieve an alternative NBBO quoting standard involving a size-setting element with respect to such designated LMP Securities.); *see also* MEMX equities trading fee schedule on its public website, (available at *https://info.memxtrading.com/fee-schedule/*), which provides for a rebate of $0.0033 per share in Tier 1 under MEMX's Displayed Liquidity Incentive (DLI) Tiers for executions of liquidity providing displayed orders in securities priced at or above $1.00 per share for members that have an NBBO Time of at least 25% in an average of at least 1,000 securities, at least 125 must be DLI Target Securities, per trading day during the month, and a rebate of $0.0031 per share in Tier 2 for executions of liquidity providing displayed orders in securities priced at or above $1.00 per share for members that have an NBBO Time of at least 25% in an average of at least 250 securities, at least 75 of which must be DLI Target Securities, per trading day during the month.

[14] *Id.*

to state that, ''[f]or the purpose of determining qualification for the Market Quality Tiers the Exchange will exclude from its calculation: (1) Any trading day that the Exchange's system experiences a disruption that lasts for more than 60 minutes during regular trading hours; (2) any day with a scheduled early market close; and (3) the ''Russell Reconstitution Day'' (typically the last Friday in June).'' The Exchange believes this adds additional clarity regarding the methodology used to determine qualification for the Market Quality Tiers.

Implementation

The proposed changes are immediately effective.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [15] in general, and furthers the objectives of Section 6(b)(4) of the Act [16] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and issuers and other persons using its facilities. The Exchange also believes that the proposed rule change is consistent with the objectives of Section 6(b)(5) [17] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, and 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, and, particularly, is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange operates in a highly fragmented and competitive market in which market participants can readily direct their order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of sixteen registered equities exchanges, and there are a number of alternative trading systems and other off-exchange venues, to which market participants may direct their order flow. Based on publicly available information, no single registered equities exchange currently has more than approximately 17% of the total market share of executed volume of equities trading.[18] Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow, and the Exchange currently represents less than 1% of the overall market share. The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [19]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. The Exchange believes the proposal reflects a reasonable and competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance liquidity and market quality in both a broad manner and in a targeted manner with respect to the MQ Securities.

Market Quality Tiers

The proposed Market Quality Tiers are intended to encourage Members to promote price discovery and market quality by quoting at the NBBO for a significant portion of each day in a large number of securities generally, and in MQ Securities in particular, thereby benefiting the Exchange and other investors by providing improved trading conditions for all market participants through narrower bid-ask spreads and increasing the depth of liquidity available at the NBBO in a broad base of securities, including the MQ Securities. Additionally, the Exchange believes the proposed enhanced rebates for all executions of a qualifying Member's Added Displayed Volume will simultaneously incentivize such Member to direct additional displayed liquidity-providing orders to the Exchange in a more general manner to receive such enhanced rebate. Thus, the Exchange believes that the proposed Market Quality Tiers will promote price discovery and market quality in the MQ Securities and more generally on the Exchange, and, further, that the resulting tightened spreads and increased displayed liquidity will benefit all investors by deepening the Exchange's liquidity pool, supporting the quality of price discovery, enhancing quoting competition across all exchanges, and promoting market transparency.

The Exchange believes the proposed enhanced rebate of $0.0032 per share provided to Members that qualify for Market Quality Tier 1 executions of Added Displayed Volume is reasonable, in that it does not reflect a disproportionate increase above the standard rebate of $0.0029 per share provided to all Members with respect to the provision of Added Displayed Volume. Similarly, the Exchange believes the proposed enhanced rebate of $0.0034 per share provided to Members that qualify for Market Quality Tier 2 executions of Added Displayed Volume is reasonable, in that it does not reflect a disproportionate increase above the enhanced rebate of $.0.0032 per share provided to qualifying Members in Tier 1 with respect to the provision of Added Displayed Volume. Moreover, the Exchange believes the proposed enhanced rebate associated with Market Quality Tier 2 is a reasonable means to incentivize Members to increase their participation on the Exchange as it provides Members with an additional opportunity to qualify for an enhanced rebate for executions of Added Displayed Volume by satisfying more stringent criteria than Tier 1.

The Exchange further believes that the proposed criteria for Tier 1 and Tier 2 of the Market Quality Tiers, and the associated enhanced rebate for each is reasonable, in that the proposed criteria for Tier 2 is incrementally more difficult to achieve than that of Tier 1, and thus Tier 2 appropriately offers a higher rebate commensurate with the corresponding higher volume threshold. Therefore, the Exchange believes that the Market Quality Tiers, as proposed, are consistent with an equitable allocation of fees and rebates, as the more stringent criteria correlates with the corresponding tier's higher rebate.

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(4).

[17] 15 U.S.C 78f(b)(5).

[18] *See supra* note 3.

[19] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37499 (June 29, 2005).

In addition the Exchange believes that it is reasonable and consistent with an equitable allocation of fees to pay a higher rebate for executions of Added Displayed Volume to Members that qualify for one of the Market Quality Tiers with respect to the MQ Securities because of the additional commitment to market quality reflected in the associated quoting requirements. Such Members benefit all investors by promoting price discovery and increasing the depth of liquidity available at the NBBO and benefit the Exchange itself by enhancing its competitiveness as a market center that attracts actionable orders. Further, the Exchange notes that the proposed Market Quality Tiers offers a new incentive on the Exchange that would apply uniformly to all Members, and any Member may choose to qualify for one of the Market Quality Tiers by meeting the associated requirements in any month, regardless of the volume of transactions that it executes on the Exchange. The Exchange acknowledges that firms that do not post displayed liquidity on the Exchange or do so on a smaller scale may not have the level of capital necessary to support meeting the proposed Incentive Criteria, however, the Exchange believes that the requirements are attainable for many market participants who do actively quote on the Exchange and are reasonably related to the enhanced market quality that the Market Quality Tiers are designed to promote. Additionally, the Exchange notes that Members that do not meet the proposed Incentive Criteria may still qualify for a rebate that is higher than the standard rebate for executions of Added Displayed Volume through the Add Volume Tiers Incentive, which does not require a Member to consistently quote at the NBBO across a broad range of securities. Accordingly, the Exchange believes that it is consistent with an equitable allocation of fees and is not unfairly discriminatory to pay a higher rebate in comparison with the rebate paid to other Members for executions of displayed liquidity providing orders in recognition of the benefits to the Exchange and market participants, particularly as the magnitude of the additional rebate is not unreasonably high, and is instead, reasonably related to such enhanced market quality.

The Exchange also believes that including in the proposed Market Quality Tiers criteria a quoting requirement for certain specified securities (*i.e.,* the MQ Securities), in addition to the more general requirements of 250 securities in Tier 1 and 1,000 securities in Tier 2, is equitable and not unfairly discriminatory because the Exchange has identified the MQ Securities as securities in which it would like to inject additional quoting competition, which the Exchange believes will generally act to narrow spreads, increase size at the NBBO, and increase liquidity depth in such securities, thereby increasing the attractiveness of the Exchange as a destination venue with respect to such securities. Accordingly, the Exchange believes that this aspect of the proposal is reasonable, equitably allocated, and not unfairly discriminatory because it is consistent with the overall goals of enhancing market quality.

Furthermore, as noted above, the proposed Market Quality Tiers are similar in structure and purpose to pricing programs in place at other exchanges that are designed to enhance market quality.[20] Specifically, these programs, like the proposed Market Quality Tiers, provide a higher rebate for executions of liquidity-adding displayed orders for members that achieve minimum quoting standards, including minimum quoting at the NBBO in a large number of securities generally, or certain designated securities in particular.[21] The Exchange also notes that the proposed Market Quality Tiers are not dissimilar from volume-based rebates and fees which have been widely adopted by exchanges [22] and are equitable and not unfairly discriminatory because they are generally open to all members on an equal basis and provide higher rebates and/or lower fees that are reasonably related to the value of an exchange's market quality. Much like volume-based tiers are designed to incentivize higher levels of liquidity provision, the proposed Market Quality Tiers are designed to incentivize enhanced market quality on the Exchange through tighter spreads, greater size at the NBBO, and greater quoting depth in a large number of securities generally, and in MQ Securities specifically, through the provision of an enhanced rebate for all executions of a qualifying Member's Added Displayed Volume, where such rebate will in turn incentivize higher levels of displayed liquidity provision in a general manner. Accordingly, the Exchange believes that the proposed Market Quality Tiers would act to enhance liquidity and competition across exchanges in the Market Quality Tiers and enhance liquidity provision in all securities on the Exchange more generally by providing a rebate reasonably related to such enhanced market quality to the benefit of all investors, thereby promoting the principles discussed in Sections 6(b)(4) and 6(b)(5) of the Act.[23]

The Exchange also believes that the calculation methodology and criteria for determining whether a Member satisfies the requirements to qualify for the Market Quality Tiers, as well as the definitions of terms that are used, is reasonable, equitable, and non-discriminatory because the definitions are designed to ensure that the Fee Schedule is clear and as easily understandable as possible with respect to the requirements of the proposed Market Quality Tiers. Additionally, the Exchange believes that excluding (1) any trading day that the Exchange's system experiences a disruption that lasts for more than 60 minutes during Regular Trading Hours; (2) any day with a scheduled early market close; and (3) the Russell Reconstitution Day, when determining whether a Member qualifies for a proposed Market Tier during a month is reasonable, equitable, and non-discriminatory because, as explained above, the Exchange believes doing so would help to avoid penalizing Members that might otherwise have met the requirements to qualify for a proposed Market Quality Tier due to Exchange system disruptions, abbreviated trading days, and/or abnormal market conditions. For similar reasons, the Exchange believes it is appropriate to exclude the Russell Reconstitution Day, as the Exchange believes the change to normal trading activity as a result of the Russell Reconstitution may affect a Member's ability to meet the quoting requirement across various securities on that day. The Exchange notes that its proposed calculation methodology is consistent with the methodologies used by other exchanges when calculating certain member trading and other volume metrics for purposes of determining whether members qualify for certain pricing incentives.[24]

For the reasons discussed above, the Exchange submits that the proposal satisfies the requirements of Sections 6(b)(4) and 6(b)(5) of the Act in that it provides for the equitable allocation of

[20] *See supra* note 11.

[21] *Id.*

[22] *See, e.g.,* the Cboe BZX equities trading fee schedule on its public website (available at *https://markets.cboe.com/us/equities/membership/fee_schedule/bzx/*); the Cboe EDGX equities trading fee schedule on its public website (available at *https://markets.cboe.com/us/equities/membership/fee_schedule/edgx/*); and the MEMX equities trading fee schedule on its public website (available at *https://info.memxtrading.com/fee-schedule/*).

[23] 15 U.S.C. 78f(b)(4) and (5).

[24] *See supra* note 13.

reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to unfairly discriminate between customers, issuers, brokers, or dealers. As described more fully below in the Exchange's statement regarding the burden on competition, the Exchange believes that its transaction pricing is subject to significant competitive forces, and that the proposed fees and rebates described herein are appropriate to address such forces.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the proposal is intended to enhance market quality on the Exchange in a large number of securities generally, and in the MQ Securities specifically, and to encourage Members to maintain or increase their order flow on the Exchange, thereby promoting price discovery and contributing to a deeper and more liquid market to the benefit of all market participants. As a result, the Exchange believes the proposal would enhance its competitiveness as a market that attracts actionable orders, thereby making it a more desirable destination venue for its customers. For these reasons, the Exchange believes that the proposal furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [25]

Intramarket Competition

The Exchange believes that the proposal would incentivize Members to promote price discovery and market quality by quoting at the NBBO for a significant portion of each day in a large number of securities, including the MQ Securities, to maintain or increase their order flow on the Exchange, thereby contributing to a deeper and more liquid market to the benefit of all market participants and enhancing the attractiveness of the Exchange as a trading venue, which the Exchange believes, in turn, would continue to encourage market participants to direct additional order flow to the Exchange. Greater liquidity benefits all Members by providing more trading opportunities and encourages Members to send additional orders to the Exchange, thereby contributing to robust levels of liquidity, which benefits all market participants. The opportunity to qualify for one of the Market Quality Tiers and thus receive the corresponding enhanced rebate for executions of Added Displayed Volume would be available to all Members that meet the associated requirements in any month. Further, as noted above, the Exchange believes that the proposed criteria for Tier 1 and Tier 2 (which has slightly more stringent criteria than Tier 1) of the Market Quality Tiers, are attainable for Members and that the respective enhanced rebates provided under each tier are reasonably related to the enhanced market quality that each tier is designed to promote. As such, the Exchange believes the proposed changes would not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intermarket Competition

The Exchange believes its proposal will benefit competition, and the Exchange notes that it operates in a highly competitive market. Members have numerous alternative venues they may participate on and direct their order flow to, including fifteen other equities exchanges and numerous alternative trading systems and other off-exchange venues. As noted above, no single registered equities exchange currently has more than 17% of the total market share of executed volume of equities trading.[26] Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. Moreover, the Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow in response to new or different pricing structures being introduced to the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates generally, including with respect to executions of Added Displayed Volume, and market participants can readily choose to send their orders to other exchanges and off-exchange venues if they deem fee levels at those other venues to be more favorable.

As described above, the proposal is designed to enhance market quality on the Exchange and to encourage additional order flow and quoting activity on the Exchange and to promote market quality through pricing incentives that are comparable to, and competitive with, pricing programs in place at other exchanges with respect to executions of Added Displayed Volume.[27] Accordingly, the Exchange believes the proposal would not be a burden on, but rather promote, intermarket competition by enabling the Exchange to better compete with other exchanges that offer similar incentives to market participants that enhance market quality and/or achieve certain volume criteria and thresholds.

Additionally, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [28] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission*, the D.C. circuit stated: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possess a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . . .''.[29] Accordingly, the Exchange does not believe its proposed pricing changes impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

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

The foregoing rule change has become effective pursuant to Section

[25] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 47396 (June 29, 2005).

[26] *See supra* note 3.

[27] *See supra* note 13.

[28] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[29] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSE–2006–21)).

19(b)(3)(A)(ii) of the Act,[30] and Rule 19b–4(f)(2)[31] 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 shall institute proceedings to determine whether the proposed rule 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–PEARL–2022–21 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–2022–21. 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 (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street, NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–PEARL–2022–21 and should be submitted on or before June 13, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–10962 Filed 5–20–22; 8:45 am]

BILLING CODE 8011–01–P

[30] 15 U.S.C. 78s(b)(3)(A)(ii).

[31] 17 CFR 240.19b–4(f)(2).

[32] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–34587; File No. 812–15337]

Allianz Global Investors U.S. LLC, et al.; Notice of Application and Temporary Order

May 17, 2022.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Temporary order and notice of application for a permanent order under section 9(c) of the Investment Company Act of 1940 (''Act'').

SUMMARY OF APPLICATION: Applicants have applied for an order exempting them from section 9(a) of the Act with respect to a guilty plea entered on May 17, 2022 (''Guilty Plea'') by Allianz Global Investors U.S. LLC (the ''Pleading Entity'') in the United States District Court for the Southern District of New York (the ''District Court'') in connection with a plea agreement (''Plea Agreement'') between the Pleading Entity and the United States Department of Justice (''DOJ''). The Pleading Entity has requested a time-limited exemption for the sole purpose of providing the Pleading Entity with adequate time to transition certain U.S. registered fund advisory relationships to other service providers (the ''Time-Limited Exemption''). Upon the expiration of the Time-Limited Exemption, the Pleading Entity will be disqualified from engaging in the fund servicing activities identified in section 9(a) of the Act in accordance with the terms thereof. The PIMCO Applicants and the Allianz Life Applicants (each as defined below and, collectively, the ''Continuing Fund Servicing Applicants'') have requested a temporary exemption from section 9(a) until the Commission takes final action on an application for a permanent order (the ''Permanent Order''). The temporary order (as set forth herein, the ''Temporary Order'' and, together with the Permanent Order, the ''Orders'') provides a Time-Limited Exemption to the Pleading Entity and a temporary exemption to the Continuing Fund Servicing Applicants and other Covered Persons (defined below) pending Commission action on the Permanent Order. The Permanent Order, if granted, would: (1) If the order is issued prior to the date that the Time-Limited Exemption would expire by its terms, reference the Time-Limited Exemption, subject to expiration at the end of its term,[1] and (2) provide a permanent exemption to the Continuing Fund Servicing Applicants and other Covered Persons.

APPLICANTS: The Pleading Entity, Allianz Investment Management LLC (''AIM''), Allianz Life Financial Services, LLC (''ALFS''), Allianz Life Insurance Company of North America (''ALICONA''), Allianz Life Insurance Company of New York (''ALICONY''), Pacific Investment Management Company LLC (''PIMCO LLC''), PIMCO Investments LLC (''PIMCO Investments'' and, collectively with the Pleading Entity, AIM, ALFS, ALICONA, ALICONY and PIMCO, the ''Fund Servicing Providers''), and, solely for the purposes of making certain representations and committing to certain undertakings as set forth in the application, Allianz SE (''Allianz SE'' and together with its wholly owned subsidiaries and affiliated entities, ''Allianz''). The term ''Continuing Fund Service Applicants'' refers to, collectively, AIM, ALFS, ALICONA, ALICONY, PIMCO and PIMCO Investments. The term ''Applicants'' refers to, collectively, Allianz SE, the Pleading Entity, and the Continuing Fund Servicing Applicants.

FILING DATE: The application was filed on May 17, 2022.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving applicants with a copy of the request, by email. Hearing requests should be received by the Commission by 5:30 p.m. on June

[1] If the Time-Limited Exemption expires by its terms prior to the issuance of the permanent order, the Time-Limited Exemption will be omitted from the permanent order.

13, 2022 and should be accompanied by proof of service on the 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 emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: John Viggiano, *john.viggiano@allianzgi.com;* Erik T. Nelson, *erik.nelson@allianzlife.com;* Paul G. Cellupica, *paul.cellupica@pimco.com;* Frederick Wertheim, *WertheimF@sullcrom.com;* and Wendy M. Goldberg, *GoldbergW@sullcrom.com.*

FOR FURTHER INFORMATION CONTACT: Asaf Barouk, Attorney-Adviser, at (202) 551–4029, Kyle R. Ahlgren, Acting Branch Chief, at (202) 551–6857 or Marc Mehrespand, Branch Chief, at (202) 551–8453 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a temporary order and a summary of the application. For Applicants' representations, legal analysis, and conditions, please refer to the application, dated May 17, 2022, which may be obtained via the Commission's website by searching for the file number at the top of this document, 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/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

Applicants' Representations

1. The Pleading Entity is a limited liability company formed under Delaware law and registered with the Commission as an investment adviser under the Investment Advisers Act of 1940 (the ''Advisers Act''). The Pleading Entity advised and sub-advised Fund [2] assets of approximately $297.2 million and $29.0 billion, respectively, as of March 31, 2022. The Pleading Entity is a wholly owned subsidiary of Allianz Global Investors U.S. Holdings LLC, which in turn is a wholly owned subsidiary of Allianz SE, the ultimate parent company of Allianz.

2. ALICONA is a stock life insurance company formed under Minnesota law offering fixed index annuities, individual life insurance and registered index-linked annuities. ALICONA serves as depositor for certain variable insurance separate account Funds and is a wholly owned subsidiary of Allianz of America, Inc., a holding company that is ultimately owned by Allianz SE.

3. AIM, a wholly owned subsidiary of ALICONA, is a limited liability company formed under Minnesota law and registered with the Commission as an investment adviser under the Advisers Act. AIM advises Fund assets of approximately $18.6 billion as of March 31, 2022.

4. ALFS, a wholly owned subsidiary of ALICONA, is a limited liability company formed under Minnesota law and registered as a broker-dealer under the Securities Exchange Act of 1934 (the ''Exchange Act''). ALFS is a member of the Financial Industry Regulatory Authority (''FINRA'') and serves as principal underwriter to certain Funds.

5. ALICONY, a wholly owned subsidiary of ALICONA, is a stock life insurance company formed under New York law offering registered index-linked annuities. Collectively, ALICONY, ALICONA, AIM, and ALFS, are referred to in the application and herein as the ''Allianz Life Applicants''.

6. PIMCO LLC is a limited liability company formed under Delaware law and registered with the Commission as an adviser under the Advisers Act. PIMCO LLC advised and sub-advised Fund assets of approximately $509.6 billion and $46.5 billion, respectively, as of March 31, 2022. Allianz SE controls 100% of the voting equity of PIMCO LLC.

7. PIMCO Investments, a wholly owned subsidiary of PIMCO LLC (and together, the ''PIMCO Applicants''), is a limited liability company formed under Delaware law and a registered broker-dealer under the Exchange Act. PIMCO Investments is a member of FINRA and serves as principal underwriter to certain Funds.

8. Other than the Continuing Fund Servicing Applicants, no existing company of which the Pleading Entity is an ''affiliated person'' within the meaning of section 2(a)(3) of the Act (''Affiliated Person'') currently serves as an investment adviser (as defined in section 2(a)(20) of the Act) or depositor of any RIC, ESC, or BDC, or as principal underwriter (as defined in section 2(a)(29) of the Act) for any registered open-end investment company (''Open-End Fund''), registered unit investment trust (''UIT''), or registered face-amount certificate company (''FACC'') (such activities performed on behalf of such persons, collectively ''Fund Servicing Activities''). Applicants request that any relief granted by the Commission to the Continuing Fund Servicing Applicants pursuant to the application also apply to any current or future subsidiary of a Continuing Fund Servicing Applicant of which the Pleading Entity is or may become an Affiliated Person (together with the Continuing Fund Servicing Applicants, the ''Covered Persons'') with respect to any activity contemplated by section 9(a) of the Act.[3]

9. On May 17, 2022, the DOJ filed a criminal information (the ''Information'') in the District Court charging the Pleading Entity with one count of securities fraud in violation of sections 10(b) and 32 of the Exchange Act and rule 10b–5 thereunder. According to the Statement of Facts that served as the basis for the Plea Agreement (as summarized in the application, the ''Statement of Facts''), beginning in at least 2014 and continuing up to and including in or about March 2020, the Pleading Entity engaged in a scheme to defraud investors in a series of private investment funds (the ''Affected Funds'' [4]) that pursued Allianz's ''Structured Alpha'' options trading strategy by making false and misleading statements to current and prospective investors that substantially understated how risky the Affected Funds were and overstated the level of independent risk oversight over the Funds (the ''Conduct'').

10. According to the Statement of Facts, the Pleading Entity carried out the scheme through, among others, the three portfolio managers with primary responsibility for managing the Structured Alpha Funds, specifically, Gregoire Tournant, Trevor Taylor, and Stephen Bond-Nelson (the ''Individual Defendants''). According to the Statement of Facts, the compliance and

[2] The terms ''Fund'' and ''Funds'' as used herein refer to any registered investment company (''RIC''), employees' securities company (''ESC'') or investment company that has elected to be treated as a business development company under the Act (''BDC'') for which a Covered Person (as defined below) currently provides Fund Servicing Activities (also defined below), or, subject to the terms and conditions of the Temporary and Permanent Orders, may in the future provide Fund Servicing Activities.

[3] Covered Persons may, if the Temporary and Permanent Orders are granted, in the future act in any of the capacities contemplated by section 9(a) of the Act. Any existing or future entities that may rely on the Temporary and Permanent Orders in the future will comply with the terms and conditions of this Application. For the avoidance of doubt, a Covered Person shall not include the Pleading Entity itself and any direct or indirect subsidiaries of the Pleading Entity.

[4] The Statement of Facts states that, in addition to the Affected Funds, AGI US also engaged in a scheme to defraud the sole investor in a UCITS fund.

risk management functions at the Pleading Entity failed to maintain adequate oversight of the team managing the Affected Funds, which allowed the portfolio managers to continue to manage the Affected Funds in a manner inconsistent with representations to investors. The control failures also facilitated the portfolio managers' actions to deceive investors by hiding, and making affirmative misstatements about, risk over the course of years. The fraudulent scheme inflated the performance of the Affected Funds, which in turn increased the profits flowing to the Pleading Entity and its parent companies, and also increased the compensation of the Individual Defendants. The Affected Funds ultimately lost more than $7 billion in value during the market dislocations caused by COVID–19, with investor victims losing over $3.2 billion in principal.

11. Pursuant to the Plea Agreement, the Pleading Entity entered the Guilty Plea on May 17, 2022 in the District Court to the charge set out in the Information. Applicants expect that the District Court will enter a judgment against the Pleading Entity (the ''Judgment'') that will require remedies that are materially the same as set forth in the Plea Agreement. The individuals referenced in the Information as responsible for the Conduct are no longer employed by the Pleading Entity or any of its affiliates.

12. The Commission instituted a cease-and-desist order against the Pleading Entity on May 17, 2022 (the ''SEC Order'') in connection with the Pleading Entity's role in the Conduct. The SEC Order requires the Pleading Entity to cease and desist from committing or causing any violations and any future violations of section 10(b) of the Exchange Act and rule 10b–5 thereunder, sections 206(1), 206(2) and 206(4) of the Advisers Act and rules 206(4)–7 and 206(4)–8 thereunder. The SEC Order also imposed a civil money penalty and requires the Pleading Entity to pay disgorgement of $315.2 million plus prejudgment interest of $34 million, which shall be deemed satisfied by forfeiture and restitution ordered by the settlement of parallel criminal charges entered into by the Pleading Entity in May 2022. In anticipation of the institution of those proceedings, the Pleading Entity submitted an Offer of Settlement consenting to the entry of such order, which the Commission has accepted.

Applicants' Legal Analysis

1. Section 9(a)(1) of the Act provides, in pertinent part, that a person may not serve or act as an investment adviser or depositor of any registered investment company or as principal underwriter for any Open-End Fund, UIT, or FACC, if such person within ten years has been convicted of any felony or misdemeanor, including those arising out of such person's conduct as a broker, dealer or bank. Section 2(a)(10) of the Act defines the term ''convicted'' to include a plea of guilty. Section 9(a)(3) of the Act extends the prohibitions of section 9(a)(1) to a company, any affiliated person of which has been disqualified under the provisions of section 9(a)(1). Section 2(a)(3) of the Act defines ''affiliated person'' to include, among others, any person directly or indirectly controlling, controlled by, or under common control with, the other person. Each Continuing Fund Servicing Applicant is an Affiliated Person of the Pleading Entity within the meaning of section 2(a)(3) of the Act. The Plea Agreement would therefore result in an immediate and automatic disqualification of the Pleading Entity and each Continuing Fund Servicing Applicant for ten years under section 9(a)(3) from acting in any of the capacities listed in section 9(a), by effect of a conviction described in section 9(a)(1).

2. Section 9(c) of the Act provides that: ''[t]he Commission shall by order grant [an] application [for relief from the prohibitions of subsection 9(a)], either unconditionally or on an appropriate temporary or other conditional basis, if it is established [i] that the prohibitions of subsection 9(a), as applied to such person, are unduly or disproportionately severe or [ii] that the conduct of such person has been such as not to make it against the public interest or the protection of investors to grant such application.'' Applicants have filed an application pursuant to section 9(c) seeking a Temporary Order on behalf of all Applicants and a Permanent Order on behalf of the Continuing Fund Servicing Applicants only. The Permanent Order would exempt the Continuing Fund Servicing Applicants and other Covered Persons from the disqualification provisions of section 9(a) of the Act. The Covered Persons may, if the Orders are granted, in the future act in any of the capacities contemplated by section 9(a) of the Act subject to the applicable terms and conditions of the Orders.

3. Applicants believe that the Time-Limited Exemption is consistent with the principle in section 9(c) that appropriate conditional, short-term relief is not against the public interest or the protection of investors. The Time-Limited Exemption is intended to provide the Pleading Entity with adequate time to transition its advisory relationships and other Fund Servicing Activities that it performs on behalf of Funds (the ''the Pleading Entity Advised Funds'') to other providers of such services. As a result of the section 9(a) disqualification and absent the Time-Limited Exemption, the Pleading Entity would be immediately unable as a matter of law to provide Fund Servicing Activities to the Pleading Entity Advised Funds. Applicants state that a disqualification of the Pleading Entity before the process of transitioning the Pleading Entity Advised Funds to replacement service providers is complete could leave them without critical advisory services for some period of time, which would be extremely disruptive to their investment programs and may result in substantial harm to such Funds and their investors.

4. Applicants believe that the Continuing Fund Servicing Applicants meet the standards for exemption specified in section 9(c). Applicants assert that: (i) The scope of the misconduct was limited and did not involve any of the Continuing Fund Servicing Applicants acting as an investment adviser, depositor or principal underwriter for any Fund, or any Fund with respect to which the Continuing Fund Servicing Applicants engage in Fund Servicing Activities (''Continuing Service Funds''); (ii) application of the statutory bar would impose significant hardships on the Continuing Service Funds and their shareholders; (iii) the prohibitions of section 9(a), if applied to the Continuing Fund Servicing Applicants, would be unduly or disproportionately severe; and (iv) the Conduct did not constitute conduct that would make it against the public interest or protection of investors to grant the exemption from section 9(a) to the Continuing Fund Servicing Applicants.

5. The Continuing Fund Servicing Applicants represent that the Conduct did not involve any of the Continuing Fund Servicing Applicants acting in the capacity as an investment adviser, depositor or principal underwriter for any Fund. Applicants represent that the Conduct similarly did not involve any Continuing Service Fund. Instead, Applicants state that the Conduct occurred entirely within the Pleading Entity and did not involve the Continuing Fund Servicing Applicants or any personnel of the Continuing Fund Servicing Applicants. As discussed above, the individuals referenced in the Information as responsible for the Conduct are no

longer employed by the Pleading Entity or any of its affiliates.

6. Applicants acknowledge that the Pleading Entity had significant gaps and weaknesses in its controls as they related to the Affected Funds. Applicants acknowledge that the control functions were not designed to and did not function to ensure that risk was being monitored in line with what investors had been told. Applicants further acknowledge that the Pleading Entity's internal audit department conducted an audit of the Pleading Entity and, although that audit identified red flags that, if pursued, might have led to identification of the fraud, no meaningful follow up was conducted. Applicants represent that Allianz and its affiliates have undertaken certain remedial measures, as described in more detail in the application. These remedial measures include compensating Structured Alpha investors, terminating employee wrongdoers, agreeing that the Pleading Entity will exit the business of providing Fund Servicing Activities, improving client communications, enhancing oversight of portfolio management teams, empowering the Allianz risk management functions, and implementing a new framework for data quality and processing. Applicants further represent that each of the Continuing Fund Servicing Applicants will review its control and risk management framework as it relates to Fund Servicing Activities, in light of applicable local legal requirements and the risks related to such Continuing Fund Servicing Applicant's business, and consider what steps may be appropriate to enhance that framework to ensure that it is reasonably designed to prevent behavior similar to the Conduct from occurring at such Continuing Fund Servicing Applicant. The results of such review will be included in the report required by Condition 5 of the application (detailed below).

7. Applicants assert that, in view of the fact that the Conduct was limited to the Pleading Entity and its personnel, it would be unduly and disproportionately severe to impose a section 9(a) disqualification on the Continuing Fund Servicing Applicants. Applicants assert that the conduct of the Continuing Fund Servicing Applicants has not been such as to make it against the public interest or the protection of investors to grant the exemption from section 9(a). Applicants further assert that neither the protection of investors nor the public interest would be served by permitting the section 9(a) disqualifications to apply to the Continuing Fund Servicing Applicants because those disqualifications would deprive the Continuing Service Funds of the advisory or sub-advisory and underwriting services that shareholders expected the Continuing Service Funds to receive when they decided to invest. Applicants also assert that the prohibitions of section 9(a) could operate to the financial detriment of the Continuing Service Funds and their shareholders, including by causing the Continuing Service Funds to spend time and resources to engage substitute advisers, subadvisers, and principal underwriters, which would be an unduly and disproportionately severe consequence given that the Conduct did not involve any of the Continuing Fund Servicing Applicants or their personnel.

8. Applicants assert that if the Continuing Fund Servicing Applicants were barred under section 9(a) from providing investment advisory services to the Continuing Service Funds and were unable to obtain the requested exemption, the effect on their businesses and employees would be severe. Applicants state that the Continuing Fund Servicing Applicants have committed substantial capital and other resources to establishing expertise in advising and sub-advising Funds with a view to continuing and expanding this business, which Applicants consider strategically important. Similarly, Applicants represent that if ALFS and PIMCO Investments were barred under section 9(a) from continuing to provide underwriting services to the Funds and were unable to obtain the requested exemption, the effect on its current business and employees would be significant. Applicants state that ALFS and PIMCO Investments have committed capital and other resources to establish expertise in underwriting the securities of the Continuing Service Funds and to establish distribution arrangements for Fund shares. Applicants further state that prohibiting the Continuing Fund Servicing Applicants from engaging in Fund Servicing Activities would not only adversely affect their business, but would also adversely affect their employees who are involved in these activities.

9. *Applicants represent that:* (1) None of the current or former directors, officers or employees of Continuing Fund Servicing Applicants engaged in the Conduct; (2) no current or former employee of the Pleading Entity or any Covered Person who previously has been or who subsequently may be identified by the Pleading Entity or any U.S. or non-U.S. regulatory or enforcement agencies as having been responsible for the Conduct will be an officer, director, or employee of any Covered Person; (3) the identified employees have had no, and will not have any, future involvement in the Covered Persons' activities in any capacity described in section 9(a) of the Act; and (4) because the personnel of the Continuing Fund Servicing Applicants did not engage in the Conduct, shareholders of the Funds served by the Continuing Fund Servicing Applicants were not affected any differently than if those Funds had received services from any other non-affiliated investment adviser.

10. Applicants have also agreed that each of the Applicants and Covered Persons will adopt and implement policies and procedures reasonably designed to ensure that it will comply with the terms and conditions of the Orders granted under section 9(c).

11. In addition, Applicants have agreed that each of the Applicants and Covered Persons will comply in all material respects with the material terms and conditions of the Plea Agreement and the SEC Order, and any other orders issued by, or settlements with, regulatory or enforcement agencies addressing the Conduct.

12. As a result of the foregoing, the Continuing Fund Servicing Applicants submit that absent relief, the prohibitions of section 9(a) as applied to the Continuing Fund Servicing Applicants would be unduly or disproportionately severe, and that the Conduct did not constitute conduct that would make it against the public interest or protection of investors to grant the exemption to the Continuing Fund Servicing Applicants.

13. To provide further assurance that the exemptive relief being requested in the application would be consistent with the public interest and the protection of the investors, the Applicants agree that they will, within two weeks from the date of the Time-Limited Exemption, as applicable, with respect to each of the Funds for which a Continuing Fund Servicing Applicant is the primary investment adviser, distribute to the boards of directors or trustees of the Funds (each, a ''Fund Board'') written materials describing the circumstances that led to the Plea Agreement, as well as any effects on the Funds and the application. The written materials will include an offer to discuss the materials at an in-person meeting with each Fund Board for which Fund Servicing Providers provide Fund Servicing Activities, including the directors who are not ''interested persons'' of the Funds as

defined in section 2(a)(19) of the Act and their ''independent legal counsel'' as defined in rule 0–1(a)(6) under the Act. With respect to each of the Funds for which a Fund Servicing Provider is not the primary investment adviser, the relevant Fund Servicing Provider will provide such materials to the Fund's primary investment adviser and offer to discuss the materials with such primary investment adviser. The Applicants undertake to provide the Fund Boards and the primary investment advisers, as relevant, with all information concerning the Plea Agreement and the application as necessary for those Funds to fulfill their disclosure and other obligations under the U.S. federal securities laws and will provide them a copy of the Judgment as entered by the District Court.

Applicants' Conditions

Applicants agree that any order granted by the Commission pursuant to the application will be subject to the following conditions:

1. Any temporary exemption granted pursuant to the application will be without prejudice to, and will not limit the Commission's rights in any manner with respect to, any Commission investigation of, or administrative proceedings involving or against, Covered Persons, including, without limitation, the consideration by the Commission of a permanent exemption from section 9(a) of the Act requested pursuant to the application or the revocation or removal of any temporary exemptions granted under the Act in connection with the application.

2. None of Allianz SE, the Applicants, the Covered Persons or any affiliate of any of the foregoing, will employ the former employees of the Pleading Entity or any other person who subsequently may be identified by the Pleading Entity or any U.S. or non-U.S. regulatory or enforcement agencies as having been responsible for the Conduct in any capacity without first making a further application to the Commission pursuant to section 9(c).

3. Each of the Applicants and the Covered Persons will adopt and implement policies and procedures reasonably designed to ensure that it will comply with the terms and conditions of the Orders applicable to it within 60 days of the date of the Permanent Order, or with respect to condition four immediately below, such later date or dates as may be contemplated by the Plea Agreement, the SEC Order, or any other orders issued by regulatory or enforcement agencies addressing the Conduct, as and to the extent that the terms and conditions of such orders are applicable to it.

4. Each of the Applicants and the Covered Persons will comply in all material respects with the material terms and conditions of the Plea Agreement, with the material terms of the SEC Order, and any other orders issued by, or settlements with, regulatory or enforcement agencies addressing the Conduct, in each case as and to the extent that such terms and conditions are applicable to it. In addition, within 30 days of each anniversary of the Permanent Order (until and including the third such anniversary), Allianz SE will submit a certification signed by its chief executive officer and its chief compliance officer, confirming that (i) the Pleading Entity has complied with the terms and conditions of the Plea Agreement in all material respects; and (ii) Allianz SE, the Pleading Entity and the Covered Persons have complied with the terms and conditions of the Orders applicable to them in all material respects. Each such certification will be submitted to the Chief Counsel of the Commission's Division of Investment Management with a copy to the Chief Counsel of the Commission's Division of Enforcement.

5. Each Applicant will provide written notification to the Chief Counsel of the Commission's Division of Investment Management with a copy to the Chief Counsel of the Commission's Division of Enforcement of a material violation by such Applicant of the terms and conditions of the Orders applicable to it within 30 days of discovery of the material violation. In addition, within 30 days of the first anniversary of the Permanent Order, the Continuing Fund Servicing Applicants will submit reports, signed by the chief executive officer of ALICONA (in the case of the Allianz Life Applicants) and the chief executive officer of PIMCO LLC (in the case of the PIMCO Applicants), to the Chief Counsel of the Commission's Division of Investment Management, summarizing the results of the reviews described in Section V.F of the application, including a description of each specific step taken by each Continuing Fund Servicing Applicant to enhance its control and risk management framework since the date of the Permanent Order.

6. The Pleading Entity commits to provide the staff of the Commission's Division of Investment Management, no later than one week from the date of the Time-Limited Exemption, a written plan for the transitioning of the Pleading Entity Advised Funds to new sub-advisers, and with respect to the Taiwan Fund, to a new adviser, which plan will include specific action items with associated timetables, and will contemplate the completion of the transition within a ten-week period with respect to the open-end Pleading Entity Advised Funds and within a four-month period with respect to the closed-end Pleading Entity Advised Funds. The Pleading Entity further commits that, during the pendency of the Time-Limited Exemption, the Pleading Entity will use its reasonable best efforts to assist each primary adviser, board of directors or trustees of each Pleading Entity Advised Fund (each such board, a ''Pleading Entity Advised Fund Board'') and/or fund administrator, as applicable, in (A) identifying a potential replacement sub-adviser or adviser, as applicable, (B) soliciting information from those firms, (C) conducting due diligence on such firms, (D) gathering information responsive to requirements of Section 15(c) of the Act, (E) negotiating an advisory contract, (F) drafting prospectus disclosure about the transition, (G) otherwise updating the Fund's registration statement, (H) obtaining Pleading Entity Advised Fund Board approval consistent with the Act, and (I) with respect to the closed-end Funds, seeking shareholder approval of the new sub-adviser or adviser, as applicable. The Pleading Entity will report to the staff of the Commission's Division of Investment Management on the progress of the transition and the actions being taken by the Pleading Entity to further such transition no less frequently than every two weeks. The Pleading Entity or one or more of its affiliates will bear all expenses associated with the transitions, and no Pleading Entity Advised Funds will directly or indirectly bear any expenses associated with such transitions, including any expenses associated with obtaining shareholder approval, if applicable.

7. The Time-Limited Exemption will remain in place: (i) With respect to the open-end Pleading Entity Advised Funds for which the Pleading Entity serves as a sub-adviser, for a ten-week period from the date of the Time-Limited Exemption; and (ii) with respect to the closed-end Pleading Entity Advised Funds, for a four-month period from the date of the Time-Limited Exemption.

Temporary Order

The Commission has considered the matter and finds that Applicants have made the necessary showing to justify granting a temporary exemption.

Accordingly,

It is hereby ordered, pursuant to section 9(c) of the Act, that: (1) The Pleading Entity is granted a temporary exemption, limited in all respects to the Time-Limited Exemption, including as to its time-limited nature, from the provisions of section 9(a); and (2) the Continuing Fund Servicing Applicants and any other Covered Persons are granted a temporary exemption from the provisions of section 9(a), in each case effective as the date of the Guilty Plea, and in each case solely with respect to the Guilty Plea entered into pursuant to the Plea Agreement, subject to the representations and conditions in the application, until the Commission takes final action on their application (or, in the case of the Time-Limited Exemption, until it expires by its terms, if sooner).

By the Commission.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–10965 Filed 5–20–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94933; File No. SR–NYSE–2022–22]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List

May 17, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on May 11, 2022, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. 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

The Exchange proposes to amend its Price List to introduce a new adding credit for providing displayed liquidity to the Exchange in Tape B and C Securities. The Exchange proposes to implement the fee changes effective May 11, 2022.[4] The proposed rule change is available on the Exchange's website at *www.nyse.com,* 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 those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes a new adding credit for providing displayed liquidity to the Exchange in Tape B and C Securities.

The proposed changes respond to the current competitive environment where order flow providers have a choice of where to direct liquidity-providing orders by offering further incentives for member organizations to send additional displayed liquidity to the Exchange.

The Exchange proposes to implement the fee changes effective May 11, 2022.

Background

Current Market and Competitive Environment

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [5]

As the Commission itself has recognized, the market for trading services in NMS stocks has become ''more fragmented and competitive.'' [6] Indeed, equity trading is currently dispersed across 16 exchanges,[7] 31 alternative trading systems,[8] and numerous broker-dealer internalizers and wholesalers. Based on publicly-available information, no single exchange has more than 20% of the market.[9] Therefore, no exchange possesses significant pricing power in the execution of equity order flow. More specifically, the Exchange's share of executed volume of equity trades in Tapes A, B and C securities is less than 12%.[10]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can move order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. With respect to non-marketable order flow that would provide displayed liquidity on an Exchange, member organizations can choose from any one of the 16 currently operating registered exchanges to route such order flow. Accordingly, competitive forces constrain exchange transaction fees that relate to orders that would provide liquidity on an exchange.

In response to the competitive environment described above, the Exchange has established incentives for its member organizations who submit orders that provide liquidity on the Exchange. The proposed fee change is designed to attract additional order flow to the Exchange by incentivizing member organizations to submit additional displayed liquidity to the Exchange.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange originally filed to amend the Price List on May 2, 2022 (SR–NYSE–2022–21). On May 11, 2002, SR–NYSE–2022–21 was withdrawn and replaced by this filing.

[5] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (''Regulation NMS'').

[6] *See* Securities Exchange Act Release No. 51808, 84 FR 5202, 5253 (February 20, 2019) (File No. S7–05–18) (Transaction Fee Pilot for NMS Stocks Final Rule) (''Transaction Fee Pilot'').

[7] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/. See generally https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.*

[8] *See* FINRA ATS Transparency Data, available at *https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[9] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[10] *See id.*

Proposed Rule Change

The Exchange proposes a new adding credit in Tape B and C securities for the market participant identifier (''MPID'') or mnemonic of member organizations that meet the current requirements for Step Up Adding Tier 5 as well as certain additional proposed requirements, as follows.

The current Step Up Tier 5 Adding Credit offers incremental credits for providing displayed liquidity to the Exchange in Tape A securities for all orders, other than MPL and Non-Displayed Limit Orders, from a qualifying member organization's MPID or mnemonic if the member organization has Adding ADV, excluding any liquidity added by a Designated Market Maker (''DMM''), that is at least 1.00% of Tape A CADV,[11] and if the MPID or mnemonic has an Adding ADV as a percentage of Tape A CADV, excluding any liquidity added by a DMM, that is:

- At least two times more than that MPID's or mnemonic's Adding ADV in January 2021 (''Baseline Month'') as a percentage of Tape A CADV, and
- at least 0.10% of Tape A CADV over that MPID's or mnemonic's Adding ADV in in the Baseline Month as a percentage of Tape A CADV.

A member organizations meeting the above requirements receives a $0.0001 incremental credit for an increase of at least 0.10% and less than 0.175% of Tape A CADV over the Baseline Month. Member organizations receive a $0.0002 incremental credit for an increase of at least 0.175% of Tape A CADV over the Baseline Month.

The Exchange proposes a new $0.0029 credit for providing displayed liquidity in Tape B and C Securities based on similar requirements to the Step Up Tier 5 Adding Credit. Specifically, the proposed credit would be available for providing displayed liquidity in Tape B and C Securities for a qualifying member organization's MPID or mnemonic that has providing volume in Tape A Securities of at least 1.0% of Tape A CADV, and the MPID or mnemonic has providing volume in Tape A Securities that is:

- At least two times more than that MPID's or mnemonic's baseline in January 2021 as a percentage of Tape A CADV, and
- at least 0.10% of Tape A CADV over that MPID's or mnemonic's Adding ADV in January 2021 baseline as a percentage of Tape A CADV, and
- at least 0.25% of Tape A CADV over that MPID's or mnemonic's Adding ADV in January 2021 as a percentage of Tape A CADV.

To effectuate this change, the Exchange would amend the chart setting forth the Adding Tiers for transaction fees and credits for Tape B and C Securities to add a new column titled ''Step Up Tier'' and set forth the proposed requirements and proposed credit.

For example, assume Member Organization A has an Adding ADV as a percentage of Tape A CADV of 1.10%, and adding ADV of Tape B and C of CADV 0.075% each, in the billing month. Member Organization A would currently qualify for Tape B and C Tier 2 credits of $0.0023 per share each based on the current Tape B and C Tier 2 requirement of 0.05% for each tape.

Further assume that one of Member Organization A's MPIDs, MPID1, has an Adding ADV of 0.30% of Tape A CADV and that MPID1 has an Adding ADV of 0.10% in the Baseline Month and, as such, MPID1's Adding ADV is 2.5 times its Baseline Month with a step up of 0.20% and qualifies for Step Up Tier 5. If instead MPID1 had a Tape A Adding ADV of 0.40% of CADV, for step up of Tape A Adding ADV of 0.30% CADV, MPID 1 would qualify for the proposed Tape B and C credit of $0.0029 for adding displayed liquidity.

The purpose of this proposed change is to incentivize member organizations to increase the liquidity-providing orders in the Tape B and C securities they send to the Exchange, which would support the quality of price discovery on the Exchange and provide additional liquidity for incoming orders. As noted above, the Exchange operates in a competitive environment, particularly as it relates to attracting non-marketable orders, which add liquidity to the Exchange. Because the proposed tier requires a member organization's MPID or mnemonic to increase the volume of its trades in orders that add liquidity over that MPID or mnemonic's January 2021 Adding ADV baseline, the Exchange believes that the proposed credit would provide an incentive for all member organizations to send additional liquidity to the Exchange in order to qualify for it. The Exchange does not know how much order flow member organizations choose to route to other exchanges or to off-exchange venues. Based on the profile of liquidity-adding firms generally, the Exchange believes that additional member organizations could qualify for the proposed credit if they choose to direct order flow to, and increase quoting on, the Exchange. However, without having a view of member organization's activity on other exchanges and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would result in any member organization directing orders to the Exchange in order to qualify for the new tier.

The proposed change is not otherwise intended to address other issues, and the Exchange is not aware of any significant problems that market participants would have in complying with the proposed changes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[13] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Change Is Reasonable

As discussed above, the Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [14] While Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [15]

The new proposed adding credit in Tape B and C credit is reasonable. Specifically, the Exchange believes that the proposed credit would provide an

[11] The terms ''ADV'' and ''CADV'' are defined in footnote * of the Price List.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(4) & (5).

[14] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (''Regulation NMS'').

[15] *See* Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

incentive for member organizations to send additional liquidity providing orders to the Exchange in Tape B and C securities. As noted above, the Exchange operates in a highly competitive environment, particularly for attracting non-marketable order flow that provides liquidity on an exchange.

The Exchange believes that it's reasonable to provide a $0.0029 credit in Tape B and C Securities to the qualifying MPID or mnemonic based on the proposed increased adding requirements because this would encourage individual MPIDs or mnemonics of a member organization to send orders that provide liquidity to the Exchange, thereby contributing to robust levels of liquidity, which benefits all market participants, and promoting price discovery and transparency. As previously noted, without a view of member organization activity on other exchanges and off-exchange venues, the Exchange has no way of knowing whether the proposed rule change would result in any member organization's MPID or mnemonic qualifying for the tier. Based on the profile of liquidity-adding firms generally, the Exchange believes that additional member organizations could qualify for the proposed credit if they choose to direct order flow to, and increase quoting on, the Exchange. The Exchange believes the proposed credit is reasonable as it would provide an additional incentive for member organization's MPID or mnemonic to direct their order flow to the Exchange and provide meaningful added levels of liquidity in order to qualify for the credit, thereby contributing to depth and market quality on the Exchange.

The Proposal Is an Equitable Allocation of Fees

The Exchange believes that the proposed credit is equitable because the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more liquidity to the Exchange, thereby improving market wide quality and price discovery. As noted, without a view of member organization activity on other exchanges and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would result in any member organization's MPID or mnemonic qualifying for the tier. Based on the profile of liquidity-adding firms generally, the Exchange believes that additional member organizations could qualify for the proposed credit if they choose to direct order flow to, and increase quoting on, the Exchange. The Exchange believes the proposed credit is equitable as it would provide an additional incentive for member organization's MPID or mnemonic to direct their order flow to the Exchange and provide meaningful added levels of liquidity in order to qualify for the credit, thereby contributing to depth and market quality on the Exchange. The proposal neither targets nor will it have a disparate impact on any particular category of market participant. All member organization's MPIDs or mnemonics that provide liquidity could be eligible to qualify for the proposed credit if they increase their Adding ADV over their own baseline of order flow and the member organization meets the 0.25% increase in Adding ADV of Tape CADV requirement. The Exchange believes that offering a step up credit for providing liquidity if the step up requirements for Tape B and C securities are met will continue to attract order flow and liquidity to the Exchange, thereby providing additional price improvement opportunities on the Exchange and benefiting investors generally. As to those market participants that do not presently qualify for the adding liquidity credits in Tape A Securities, the proposal will not adversely impact their existing pricing or their ability to qualify for other credits provided by the Exchange.

The Proposal Is Not Unfairly Discriminatory

The Exchange believes it is not unfairly discriminatory to provide an additional per share step up credit in Tape B and C Securities, as the proposed credit would be provided on an equal basis to all member organizations and their MPIDs or mnemonics that add liquidity by meeting the new proposed requirements and would equally encourage all member organizations and their MPIDs or mnemonics to provide additional displayed liquidity on the Exchange. As noted, the Exchange believes that the proposed credit would provide an incentive for member organizations and their MPIDs or mnemonics to send additional liquidity to the Exchange in order to qualify for the additional credit. The Exchange also believes that the proposed change is not unfairly discriminatory because it is reasonably related to the value to the Exchange's market quality associated with higher volume. Finally, the submission of orders to the Exchange is optional for member organizations and their MPIDs or mnemonics in that they could choose whether to submit orders to the Exchange and, if they do, the extent of its activity in this regard.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[16] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for member organizations. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes "more efficient pricing of individual stocks for all types of orders, large and small." [17]

Intramarket Competition. The proposed changes are designed to attract additional order flow to the Exchange. The Exchange believes that the proposed changes would continue to incentivize market participants to direct displayed order flow to the Exchange. Greater liquidity benefits all market participants on the Exchange by providing more trading opportunities and encourages member organizations to send orders, thereby contributing to robust levels of liquidity, which benefits all market participants on the Exchange. The current credits would be available to all similarly-situated market participants, and, as such, the proposed change would not impose a disparate burden on competition among market participants on the Exchange. As noted, the proposal would apply to all similarly situated member organizations on the same and equal terms, who would benefit from the change on the same basis. Accordingly, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive

[16] 15 U.S.C. 78f(b)(8).

[17] Regulation NMS, 70 FR at 37498–99.

with other exchanges and with off-exchange venues. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [18] of the Act and subparagraph (f)(2) of Rule 19b–4 [19] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such 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 shall institute proceedings under Section 19(b)(2)(B) [20] of the Act 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2022–22 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–NYSE–2022–22. 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 (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2022–22 and should be submitted on or before June 13, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–10959 Filed 5–20–22; 8:45 am]

BILLING CODE 8011–01–P

[18] 15 U.S.C. 78s(b)(3)(A).

[19] 17 CFR 240.19b–4(f)(2).

[20] 15 U.S.C. 78s(b)(2)(B).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2 p.m. on Thursday, May 26, 2022.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.sec.gov.*

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;
Institution and settlement of administrative proceedings;
Resolution of litigation claims; and
Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Authority: 5 U.S.C. 552b.

Dated: May 19, 2022.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2022–11177 Filed 5–19–22; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94936; File No. SR–BX–2022–009]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Nasdaq Amended and Restated Certificate of Incorporation

May 17, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

on May 6, 2022, Nasdaq BX, Inc. (''BX'' or ''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

The Exchange proposes to amend the Amended and Restated Certificate of Incorporation (''Certificate'') of its parent corporation, Nasdaq, Inc. (''Nasdaq'' or the ''Company''), to increase Nasdaq's authorized share capital.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/bx/rules,* 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 Exchange 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 Exchange 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 purpose of the proposed rule change is to amend the Nasdaq Certificate [3] to increase the total number of authorized shares of Nasdaq common stock, par value $0.01 per share (''Common Stock''). Specifically, the Exchange proposes to amend Article Fourth, Section A such that the total number of shares of Stock (*i.e.,* capital stock) that Nasdaq is authorized to issue would be increased from 330,000,000 to 930,000,000 shares, and the portion of that total constituting Common Stock would be changed from 300,000,000 to 900,000,000 shares. As amended, Article Fourth, Section A of the Certificate would provide:

> The total number of shares of Stock which Nasdaq shall have the authority to issue is Nine Hundred Thirty Million (930,000,000), consisting of Thirty Million (30,000,000) shares of Preferred Stock, par value $.01 per share (hereinafter referred to as ''Preferred Stock''), and Nine Hundred Million (900,000,000) shares of Common Stock, par value $.01 per share (hereinafter referred to as ''Common Stock'').[4]

As noted above, the proposed amendments to the Certificate were approved by the Nasdaq Board of Directors (''Nasdaq Board'') on March 23, 2022. The proposed amendments to the Certificate would be effective when filed with the Secretary of State of Delaware, which would not occur until approval of the amendments by the stockholders of Nasdaq is obtained at the 2022 Annual Meeting of the Stockholders on June 22, 2022 and until this proposed rule change becomes effective and operative.

The trading price of Nasdaq's Common Stock has risen significantly over the past several years. Since Nasdaq first became a publicly traded company in 2002, the total number of authorized shares of Common Stock has remained constant at 300,000,000 shares. However, over the last five years, the trading price of Nasdaq's Common Stock has increased by approximately 162%.[5] As the trading price of Nasdaq's Common Stock has risen, the Nasdaq Board has carefully evaluated the effect of the trading price of the Common Stock on the liquidity and marketability of the Common Stock. The Nasdaq Board believes that this price appreciation may be affecting the liquidity of the Common Stock, making it more difficult to efficiently trade and potentially less attractive to certain investors. Accordingly, the Nasdaq Board approved pursuing a 3-for-1 stock split by way of a stock dividend, pursuant to which the holders of record of shares of Common Stock would receive, by way of a dividend, two shares of Common Stock for each share of Common Stock held by such holder (the ''Stock Dividend''). The Nasdaq Board's approval of the Stock Dividend was contingent upon this proposed rule change becoming effective and operative, and Nasdaq stockholder approval of the proposed amendments to the Certificate.

The number of shares of Common Stock proposed to be issued in the Stock Dividend exceeds Nasdaq's authorized but unissued shares of Common Stock. The proposed rule change would increase Nasdaq's authorized shares of Common Stock and shares of capital stock sufficient to allow Nasdaq to effectuate the Stock Dividend.

The proposed changes would not otherwise alter the Certificate, including the limitations on voting and ownership set forth in Article Fourth, Section C of the Certificate that generally provides no person who beneficially owns shares of common stock or preferred stock of Nasdaq in excess of 5% of the then-outstanding securities generally entitled to vote may vote the shares in excess of 5%. This limitation mitigates the potential for any Nasdaq shareholder to exercise undue control over the operations of Nasdaq's self-regulatory subsidiaries, and facilitates the self-regulatory subsidiaries' and the Commission's ability to carry out their regulatory obligations under the Act.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[6] in general, and furthers the objectives of Section 6(b)(1) of the Act,[7] in that it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the Exchange.

The proposal to increase Nasdaq's authorized shares of Common Stock and shares of capital stock sufficient to allow Nasdaq to effectuate the Stock Dividend would not impact the Exchange's ability to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act. In particular, the proposed changes would not alter the limitations on voting and ownership set forth in Article Fourth, Section C of the Certificate, and so the proposed changes would not enable a person to exercise undue control over the operations of Nasdaq's self-regulatory subsidiaries or to restrict the ability of the Commission or the Exchange to effectively carry out their regulatory oversight responsibilities under the Act.

[3] Nasdaq owns 100% of the equity interest in the Exchange. The Exchange's affiliates, Boston Stock Exchange Clearing Corporation, Nasdaq GEMX, LLC, Nasdaq ISE, LLC, Nasdaq MRX, LLC, The Nasdaq Stock Market LLC, Nasdaq PHLX LLC, and Stock Clearing Corporation of Philadelphia will each concurrently submit substantially the same rule filings to propose the changes described herein.

[4] Nasdaq currently has no Preferred Stock outstanding.

[5] The price of one share of Common Stock on March 31, 2017 was $69.45 and the closing market price of one share of Common Stock on April 1, 2022 was $181.92 as reported on the Nasdaq Stock Market.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(1).

The Exchange also believes that the proposal is consistent with Section 6(b)(5) of the Act[8] because it would not impact the Exchange's governance or regulatory structure, which would continue to 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 system, and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change would 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, because by increasing Nasdaq's authorized shares of Common Stock and shares of capital stock sufficient to allow Nasdaq to effectuate the Stock Dividend, the proposed rule change will facilitate broader ownership of Nasdaq.

The Exchange also notes that the proposed rule change is substantially similar to a prior proposal by Intercontinental Exchange, Inc. (''ICE''), which is the holding company for three national securities exchanges, including the New York Stock Exchange. The ICE proposal amended ICE's Certificate of Incorporation to effectuate a similar stock split as proposed by the Exchange herein.[9] As such, the Exchange does not believe that its proposal raises any new or novel issues not already considered by the Commission.

B. Self-Regulatory Organization's Statement on Burden on Competition

Because the proposed rule change relates solely to the number of authorized shares of Common Stock and shares of capital stock of the Company and not to the operations of the Exchange, 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.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 Act[10] and Rule 19b–4(f)(6) thereunder.[11]

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 shall institute proceedings to determine whether the proposed rule 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2022–009 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–BX–2022–009. 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 (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2022–009 and should be submitted on or before June 13, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–10961 Filed 5–20–22; 8:45 am]

BILLING CODE 8011–01–P

[8] 15 U.S.C. 78f(b)(5).

[9] In particular, the ICE proposal increased ICE's total number of authorized shares of ICE common stock in order to effectuate a 5-for-1 stock split by way of a stock dividend. *See* Securities Exchange Act Release No. 78992 (September 29, 2016), 81 FR 69092 (October 5, 2016) (SR–NYSE–2016–57, SR–NYSEArca–2016–119, and SR–NYSEMKT–2016–80) (hereinafter, ''ICE Approval'').

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its 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.

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94934; File No. SR–MRX–2022–05]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Nasdaq Amended and Restated Certificate of Incorporation

May 17, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

on May 6, 2022, Nasdaq MRX, LLC (''MRX'' or ''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

The Exchange proposes to [sic] Amended and Restated Certificate of Incorporation (''Certificate'') of its parent corporation, Nasdaq, Inc. (''Nasdaq'' or the ''Company''), to increase Nasdaq's authorized share capital.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/mrx/rules,* 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 Exchange 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 Exchange 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 purpose of the proposed rule change is to amend the Nasdaq Certificate [3] to increase the total number of authorized shares of Nasdaq common stock, par value $0.01 per share (''Common Stock''). Specifically, the Exchange proposes to amend Article Fourth, Section A such that the total number of shares of Stock (*i.e.,* capital stock) that Nasdaq is authorized to issue would be increased from 330,000,000 to 930,000,000 shares, and the portion of that total constituting Common Stock would be changed from 300,000,000 to 900,000,000 shares. As amended, Article Fourth, Section A of the Certificate would provide:

> The total number of shares of Stock which Nasdaq shall have the authority to issue is Nine Hundred Thirty Million (930,000,000), consisting of Thirty Million (30,000,000) shares of Preferred Stock, par value $.01 per share (hereinafter referred to as ''Preferred Stock''), and Nine Hundred Million (900,000,000) shares of Common Stock, par value $.01 per share (hereinafter referred to as ''Common Stock'').[4]

As noted above, the proposed amendments to the Certificate were approved by the Nasdaq Board of Directors (''Nasdaq Board'') on March 23, 2022. The proposed amendments to the Certificate would be effective when filed with the Secretary of State of Delaware, which would not occur until approval of the amendments by the stockholders of Nasdaq is obtained at the 2022 Annual Meeting of the Stockholders on June 22, 2022 and until this proposed rule change becomes effective and operative.

The trading price of Nasdaq's Common Stock has risen significantly over the past several years. Since Nasdaq first became a publicly traded company in 2002, the total number of authorized shares of Common Stock has remained constant at 300,000,000 shares. However, over the last five years, the trading price of Nasdaq's Common Stock has increased by approximately 162%.[5] As the trading price of Nasdaq's Common Stock has risen, the Nasdaq Board has carefully evaluated the effect of the trading price of the Common Stock on the liquidity and marketability of the Common Stock. The Nasdaq Board believes that this price appreciation may be affecting the liquidity of the Common Stock, making it more difficult to efficiently trade and potentially less attractive to certain investors. Accordingly, the Nasdaq Board approved pursuing a 3-for-1 stock split by way of a stock dividend, pursuant to which the holders of record of shares of Common Stock would receive, by way of a dividend, two shares of Common Stock for each share of Common Stock held by such holder (the ''Stock Dividend''). The Nasdaq Board's approval of the Stock Dividend was contingent upon this proposed rule change becoming effective and operative, and Nasdaq stockholder approval of the proposed amendments to the Certificate.

The number of shares of Common Stock proposed to be issued in the Stock Dividend exceeds Nasdaq's authorized but unissued shares of Common Stock. The proposed rule change would increase Nasdaq's authorized shares of Common Stock and shares of capital stock sufficient to allow Nasdaq to effectuate the Stock Dividend.

The proposed changes would not otherwise alter the Certificate, including the limitations on voting and ownership set forth in Article Fourth, Section C of the Certificate that generally provides no person who beneficially owns shares of common stock or preferred stock of Nasdaq in excess of 5% of the then-outstanding securities generally entitled to vote may vote the shares in excess of 5%. This limitation mitigates the potential for any Nasdaq shareholder to exercise undue control over the operations of Nasdaq's self-regulatory subsidiaries, and facilitates the self-regulatory subsidiaries' and the Commission's ability to carry out their regulatory obligations under the Act.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[6] in general, and furthers the objectives of Section 6(b)(1) of the Act,[7] in that it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the Exchange.

The proposal to increase Nasdaq's authorized shares of Common Stock and shares of capital stock sufficient to allow Nasdaq to effectuate the Stock Dividend would not impact the Exchange's ability to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act. In particular, the proposed changes would not alter the limitations on voting and ownership set forth in Article Fourth, Section C of the Certificate, and so the proposed changes would not enable a person to exercise undue control over the operations of Nasdaq's self-regulatory subsidiaries or to restrict the ability of the Commission or the

[3] Nasdaq owns 100% of the equity interest in U.S. Exchange Holdings, Inc., which in turn owns 100% of the equity interest in International Securities Exchange Holdings, Inc., which in turn owns 100% of the equity interest in the Exchange. The Exchange's affiliates, Boston Stock Exchange Clearing Corporation, Nasdaq BX, Inc., Nasdaq GEMX, LLC, Nasdaq ISE, LLC, The Nasdaq Stock Market LLC, Nasdaq PHLX LLC, and Stock Clearing Corporation of Philadelphia will each concurrently submit substantially the same rule filings to propose the changes described herein.

[4] Nasdaq currently has no Preferred Stock outstanding.

[5] The price of one share of Common Stock on March 31, 2017 was $69.45 and the closing market price of one share of Common Stock on April 1, 2022 was $181.92 as reported on the Nasdaq Stock Market.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(1).

Exchange to effectively carry out their regulatory oversight responsibilities under the Act.

The Exchange also believes that the proposal is consistent with Section 6(b)(5) of the Act[8] because it would not impact the Exchange's governance or regulatory structure, which would continue to 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 system, and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change would 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, because by increasing Nasdaq's authorized shares of Common Stock and shares of capital stock sufficient to allow Nasdaq to effectuate the Stock Dividend, the proposed rule change will facilitate broader ownership of Nasdaq.

The Exchange also notes that the proposed rule change is substantially similar to a prior proposal by Intercontinental Exchange, Inc. (''ICE''), which is the holding company for three national securities exchanges, including the New York Stock Exchange. The ICE proposal amended ICE's Certificate of Incorporation to effectuate a similar stock split as proposed by the Exchange herein.[9] As such, the Exchange does not believe that its proposal raises any new or novel issues not already considered by the Commission.

B. Self-Regulatory Organization's Statement on Burden on Competition

Because the proposed rule change relates solely to the number of authorized shares of Common Stock and shares of capital stock of the Company and not to the operations of the Exchange, 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.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 Act[10] and Rule 19b–4(f)(6) thereunder.[11]

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 shall institute proceedings to determine whether the proposed rule 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MRX–2022–05 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–MRX–2022–05. 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 (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MRX–2022–05 and should be submitted on or before June 13, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–10958 Filed 5–20–22; 8:45 am]

BILLING CODE 8011–01–P

[8] 15 U.S.C. 78f(b)(5).

[9] In particular, the ICE proposal increased ICE's total number of authorized shares of ICE common stock in order to effectuate a 5-for-1 stock split by way of a stock dividend. *See* Securities Exchange Act Release No. 78992 (September 29, 2016), 81 FR 69092 (October 5, 2016) (SR–NYSE–2016–57, SR–NYSEArca–2016–119, and SR–NYSEMKT–2016–80) (hereinafter, ''ICE Approval'').

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its 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.

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94928; File No. SR–CBOE–2022–009]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Order Approving a Proposed Rule Change To Amend Rule 4.3.06 To Allow the Exchange To List and Trade Options on the Goldman Sachs Physical Gold ETF

May 17, 2022.

I. Introduction

On March 25, 2022, Cboe Exchange, Inc. (''Exchange'' or ''Cboe'') 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 list and trade options on the Goldman Sachs Physical Gold ETF (''AAAU'' or ''Trust''). The proposed rule change was published for comment in the **Federal Register** on April 8, 2022.[3] The Commission received one comment on the proposed rule change.[4] This order approves the proposed rule change.

II. Description of the Proposed Rule Change

Under Cboe Rule 4.3.06(a), securities deemed appropriate for options trading include Units [5] that represent certain types of interests.[6] Cboe Rule 4.3.06(a)(4) specifies Units that represent interests in the SPDR Gold Trust, the iShares COMEX Gold Trust, the iShares Silver Trust, the ETFS Silver Trust, the ETFS Gold Trust, the ETFS Palladium Trust, the ETFS Platinum Trust, or the Sprott Physical Gold Trust. The proposed rule change would add AAAU to the list of ETFs under Rule 4.3.06(a)(4) that may be approved for options trading on the Exchange.

The Exchange states that AAAU is a gold-backed commodity ETF structured as a trust, much like other Units currently deemed appropriate for options trading pursuant to Cboe Rule 4.3.06(a)(4), such as the SPDR Gold Trust (''GLD''), iShares COMEX Gold Trust (''IAU''), Aberdeen Standard Physical Gold Trust (''SGOL''), and Sprott Physical Gold Trust (''PHYS'').[7] According to the Exchange, the Trust's investment objective is for its shares to reflect the performance of the price of gold (less the expenses of the Trust's operations), which offers investors an opportunity to gain exposure to gold without the complexities of gold delivery.[8] The Trust issues Goldman Sachs Physical Gold ETF Shares, which represent units of fractional undivided beneficial interest in the Trust, the assets of which consist principally of gold.[9] The Exchange states that AAAU is a competitively-priced commodity ETF whose cost is comparatively lower than the industry average for commodity ETFs.[10] The Exchange asserts that AAAU provides investors with a cost-efficient alternative that allows a level of participation in the gold market through the securities market.[11] The GLD, IAU, SGOL and PHYS trusts also issue shares that represent fractional undivided beneficial interest in the respective trust, each of which holds physical gold and is designed to track gold or the performance of the price of gold and offer access to the gold market.[12]

AAAU options will trade in the same manner as any other ETF options on the Exchange.[13] The Exchange states that Cboe rules that currently apply to the listing and trading of the aforementioned options on gold-backed commodity ETFs also will apply to the listing and trading of AAAU options on the Exchange.[14] The Exchange notes that these include rules governing, among other things, listing criteria, expiration and exercise prices, minimum increments, position and exercise limits, margin requirements, customer accounts and trading halt procedures.[15]

The Exchange's initial listing standards for ETFs on which options may be listed and traded on the Exchange will apply to AAAU.[16] The Exchange represents that AAAU satisfies the Exchange's initial listing standards as set forth in Cboe Rule 4.3(a) and Cboe Rule 4.3.06(b).[17] Pursuant to Cboe Rule 4.3(a), an underlying security on which options may be listed and traded on the Exchange must be duly registered and be an NMS stock,[18] and be characterized by a substantial number of outstanding shares which are widely held and actively traded.[19] In addition, Cboe Rule 4.3.06(b) requires that Units must either (1) meet the criteria and guidelines under Cboe Rule 4.3.01,[20] or (2) be available for creation or redemption each business day from or through the issuing trust, investment company, commodity pools or other issuer in cash or in kind at a price related to net asset value, and the issuing trust, investment company, commodity pools or other issuer is obligated to issue Units in a specified aggregate number even if some or all of the investment assets and/or cash required to be deposited have not been received by the issuing trust, investment company, commodity pools or other issuer, subject to the condition that the person obligated to deposit the investments has undertaken to deliver the investment assets and/or cash as soon as possible and such undertaking is secured by the delivery and maintenance of collateral consisting of cash or cash equivalents satisfactory to the issuer of the Units which underlie the option as described in the Units' prospectus.[21] The Exchange represents that, at minimum, AAAU satisfies Cboe Rule 4.3.06(b)(2).[22]

The Exchange states that AAAU also will be subject to the Exchange's continued listing requirements, set forth in Cboe Rule 4.4.06, for ETFs deemed appropriate for options trading pursuant to Cboe Rule 4.3.06.[23] Cboe Rule 4.4.06 provides that Units that were initially approved for options trading pursuant to Cboe Rule 4.3.06 shall be deemed not to meet the requirements for continued approval, and the Exchange shall not open for trading any additional series of option contracts of the class covering such Units, if the Units cease to be an NMS stock or the Units are halted from trading in their primary market.[24] Additionally, options on Units may be subject to the suspension of opening transactions in any of the following circumstances: (1) In the case of options covering Units approved for trading under Cboe Rule 4.3.06(b)(1), in accordance with the terms of paragraphs (a), (b), and (c) of Cboe Rule 4.4.01; (2) in the case of options covering Units approved for trading under Cboe Rule

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 94594 (Apr. 4, 2022), 87 FR 20901 (Apr. 8, 2022) (''Notice'').

[4] *See* Letter from Andrew Robison, dated April 28, 2022, available at *https://www.sec.gov/comments/sr-cboe-2022-009/srcboe2022009.htm.* The comments expressed by the commenter are not relevant to the proposed rule change.

[5] The terms ''Unit'' and Exchange-Traded Fund (''ETF'') mean a share or other security traded on a national securities exchange and defined as an NMS stock as set forth in Cboe Rule 4.3. *See* Cboe Rule. 1.1. Capitalized terms not otherwise defined herein have the meanings set forth in CBOE's rules or the Notice.

[6] *See* Cboe Rules 4.3.06(a)(1)–(5).

[7] *See* Notice, *supra* note 3, 87 FR at 20902.

[8] *See id.*

[9] *See id.* The Trust may include minimal cash. *See id.* at n. 5.

[10] *See* Notice, *supra* note 3, 87 FR at 20902.

[11] *See id.*

[12] *See id.* The trusts may include minimal cash. *See id.* at n.6.

[13] *See* Notice, *supra* note 3, 87 FR at 20902.

[14] *See id.*

[15] *See id.*

[16] *See id.*

[17] *See id.*

[18] *See id.* The term ''NMS stock'' has the meaning set forth in Rule 600 of Regulation NMS. *See* Cboe Rule 1.1.

[19] *See* Notice, *supra* note 3, 87 FR at 20902. The Exchange notes that the year-to-date (March 23, 2022) average daily volume (''ADV'') of AAAU shares is approximately 845,200 shares, the market capitalization of AAAU as of March 23, 2022 is approximately $727.3 million and the NAV of its shares is $19.19. *See id.* at n. 7.

[20] *See* Cboe Rule 4.3.01 (providing guidelines established by the Board of Directors to be considered by the Exchange in evaluating potential underlying securities for Exchange option transactions).

[21] *See* Notice, *supra* note 3, 87 FR at 20902–03.

[22] *See id. See also* Goldman Sachs Physical Gold ETF, Prospectus (January 8, 2021) available at *https://www.gsam.com/content/gsam/us/en/individual/products/etf-fund-finder/goldman-sachs-physical-gold-etf.html#activeTab=overview.*

[23] *See* Notice, *supra* note 3, 87 FR at 20903.

[24] *See id.*

4.3.06(b)(2), following the initial twelve-month period beginning upon the commencement of trading in the Units on a national securities exchange and are defined [sic] as an NMS stock, there are fewer than 50 record and/or beneficial holders of such Units for 30 or more consecutive trading days; (3) the value of the index or portfolio of securities, non-U.S. currency, or portfolio of commodities including commodity futures contracts, options on commodity futures contracts, swaps, forward contracts and/or options on physical commodities and/or Financial Instruments and Money Market Instruments on which the Units are based is no longer calculated or available; or (4) such other event occurs or condition exists that in the opinion of the Exchange makes further dealing in such options on the Exchange inadvisable.[25]

AAAU options will be physically-settled contracts with American-style exercise.[26] The Exchange states that, consistent with Cboe Rule 4.5, which governs the opening of options series on a specific underlying security (including ETFs), the Exchange will open at least one expiration month for options on AAAU[27] and may also list series of options on AAAU for trading on a weekly[28] or quarterly[29] basis.[30] The Exchange states that it may also list long-term equity option series (''LEAPS'') that expire from 12 to 180 months from the time they are listed.[31]

The Exchange states that, pursuant to Rule 4.5.07, which governs strike prices of series of options on Units, the interval between strike prices for series of options on AAAU will be $1 or greater where the strike price is $200 or less and $5.00 or greater where the strike price is greater than $200.[32] The Exchange states that, pursuant to Cboe Rule 5.4, where the price of a series of AAAU options is less than $3.00 the minimum increment will be $0.05, and where the price is $3.00 or higher, the minimum increment will be $0.10.[33] The Exchange states that any and all new series of AAAU options that the Exchange lists will be consistent and comply with the expirations, strike prices and minimum increments set forth in Cboe Rules 4.5 and 5.4, as applicable.[34]

The Exchange states that position and exercise limits for options on ETFs, including options on AAAU, are determined pursuant to Cboe Rules 8.30 and 8.32, respectively.[35] The Exchange states that position and exercise limits for ETF options vary according to the number of outstanding shares and the trading volumes of the underlying ETF over the past six months, where the largest in capitalization and the most frequently traded ETFs have an option position and exercise limit of 250,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market, and smaller capitalization ETFs have position and exercise limits of 200,000, 75,000, 50,000 or 25,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market.[36] The Exchange states that, given AAAU volume over the previous six months, the Exchange anticipates that upon initial listing, AAAU options will fall into the position limit bucket of 75,000 contracts.[37] The Exchange further notes that Cboe Rule 10.3, which governs margin requirements applicable to the trading of all options on the Exchange, including options on ETFs, will also apply to the trading of AAAU options.[38]

The Exchange represents that the same surveillance procedures applicable to all other options on other Units currently listed and traded on the Exchange will apply to options on AAAU, and that it has the necessary systems capacity to support the new option series.[39] The Exchange states it believes that its existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior which might potentially arise from listing and trading ETF options, including AAAU options, as proposed.[40] Also, the Exchange states it may obtain information from the CME Group New York Mercantile Exchange, Inc. (''NYMEX'') (a member of the Intermarket Surveillance Group (''ISG''))[41] related to any financial instrument that is based, in whole or in part, upon an interest in or performance of gold.[42]

The Exchange represents that it has also analyzed its capacity and believes the Exchange and OPRA have the necessary systems capacity to handle the additional traffic associated with the listing of new series that may result from the introduction of options on AAAU, up to the number of expirations currently permissible under its rules.[43] The Exchange believes that because the proposal is limited to one class, any additional traffic that may be generated from the introduction of AAAU options will be manageable.[44] The Exchange also proposes to amend Cboe Rule 4.3.06(a)(4) to update the names of the ''ETFS Silver Trust,'' the ''ETFS Gold Trust,'' the ''ETFS Palladium Trust'' and the ''ETFS Platinum Trust'' to the ''Aberdeen Standard Physical Silver Trust,'' the ''Aberdeen Standard Physical Gold Trust,'' the ''Aberdeen Standard Physical Palladium Trust,'' and the ''Aberdeen Standard Physical Platinum Trust,'' respectively,[45] and make a non-substantive change to the rule to replace superfluous commas with conjunctions.[46]

III. Discussion and Commission Findings

After careful consideration, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange[47] and, in particular, the requirements of Section 6

[25] *See id.*

[26] *See id. See also* Cboe Rule 4.2 (providing that the rights and obligations of holders and writers shall be as set forth in the Rules of The Options Clearing Corporation (''OCC'')); Cboe Equity Options Product Specifications (March 23, 2022) available at *https://www.cboe.com/exchange_traded_stock/equity_options_spec/?msclkid=8079efbbaaf111ec83b46e77a2984348*; OCC Rules, Chapter VIII (governing exercise and assignment) and Chapter IX (governing the discharge of delivery and payment obligations arising out of the exercise of physically-settled stock option contracts).

[27] *See* Notice, *supra* note 3, 87 FR at 20903 n. 11; *see also* Cboe Rule 4.5(b).

[28] *See* Notice, *supra* note 3, 87 FR at 20903. The weekly listing program is known as the Short Term Option Series Program and is described within Cboe Rule 4.5(d). *See id.* at n.12.

[29] *See* Notice, *supra* note 3, 87 FR at 20903; *see also* Cboe Rule 4.5(e).

[30] *See* Notice, *supra* note 3, 87 FR at 20903.

[31] *See id.; see also* Cboe Rule 4.5(f).

[32] *See Notice, supra* note 3, 87 FR at 20903. The Exchange notes that for options listed pursuant to the Short Term Option Series Program, Rule 4.5(d)(5) specifically sets forth intervals between strike prices on Short Term Option Series. *See id.* at n. 15.

[33] *See* Notice, *supra* note 3, 87 FR at 20903; *see also* Cboe Rule 5.4. The Exchange states that, if options on AAAU are eligible to participate in the Penny Interval Program, the minimum increment will be $0.01 below $3.00 and $0.50 above $3.00. *See* Notice, *supra* note 3, 87 FR at 20903 n. 20.

[34] *See* Notice, *supra* note 3, 87 FR at 20903.

[35] *See id.*

[36] *See id.*

[37] *See* Notice, *supra* note 3, 87 FR at 20903 n. 21.

[38] *See* Notice, *supra* note 3, 87 FR at 20903.

[39] *See id.*

[40] *See* Notice, *supra* note 3, 87 FR at 20903–04.

[41] The purpose of the ISG is to provide a framework for the sharing of information and the coordination of regulatory efforts among exchanges trading securities and related products to address potential intermarket manipulations and trading abuses. *See https://isgportal.org/.*

[42] *See* Notice, *supra* note 3, 87 FR at 20904.

[43] *See id.*

[44] *See id.*

[45] *See* Notice, *supra* note 3, 87 FR at 20902. The Exchange states that these ETFs were renamed in 2018. *See id.*

[46] *See id.*

[47] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

of the Act.[48] Specifically, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[49] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in 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.

The Commission believes that the proposal to list and trade options on AAAU on the Exchange will provide investors with the ability to transact in AAAU options in a listed market environment, which could provide investors with heightened contra-party creditworthiness due to the role of OCC as issuer and guarantor of all listed options, as well as increased transparency and enhanced price discovery. Moreover, the Exchange already lists options on other gold-based ETFs, which, as described above, are trusts structured in substantially the same manner as AAAU,[50] and the Exchange represents that it has not identified any issues with the continued listing and trading of the gold-backed ETF options that it currently lists for trading.[51]

As a national securities exchange, Cboe is required under Section 6(b)(1) of the Act[52] to enforce compliance by its members, and persons associated with its members, with the provisions of the Act, Commission rules and regulations thereunder, and its own rules. In addition, brokers that trade AAAU options also will be subject to best execution obligations and FINRA rules.[53] Applicable exchange rules also require that customers receive appropriate disclosure before trading AAAU Options.[54] Further, brokers opening accounts and recommending options transactions must comply with relevant customer suitability standards.[55]

Options on AAAU will trade as options under the trading rules of the Exchange.[56] AAAU options must also satisfy Exchange initial listing and continued listing standards applicable to options on all Units, including the gold-backed commodity ETFs already approved for options trading on the Exchange. A security on which options may be listed and traded on the Exchange must be duly registered and be an ''NMS stock'' as defined under Rule 600 of Regulation NMS[57] and be characterized by a substantial number of outstanding shares which are widely held and actively traded.[58] Additionally, Units must meet either (1) the criteria and guidelines under Cboe Rule 4.3.01,[59] or (2) they must be available for creation or redemption each business day from or through the issuer in cash or in kind at a price related to net asset value, and the issuer must be obligated to issue Units in a specified aggregate number even if some or all of the investment assets required to be deposited have not been received by the issuer, subject to the condition that the person obligated to deposit the investments has undertaken to deliver the investment assets as soon as possible and such undertaking is secured by the delivery and maintenance of collateral consisting of cash or cash equivalents satisfactory to the issuer, as provided in the respective prospectus.[60]

Series of AAAU options also will be subject to the Exchange's continued listing requirements, including standards applicable to the underlying Trust. If the Units cease to be an NMS stock or the Units are halted from trading in their primary market, the Exchange will deem Units that were initially approved for options trading pursuant to Cboe Rule 4.3.06 not to meet the requirements for continued approval, and the Exchange shall not open for trading any additional series of option contracts of the class covering such Units.[61]

The Exchange represents that its existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior which might arise from listing and trading ETF options, including AAAU options.[62] The Exchange also represents that it has the necessary systems capacity to support the new ETF option series.[63] Additionally, the Commission notes that AAAU options will trade in the same manner as any other options on ETFs, and the same Exchange rules that currently govern the listing and trading of ETF options, including permissible expirations, strike prices and minimum increments, and applicable position and exercise limits and margin requirements, will govern the listing and trading of options on AAAU.

Finally, the Commission believes that the Exchange's proposals to make grammatical edits to the rule text and update the names of certain ETFs in Cboe Rule 4.3.06(a)(4) are helpful technical changes that add clarity and accuracy to the rule text.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[64] that the proposed rule change (SR–CBOE–2022–009) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[65]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–10967 Filed 5–20–22; 8:45 am]

BILLING CODE 8011–01–P

[48] 15 U.S.C. 78f.

[49] 15 U.S.C. 78f(b)(5).

[50] *See e.g.,* Securities Exchange Act Release No. 59055 (Dec. 4, 2008), 73 FR 75148 (Dec. 10, 2008) (approving proposals to list and trade options on IAU and the iShares Silver Trust); Securities Exchange Act Release No. 57894 (May 30, 2008), 73 FR 32061 (Jun. 5, 2008) (approving proposals to list and trade options on GLD); and Securities Exchange Act Release No. 61483 (Feb. 3, 2010), 75 FR 6753 (Feb. 10, 2010) (approving proposals to list and trade options on the ETFS Gold Trust and ETFS Silver Trust).

[51] *See* Notice, *supra* note 3, at 20904.

[52] 15 U.S.C. 78f(b)(1).

[53] *See* FINRA Rule 5310.

[54] *See* Cboe Rule 9.9 and Rule 9.15.

[55] *See* Cboe Rule 9.3.

[56] *See* Chapter 5 of Cboe's Rules.

[57] 17 CFR 242.600.

[58] *See* Cboe Rule 4.3(a); *see also supra* note 19.

[59] *See* Cboe Rule 4.3.06(b)(1). *See also* Cboe Rule 4.3.01 (providing guidelines established by the Board of Directors to be considered by the Exchange in evaluating potential underlying securities for Exchange option transactions).

[60] *See* Cboe Rule 4.3.06(b)(2). The Exchange represents that, at minimum, the AAAU satisfies this initial listing criteria. *See* Notice, *supra* note 3, 87 FR at 20903.

[61] *See* Cboe Rule 4.4.06.

[62] *See* Notice, *supra* note 3, 87 FR at 20903.

[63] *See id.*

[64] 15 U.S.C. 78s(b)(2).

[65] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94935; File No. SR–GEMX–2022–07]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Nasdaq Amended and Restated Certificate of Incorporation

May 17, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 6, 2022, Nasdaq GEMX, LLC (''GEMX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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

The Exchange proposes to amend the Amended and Restated Certificate of Incorporation (''Certificate'') of its parent corporation, Nasdaq, Inc. (''Nasdaq'' or the ''Company''), to increase Nasdaq's authorized share capital.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/gemx/rules,* 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 Exchange 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 Exchange 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 purpose of the proposed rule change is to amend the Nasdaq Certificate [3] to increase the total number of authorized shares of Nasdaq common stock, par value $0.01 per share (''Common Stock''). Specifically, the Exchange proposes to amend Article Fourth, Section A such that the total number of shares of Stock (*i.e.,* capital stock) that Nasdaq is authorized to issue would be increased from 330,000,000 to 930,000,000 shares, and the portion of that total constituting Common Stock would be changed from 300,000,000 to 900,000,000 shares. As amended, Article Fourth, Section A of the Certificate would provide:

> The total number of shares of Stock which Nasdaq shall have the authority to issue is Nine Hundred Thirty Million (930,000,000), consisting of Thirty Million (30,000,000) shares of Preferred Stock, par value $.01 per share (hereinafter referred to as ''Preferred Stock''), and Nine Hundred Million (900,000,000) shares of Common Stock, par value $.01 per share (hereinafter referred to as ''Common Stock'').[4]

As noted above, the proposed amendments to the Certificate were approved by the Nasdaq Board of Directors (''Nasdaq Board'') on March 23, 2022. The proposed amendments to the Certificate would be effective when filed with the Secretary of State of Delaware, which would not occur until approval of the amendments by the stockholders of Nasdaq is obtained at the 2022 Annual Meeting of the Stockholders on June 22, 2022 and until this proposed rule change becomes effective and operative.

The trading price of Nasdaq's Common Stock has risen significantly over the past several years. Since Nasdaq first became a publicly traded company in 2002, the total number of authorized shares of Common Stock has remained constant at 300,000,000 shares. However, over the last five years, the trading price of Nasdaq's Common Stock has increased by approximately 162%.[5] As the trading price of Nasdaq's Common Stock has risen, the Nasdaq Board has carefully evaluated the effect of the trading price of the Common Stock on the liquidity and marketability of the Common Stock. The Nasdaq Board believes that this price appreciation may be affecting the liquidity of the Common Stock, making it more difficult to efficiently trade and potentially less attractive to certain investors. Accordingly, the Nasdaq Board approved pursuing a 3-for-1 stock split by way of a stock dividend, pursuant to which the holders of record of shares of Common Stock would receive, by way of a dividend, two shares of Common Stock for each share of Common Stock held by such holder (the ''Stock Dividend''). The Nasdaq Board's approval of the Stock Dividend was contingent upon this proposed rule change becoming effective and operative, and Nasdaq stockholder approval of the proposed amendments to the Certificate.

The number of shares of Common Stock proposed to be issued in the Stock Dividend exceeds Nasdaq's authorized but unissued shares of Common Stock. The proposed rule change would increase Nasdaq's authorized shares of Common Stock and shares of capital stock sufficient to allow Nasdaq to effectuate the Stock Dividend.

The proposed changes would not otherwise alter the Certificate, including the limitations on voting and ownership set forth in Article Fourth, Section C of the Certificate that generally provides no person who beneficially owns shares of common stock or preferred stock of Nasdaq in excess of 5% of the then-outstanding securities generally entitled to vote may vote the shares in excess of 5%. This limitation mitigates the potential for any Nasdaq shareholder to exercise undue control over the operations of Nasdaq's self-regulatory subsidiaries, and facilitates the self-regulatory subsidiaries' and the Commission's ability to carry out their regulatory obligations under the Act.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[6] in general, and furthers the objectives of Section 6(b)(1) of the Act,[7] in that it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the Exchange.

The proposal to increase Nasdaq's authorized shares of Common Stock and shares of capital stock sufficient to allow Nasdaq to effectuate the Stock Dividend would not impact the Exchange's ability to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act. In particular, the proposed changes would not alter the limitations on voting and ownership set forth in Article Fourth, Section C of the Certificate, and so the proposed changes would not enable a person to exercise undue control over the operations of Nasdaq's self-regulatory subsidiaries or to restrict the ability of the Commission or the Exchange to effectively carry out their regulatory oversight responsibilities under the Act.

[3] Nasdaq owns 100% of the equity interest in U.S. Exchange Holdings, Inc., which in turn owns 100% of the equity interest in International Securities Exchange Holdings, Inc., which in turn owns 100% of the equity interest in the Exchange. The Exchange's affiliates, Boston Stock Exchange Clearing Corporation, Nasdaq BX, Inc., Nasdaq MRX, LLC, Nasdaq ISE, LLC, The Nasdaq Stock Market LLC, Nasdaq PHLX LLC, and Stock Clearing Corporation of Philadelphia will each concurrently submit substantially the same rule filings to propose the changes described herein.

[4] Nasdaq currently has no Preferred Stock outstanding.

[5] The price of one share of Common Stock on March 31, 2017 was $69.45 and the closing market price of one share of Common Stock on April 1, 2022 was $181.92 as reported on the Nasdaq Stock Market.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(1).

The Exchange also believes that the proposal is consistent with Section 6(b)(5) of the Act[8] because it would not impact the Exchange's governance or regulatory structure, which would continue to 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 system, and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change would 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, because by increasing Nasdaq's authorized shares of Common Stock and shares of capital stock sufficient to allow Nasdaq to effectuate the Stock Dividend, the proposed rule change will facilitate broader ownership of Nasdaq.

The Exchange also notes that the proposed rule change is substantially similar to a prior proposal by Intercontinental Exchange, Inc. (''ICE''), which is the holding company for three national securities exchanges, including the New York Stock Exchange. The ICE proposal amended ICE's Certificate of Incorporation to effectuate a similar stock split as proposed by the Exchange herein.[9] As such, the Exchange does not believe that its proposal raises any new or novel issues not already considered by the Commission.

B. Self-Regulatory Organization's Statement on Burden on Competition

Because the proposed rule change relates solely to the number of authorized shares of Common Stock and shares of capital stock of the Company and not to the operations of the Exchange, 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.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 Act[10] and Rule 19b–4(f)(6) thereunder.[11]

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 shall institute proceedings to determine whether the proposed rule 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–GEMX–2022–07 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 Number SR–GEMX–2022–07. 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 (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–GEMX–2022–07 and should be submitted on or before June 13, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–10957 Filed 5–20–22; 8:45 am]

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[8] 15 U.S.C. 78f(b)(5).

[9] In particular, the ICE proposal increased ICE's total number of authorized shares of ICE common stock in order to effectuate a 5-for-1 stock split by way of a stock dividend. *See* Securities Exchange Act Release No. 78992 (September 29, 2016), 81 FR 69092 (October 5, 2016) (SR–NYSE–2016–57, SR–NYSEArca–2016–119, and SR–NYSEMKT–2016–80) (hereinafter, ''ICE Approval'').

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its 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.

[12] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Docket No. SBA–2022–001]

Class Waiver of the Nonmanufacturer Rule

AGENCY: U.S. Small Business Administration.

ACTION: Notification of class waiver of the Nonmanufacturer Rule for dental equipment and supplies.

SUMMARY: The U.S. Small Business Administration (SBA) is granting a request for a class waiver of the Nonmanufacturer Rule (NMR) for dental equipment and supplies.

DATES: This action will be effective thirty days after publication of this notice.

FOR FURTHER INFORMATION CONTACT: Carol Hulme, Attorney Advisor, by telephone at 202–205–6347; or by email at *Carol-Ann.Hulme@sba.gov.*

SUPPLEMENTARY INFORMATION: Sections 8(a)(17) and 46 of the Small Business Act (Act), 15 U.S.C. 637(a)(17) and 657s, and SBA's implementing regulations, found at 13 CFR 121.406(b), require that recipients of Federal supply contracts provide the product of a small business manufacturer or processor if the recipient of the set-aside contract is not the actual manufacturer or processor of the product. This requirement is commonly referred to as the Nonmanufacturer Rule (NMR). 13 CFR 121.406(b). The NMR applies to a contract issued as a small business set-aside (except as stated below); a service-disabled veteran-owned small business (SDVOSB) set-aside or sole-source contract; a Historically Underutilized Business Zone (HUBZone) set-aside or sole source contract; a women-owned small business (WOSB) or economically disadvantaged women-owned small business (EDWOSB) set-aside or sole source contract; or 8(a) set-aside or sole source contract; a partial set-aside; or a set-aside of an order against a multiple award contract. The NMR does not apply to small business set-aside acquisitions with an estimated value between the micro-purchase threshold and the simplified acquisition threshold.

Sections 8(a)(17)(B)(iv)(II) and 46(a)(4)(B) of the Act authorize SBA to waive the NMR for a ''class of products'' for which there are no small business manufacturers or processors available to participate in the Federal market. The SBA identifies a ''class of products'' based on a combination of the six-digit North American Industry Classification (NAICS) code and a description of the class of products. A waiver would not have any effect on the requirements in 13 CFR 121.406(b) or on requirements external to the Act that involve domestic sources of supply, such as the Buy American Act, 41 U.S.C. 8301–8305, or the Trade Agreements Act, 19 U.S.C. 2501 *et. seq.* As implemented in SBA's regulations at 13 CFR 121.1202(c), to be considered available to participate in the Federal market for a class of products, a small business manufacturer must have submitted a proposal for a contract solicitation or been awarded a contract to supply the class of products within the last 24 months.

SBA received a request for a class waiver for dental supplies and equipment. Specifically, the waiver would apply to dental chairs, dental delivery systems, dental lights, dental cabinets, dental stools, dental handpieces, dental infection control apparatus, dental air management systems, and mechanical room equipment under NAICS code 339114. A search of the Federal marketplace confirmed that no small business manufacturers have submitted a proposal or been awarded a contract to supply these products within the last 24 months.

On March 11, 2022, SBA issued a Notice of Intent to grant a class waiver for dental equipment and supplies and provided until April 11, 2022, for members of the public to submit comments. That notice can be found at 87 FR 14084. As there were no comments submitted pertaining to issuance of the waiver, SBA has determined a class waiver is appropriate for dental chairs, dental delivery systems, dental lights, dental cabinets, dental stools, dental handpieces, dental infection control apparatus, dental air management systems, and mechanical room equipment under NAICS code 339114. This class waiver allows otherwise qualified regular dealers to supply the waived items on certain small business contracts, regardless of the business size of the manufacturer. More information on the NMR and class waivers can be found at *https://www.sba.gov/partners/contracting-officials/small-business-procurement/nonmanufacturer-rule.*

Wallace D. Sermons, II,

Acting Director, Office of Government Contracting.

[FR Doc. 2022–10953 Filed 5–20–22; 8:45 am]

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DEPARTMENT OF STATE

[Public Notice: 11732]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Park Dae Sung: Virtuous Ink, Contemporary Brush'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition ''Park Dae Sung: Virtuous Ink, Contemporary Brush'' at the Los Angeles County Museum of Art, Los Angeles, California, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Stacy E. White,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2022–11005 Filed 5–20–22; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway Projects in Texas

AGENCY: Texas Department of Transportation (TxDOT), Federal Highway Administration (FHWA), U.S. Department of Transportation.

ACTION: Notice of limitation on claims for judicial review of actions by TxDOT and Federal agencies.

SUMMARY: This notice announces actions taken by TxDOT and Federal agencies that are final. The environmental review, consultation, and other actions required by applicable Federal environmental laws for these projects are being, or have been, carried-out by TxDOT pursuant to an assignment agreement executed by FHWA and TxDOT. The actions relate to various proposed highway projects in the State of Texas. These actions grant licenses, permits, and approvals for the projects.

DATES: By this notice, TxDOT is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of TxDOT and Federal agency actions on the highway projects will be barred unless the claim is filed on or before the deadline. For the projects listed below, the deadline is October 20, 2022. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such a claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Patrick Lee, Environmental Affairs Division, Texas Department of Transportation, 125 East 11th Street, Austin, Texas 78701; telephone: (512) 416–2358; email: *Patrick.Lee@txdot.gov.* TxDOT's normal business hours are 8:00 a.m.–5:00 p.m. (central time), Monday through Friday.

SUPPLEMENTARY INFORMATION: The environmental review, consultation, and other actions required by applicable Federal environmental laws for these projects are being, or have been, carried-out by TxDOT pursuant to 23 U.S.C. 327 and a Memorandum of Understanding dated December 9, 2019, and executed by FHWA and TxDOT.

Notice is hereby given that TxDOT and Federal agencies have taken final agency actions by issuing licenses, permits, and approvals for the highway projects in the State of Texas that are listed below.

The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion (CE), Environmental Assessment (EA), or Environmental Impact Statement (EIS) issued in connection with the projects and in other key project documents. The CE, EA, or EIS and other key documents for the listed projects are available by contacting the local TxDOT office at the address or telephone number provided for each project below.

This notice applies to all TxDOT and Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109].
2. *Air:* Clean Air Act [42 U.S.C. 7401–7671(q)].
3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Landscaping and Scenic Enhancement (Wildflowers) [23 U.S.C. 319].
4. *Wildlife:* Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536], Marine Mammal Protection Act [16 U.S.C. 1361], Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)], Migratory Bird Treaty Act [16 U.S.C. 703–712].
5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 300101 *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–11]; Archeological and Historic Preservation Act [54 U.S.C. 312501 *et seq.*]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].
6. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].
7. *Wetlands and Water Resources:* Clean Water Act [33 U.S.C. 1251–1377] (Section 404, Section 401, Section 319); Land and Water Conservation Fund (LWCF) [16 U.S.C. 4601–4604]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300(f)–300(j)(6)]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287]; Emergency Wetlands Resources Act [16 U.S.C. 3921, 3931]; TEA–21 Wetlands Mitigation [23 U.S.C. 103(b)(6)(m), 133(b)(11)]; Flood Disaster Protection Act [42 U.S.C. 4001–4128].
8. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898 Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species. (Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction.)

The projects subject to this notice are:

1. Cesar Chavez Road, from BUS US 83 to Nolana Loop, in Hidalgo County, Texas. The purpose of the project is to improve safety and mobility by reconstructing Cesar Chavez Road from a rural 24-foot-wide roadway to an urban 64-foot-wide roadway with two travel lanes, shared use lanes, sidewalks, and storm drain improvements. The proposed project length is approximately 3.8 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on December 2, 2021, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting the TxDOT Pharr District Office 600 W Interstate 2, Pharr, TX 78577; telephone: (956) 702–6100.

2. FM 1925, from Wallace Street to McColl Road, in Hidalgo County, Texas. The purpose of the project is to improve safety and mobility by widening and reconstructing FM 1925 from a rural 40-foot-wide roadway to an urban 110-foot-wide roadway with six travel lanes, shoulders, a raised median, sidewalks, and storm drain improvements. The proposed project length is approximately 5.2 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on December 8, 2021, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting the TxDOT Pharr District Office 600 W Interstate 2, Pharr, TX 78577; telephone: (956) 702–6100.

3. SL 378 Widening and Intersection, in Tom Green County, Texas. This project would extend for a total of 2.4 miles along SL 378, from 500 feet north of FM 1223 to 1,300 feet south of Fairview School Road and The Crossings Avenue. SL 378 would be widened to a five-lane facility, providing two travel lanes in each direction with a center turn lane. Sidewalks would be provided on both sides of the roadway. The project would primarily take place within the 100-foot-wide ROW on SL 378; however, the project proposes to realign the intersection at Fairview School Road which would require 1.47 acres of new ROW. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on December 13, 2021, and other documents in the TxDOT project file. The Categorical Exclusions Determination and other documents in the TxDOT project file are available by contacting the TxDOT San Angelo District Office at 4502 Knickerbocker Rd., San Angelo, TX 76904; telephone: (325) 944–1501.

4. FM 1593 from 1.62 miles north of the Calhoun County line to SH 35 in Jackson and Calhoun Counties, Texas. The proposed FM 1593 improvements would include widening the existing roadway for a total of 3.5 miles in Jackson and Calhoun counties, in front of the Formosa Plastics Corp. plant and north of Point Comfort, Texas. The roadway would be widened to support two 12-foot northbound and southbound lanes, 8-foot shoulders on each side and a 14-foot center turn lane throughout the limits. At all Formosa plant entrances, northbound 12-foot acceleration and deceleration lanes with 4 ft. shoulders would be constructed. Approximately 12.95 acres of new ROW would be needed; the existing ROW will be widened from 120 feet to 150–160

feet. The purpose of the project is to improve mobility and enhance safety along FM 1593. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on January 12, 2022, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting the TxDOT Yoakum District Office at 403 Huck St., Yoakum, TX 77995; telephone: (361) 293–4436.

5. IH 20 Corridor, JBS Parkway to East of SH 349, Ector and Midland Counties, Texas. TxDOT is proposing improvements along 1–20 from east of SH 349 in the City of Midland, Midland County to east of John Ben Shepperd Parkway in the City of Odessa, Ector County. The total project length is approximately 16.4 miles. Improvements would include adding main lanes, constructing new interchanges, reconfiguring ramps, converting frontage roads from two-way operation to one-way operation, and adding turn lanes at intersections. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on February 8, 2022, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting the TxDOT Odessa District Office at 3901 East Highway 80, Odessa, Texas 79761; telephone: (432) 498–4746.

6. FM 3349/CR 101 at US 79 from CR 395 to CR 404, Williamson County, Texas. The project includes widening the existing undivided two-lane FM 3349 and CR 101 facilities into four-lane divided facilities, constructing a grade-separation to elevate FM 3349/CR 101 over US 79 and the Union Pacific Railroad (which is adjacent to and paralleling US 79), and constructing a local access road ''jug handle'' to provide connectivity between the existing US 79 facility and the proposed FM 3349/CR 101 facility. The length of the jug handle would be approximately 0.65 mile. The length of the project along FM 3349 and CR 101 would be approximately 2.89 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA), Finding of No Significant Impact (FONSI) issued on January 6, 2022, and other documents in the TxDOT project file. The EA, FONSI, and other documents in the TxDOT project file are available by contacting the TxDOT Austin District Office at 7901 North I–35, Austin, TX 78753; telephone: (512) 832–7000.

7. FM 756 Paluxy Widening, from Jeff Davis Drive to FM 344, in Smith County, Texas. The purpose of the project is to improve mobility, safety, and upgrade the roadway design by widening the existing two-lane facility to a four-lane facility divided by a flush two-way left turn lane, including a grade-separated intersection at FM 346. The proposed project is approximately 6.8 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA), the Finding of No Significant Impact (FONSI) issued on January 7, 2022, and other documents in the TxDOT project file. The EA, FONSI, and other documents in the TxDOT project file are available by contacting the TxDOT Tyler District Office 2709 W Front St., Tyler, TX 75702; telephone: (903) 510–9100. The EA and FONSI can also be viewed and downloaded from the following website: *https://www.txdot.gov/inside-txdot/projects/studies/tyler/fm-756.html.*

8. US Highway 77 from SH 71 to approximately 0.56 miles north of County Road 156 in Fayette and Lee counties, Texas. The proposed US 77 improvements would include the expansion of the existing roadway to a four-lane divided facility for a total length of approximately 11.6 miles in Fayette and Lee counties north of La Grange, Texas. The northbound and southbound roadways would be constructed with two 12-foot travel lanes, 10-foot outside shoulders, and 4-foot inside shoulders. The median would vary between 56 and 68 feet wide. Twelve-foot left turn lanes would be constructed at multiple intersections within the project area. Near the southern project terminus and through Warda, where right-of-way is restricted to a width between 120 to 175 feet, a 14-foot dual center left turn lane would be constructed between the mainlanes. The purpose of the project is to improve mobility and enhance safety along US 77. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA), the Finding of No Significant Impact (FONSI) issued on January 19, 2022, and other documents in the TxDOT project file. The EA, FONSI, and other documents in the TxDOT project file are available by contacting the TxDOT Yoakum District Office at 403 Huck St., Yoakum, TX 77995; telephone: (361) 293–4436.

9. US 59 and US 77 from FM 236 to BU 77 in Victoria County, Texas. The proposed project would extend for a total of 5.12 miles along US 59 and US 77 from FM 236 to BU 77. The proposed improvements would upgrade the existing roadway to a controlled access facility. This includes the construction of divided mainlanes that consist of four 12-foot-wide travel lanes, two in each direction, 4-foot-wide inside shoulders, and 10-foot-wide outside shoulders. One-way frontage roads that consist of two 12-foot-wide travel lanes with a 4-foot inside shoulder and a 10-foot outside shoulder would also be constructed throughout the project limits. The project would include the construction of direct connectors for US 59 northbound and southbound at BU 77, and a grade separated interchange is proposed at US 77 and Old Goliad Road. The purpose of the project is to improve mobility and safety by providing a divided roadway with one-way frontage roads. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA), the Finding of No Significant Impact (FONSI) issued on February 11, 2022, and other documents in the TxDOT project file. The EA, FONSI, and other documents in the TxDOT project file are available by contacting the TxDOT Yoakum District Office at 403 Huck St., Yoakum, TX 77995; telephone: (361) 293–4436.

Authority: 23 U.S.C. 139(l)(1).

Michael T. Leary,

Director, Planning and Program Development, Federal Highway Administration.

[FR Doc. 2022–10864 Filed 5–20–22; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Requirements; Information Collection Renewal; Submission for OMB Review; Request for COVID–19 Vaccine Status and Proof of Vaccination

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and requests for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to

comment on the renewal of an information collection as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning the renewal of its information collection titled, ''Request for COVID–19 Vaccine Status and Proof of Vaccination.'' The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: You should submit written comments by June 22, 2022.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, 1557–0355, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–0355'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Written comments and recommendations for the proposed information collection should also 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.

On March 8, 2022, the OCC published a 60-day notice for this information collection, 87 FR 13042. You may review comments and other related materials that pertain to this information collection following the close of the 30-day comment period for this notice by the method set forth in the next bullet.

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Hover over the ''Information Collection Review'' tab and click on ''Information Collection Review'' drop-down menu. From the ''Currently under Review'' drop-down menu, select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0355'' or ''Request for COVID–19 Vaccine Status and Proof of Vaccination.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The OCC asks that OMB renew its approval of this collection, which was approved on an emergency basis.

Title: Request for COVID–19 Vaccine Status and ''Proof of Vaccination.''

OMB Control No.: 1557–0355.

Abstract: The President, by Executive order 13991 (January 20, 2021) established the Safer Federal Workforce Task Force (Task Force). The Task Force was established to give the heads of Federal agencies ongoing guidance to keep their employees safe and their agencies operating during the COVID–19 pandemic. The Task Force issued guidance, in accordance with the President's Executive Order 14043 (September 9, 2021), which required Federal employees to be vaccinated against COVID–19 by November 22, 2021, absent a legally-required exception. The Task Force issued guidance regarding individuals who start their government service after November 22, 2021, stating that those individuals should be fully vaccinated prior to their start date, except in limited circumstances where an accommodation is legally required. The guidance also provided that agencies should require documentation to prove vaccination status of those individuals prior to the enter on-duty date. To determine whether individuals who have been offered a position with the OCC are fully vaccinated during the onboarding process and before their enter on-duty date, the OCC developed the Appian vaccine attestation form in an online application (Attestation Form). The Attestation Form was developed, consistent with guidance issued by the Task Force and the U.S. Department of Treasury, to gather information from current and prospective employees regarding their vaccination status and secure proof of vaccination.

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the OCC will take no action to implement or enforce the COVID–19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees while the injunction is in effect.

Type of Review: Extension, without change, of a currently approved collection.

Affected Public: Individuals.

Burden Estimate:

Estimated Number of Respondents: 250.

Estimated Burden per Respondent: 0.25 Hours.

Total Burden: 62.5 Hours.

On March 8, 2022, the OCC published a 60-day notice for this information collection, 87 FR 13042. No comments were received. Comments continue to be solicited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;

(b) The accuracy of the agency's estimates of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2022–11007 Filed 5–20–22; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities; Information Collection Renewal; Submission for OMB Review; Funding and Liquidity Risk Management

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and respondents are not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning renewal of its information collection titled, ''Funding and Liquidity Risk Management.'' The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be received by June 22, 2022.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, 1557–0244, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–0244'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Written comments and recommendations for the proposed information collection should also 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.

On February 24, 2022, the OCC published a 60-day notice for this information collection, 87 FR 10429. You may review comments and other related materials that pertain to this information collection following the close of the 30-day comment period for this notice by the method set forth in the next bullet.

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Hover over the ''Information Collection Review'' tab and click on ''Information Collection Review'' from the drop-down menu. From the ''Currently under Review'' drop-down menu, select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0244'' or ''Funding and Liquidity Risk Management.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649–5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The OCC asks that OMB extend its approval of the collection in this document.

Title: Funding and Liquidity Risk Management.

OMB Control No.: 1557–0244.

Description: The Interagency Policy Statement on Funding and Liquidity Risk Management [1] (Policy Statement) summarizes the principles of sound liquidity risk management that the Federal banking agencies have issued in the past [2] and, where appropriate, harmonizes these principles with the international statement, issued by the Basel Committee on Banking Supervision, titled ''Principles for Sound Liquidity Risk Management and Supervision.'' [3] The Policy Statement describes supervisory expectations for all depository institutions, including banks, savings associations, and credit unions.

Section 14 of the Policy Statement provides that financial institutions should consider liquidity costs, benefits, and risks in strategic planning and budgeting processes. Significant business activities should be evaluated for liquidity risk exposure as well as profitability. More complex and sophisticated financial institutions should incorporate liquidity costs, benefits, and risks in the internal product pricing, performance measurement, and new product approval process for all material business lines, products, and activities. Incorporating the cost of liquidity into these functions should align the risk-taking incentives of individual business lines with the liquidity risk exposure their activities create for the institution as a whole. The quantification and attribution of liquidity risks should be

[1] 75 FR 13656 (Mar. 22, 2010).

[2] For national banks and Federal savings associations, see the *Comptroller's Handbook on Liquidity.* For state member banks and bank holding companies, see the Federal Reserve's *Commercial Bank Examination Manual* (section 4020), *Bank Holding Company Supervision Manual* (section 4010), and *Trading and Capital Markets Activities Manual* (section 2030). For state non-member banks, see the FDIC's *Revised Examination Guidance for Liquidity and Funds Management* (Trans. No. 2002–01) (Nov. 19, 2001), and Financial Institution Letter 84–2008, *Liquidity Risk Management* (August 2008). For federally insured credit unions, see Letter to Credit Unions No. 02–CU–05, Examination Program Liquidity Questionnaire (March 2002).

[3] Basel Committee on Banking Supervision, ''Principles for Sound Liquidity Risk Management and Supervision,'' September 2008. See *www.bis.org/publ/bcbs144.htm.* Federally insured credit unions are not directly referenced in the principles issued by the Basel Committee.

explicit and transparent at the line management level, and should include consideration of how liquidity would be affected under stressed conditions.

Section 20 of the Policy Statement states that liquidity risk reports should provide aggregate information with sufficient supporting detail to enable management to assess the sensitivity of the institution to changes in market conditions, its own financial performance, and other important risk factors. Institutions also should report on the use and availability of government support, such as lending and guarantee programs, and implications on liquidity positions, particularly because these programs are generally temporary or reserved as a source for contingent funding.

Type of Review: Regular.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 1,069.

Frequency of Response: On occasion.

Estimated Total Burden Hours: 78,096 hours.

Comments: On February 24, 2022, the OCC published a 60-day notice for this information collection, 87 FR 10429. No comments were received. Comments continue to be invited on:

(a) Whether the information collections are necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of the services necessary to provide the required information.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2022–10994 Filed 5–20–22; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Comment Request; Securities Exchange Act Disclosure Rules

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment; correction.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and respondents are not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning the renewal of its information collection titled ''Securities Exchange Act Disclosure Rules.''

DATES: Comments must be received on or before July 22, 2022.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557–0106, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–0106'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Following the close of this notice's 60-day comment period, the OCC will publish a second notice with a 30-day comment period. You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection by the method set forth in the next bullet.

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Hover over the ''Information Collection Review'' drop down menu. From the ''Currently under Review'' drop-down menu, select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0106'' or ''Securities Exchange Act Disclosure Rules.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649–5490 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of title 44 requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the renewal of the collection of information set forth in this document.

Title: Securities Exchange Act Disclosure Rules.

OMB Control No.: 1557–0106.

Description: This submission covers an existing regulation and involves no change to the regulation or to the

information collection requirements. The OCC requests only that OMB approve its revised burden estimates.

The Securities and Exchange Commission (SEC) is required by statute to collect, in accordance with its regulations, certain information and documents from any firm that is required to register its stock with the SEC.[1] Federal law requires the OCC to apply similar regulations to any national bank or Federal savings association similarly required to be registered with the SEC (generally those with a class of equity securities held by 2,000 or more shareholders).[2]

12 CFR part 11 ensures that a national bank or Federal savings association whose securities are subject to registration provides adequate information about its operations to current and potential shareholders and the public. The OCC reviews the information to ensure that it complies with Federal law and makes public all information required to be filed under the rule.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals; Businesses or other for-profit.

Frequency of Response: On occasion.

Estimated Number of Respondents: 44.

Estimated Total Annual Burden: 332.02 hours.

Comments submitted in response to this notice will be summarized and included in the submission to OMB. Comments are requested on:

(a) Whether the information collections are necessary for the proper performance of the OCC's functions, including whether the information has practical utility;

(b) The accuracy of the OCC's 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;

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2022–11006 Filed 5–20–22; 8:45 am]

BILLING CODE 4810–33–P

[1] 15 U.S.C. 78m(a)(1).

[2] 15 U.S.C. 78l(i).

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request Burden Related to the Quarterly Federal Excise Tax Returns

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning the burden associated with the quarterly federal excise tax returns.

DATES: Written comments should be received on or before July 22, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments to Andrés Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Please include, ''OMB Number: 1545–0023—Public Comment Request Notice'' in the Subject line.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Ronald J. Durbala, at (202) 317–5746, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Quarterly Federal Excise Tax Return.

OMB Number: 1545–0023.

Project Number: Form 720, Form 720–X, and Form 6627.

Abstract: Excise taxes are taxes paid when purchases are made on a specific good, such as gasoline. 26 U.S.C. 4081 imposes tax for miscellaneous excise taxes, manufacturers excise taxes, automotive and related items, petroleum products and motor and aviation fuel. Form 720, *Quarterly Federal Excise Tax Return,* is used to report liability by IRS number and to pay the excise taxes listed on the form. Form 720–X is used to make adjustments to liability reported on Form 720 filed in previous quarters. Form 6627 is used to figure the environmental tax on petroleum, ODCs, imported products that used ODCs as materials in the manufacture or production of the product, and the floor stocks tax on ODCs. Form 6627 is filed with Form 720.

Current Actions: There is no change in the paperwork burden previously approved by OMB. These forms are being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals, not-for-profit institutions, farms, and Federal, state, local or tribal governments.

Estimated Number of Respondents: 205,400.

Estimated Time per Respondent: 11 hrs., 38 min.

Estimated Total Annual Burden Hours: 2,391,400.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Desired Focus of Comments: The Internal Revenue Service (IRS) is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, 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.
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including using

appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: May 18, 2022.

Ronald J. Durbala,

IRS Tax Analyst.

[FR Doc. 2022–11002 Filed 5–20–22; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

Vol. 87 Monday,

No. 99 May 23, 2022

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 4, 16, 201, et al.

Current Good Manufacturing Practice, Certification, Postmarketing Safety Reporting, and Labeling Requirements for Certain Medical Gases; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 4, 16, 201, 210, 211, 213, 230, 314, and 514

[Docket No. FDA–2021–N–1333]

RIN 0910–AH96

Current Good Manufacturing Practice, Certification, Postmarketing Safety Reporting, and Labeling Requirements for Certain Medical Gases

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing new regulations that would amend the requirements concerning current good manufacturing practice (CGMP) and postmarketing safety reporting that apply to certain medical gases. FDA further proposes to establish regulations regarding certification of designated medical gases and amend the labeling regulations that apply to certain medical gases. This action, if finalized, will clarify the regulatory obligations of entities that manufacture, process, pack, label, or distribute certain medical gases, as well as reduce regulatory burden in this area. This proposed rule is intended to establish requirements that are more specifically tailored to the medical gas industry.

DATES: Submit either electronic or written comments on the proposed rule by August 22, 2022. Submit written comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 by July 22, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 22, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 22, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–1333 for ''Current Good Manufacturing Practice, Certification, Postmarketing Safety Reporting, and Labeling Requirements for Certain Medical Gases.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) at *https://www.reginfo.gov/public/do/PRAMain.* Find these particular information collections by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The titles of the proposed collections are:

- Current Good Manufacturing Practice (CGMP): Manufacturing, Processing, Packing, and Holding of Drugs; GMP for Finished Pharmaceuticals (Including Medical Gases and Active Pharmaceutical Ingredients); OMB control number 0910–0139—Revision
- Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products; OMB control number 0910–0572—Revision
- Current Good Manufacturing Practice for Medical Gases; OMB control number for 21 CFR part 213—New
- Certification and Postmarketing Reporting for Designated Medical Gases; OMB control number for 21 CFR part 230—New

FOR FURTHER INFORMATION CONTACT:

With regard to the proposed rule: David Faranda, Center for Drug Evaluation and Research, Food and

Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8767, *David.Faranda@fda.hhs.gov.*

With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary
A. Purpose of the Proposed Rule
B. Summary of the Major Provisions of the Proposed Rule
C. Legal Authority
D. Costs and Benefits
II. Table of Abbreviations/Commonly Used Acronyms in This Document
III. Background
A. Introduction
B. Need for the Regulation
C. FDA's Current Regulatory Framework
D. History of the Rulemaking
IV. Legal Authority
V. Description of the Proposed Rule
A. Proposed Labeling Provisions
B. Proposed Current Good Manufacturing Practice Provisions
C. Proposed Certification and Annual Reporting Provisions
D. Proposed Postmarketing Quality and Safety Reporting Provisions
VI. Proposed Effective Date
VII. Preliminary Economic Analysis of Impacts
VIII. Analysis of Environmental Impact
IX. Paperwork Reduction Act of 1995
X. Federalism
XI. Consultation and Coordination With Indian Tribal Governments
XII. References

I. Executive Summary

A. Purpose of the Proposed Rule

Section 756 of the Consolidated Appropriations Act, 2017 (Pub. L. 115–31) required FDA to issue final regulations revising the Federal drug regulations with respect to medical gases by July 15, 2017. These proposed regulations, if finalized, would satisfy that requirement and are intended to be more specifically tailored to the medical gas industry and decrease regulatory burden where appropriate.

FDA proposes revisions to its labeling regulations to provide clarity and consistency regarding how information is presented in the labeling of certain medical gases, as well as to ensure important safety information is included. FDA also proposes new CGMP regulations for medical gases to reflect appropriate requirements for the manufacturing, processing, packing, and holding of such products. These proposed regulations generally cover the same categories of provisions as the CGMP regulations in parts 210 and 211 (21 CFR parts 210 and 211) (hereafter the ''general drug CGMP regulations''), revised as appropriate for medical gases. FDA also proposes regulations that would implement and clarify the certification process for designated medical gases described in section 576 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360ddd–1). Lastly, FDA proposes new postmarketing safety reporting regulations for designated medical gases that would address human and animal use and would better reflect the development, manufacturing, and distribution of designated medical gases.

B. Summary of the Major Provisions of the Proposed Rule

1. Labeling Provisions

This proposed rule includes several proposed changes to FDA's drug labeling regulations including adding certain operations required to produce a medical gas to the list of operations that are performed by its manufacturer. We propose to revise the requirements for stating the ingredients in the labeling of a designated medical gas or medically appropriate combination of designated medical gases (referred to hereafter in this preamble as ''medically appropriate combination'').[1] We propose to specify requirements for the declaration of net quantity of contents in the labeling of designated medical gases and medically appropriate combinations.

We propose that all designated medical gases—whether certified for human use, animal use, or both—and medically appropriate combinations bear labeling that is in a standardized format.

FDA further proposes revisions to warning statements for certain medical gases including that the labeling of medical air and carbon monoxide bear certain warning statements. We propose different labeling requirements for final use containers and bulk or transport containers. We also propose a new oxygen warning statement and graphic warning symbol to alert users of the risks of smoking, vaping, and open flames near an oxygen container.

FDA proposes revisions to the medical gas container labeling regulations to clarify that the owner of a designated medical gas container or a container of a medically appropriate combination can be mentioned on the container to facilitate return of the container to the owner, and to ensure that product quality issues are directed to the appropriate entity.

2. CGMP Provisions

FDA proposes CGMP regulations specific to medical gases. These proposed regulations include many of the same categories of provisions as the general drug CGMP regulations but reflect differences in how medical gases are manufactured, processed, packed, and held. If finalized as proposed, these regulations would represent the minimum CGMP for medical gases. Of note, we propose different cleaning requirements for medical gases because these gases are generally manufactured in a sealed, closed system, and because cleaning at inappropriate times can introduce contaminants. Additionally, FDA proposes requirements for medical gas containers and closures that are similar to the general drug CGMP regulations, with an additional proposed requirement that portable cryogenic medical gas containers and small cryogenic gas containers for use by individual patients have a working gauge to indicate whether there is an adequate supply of gas for continued use. This would help users determine when a container must be refilled or replaced and when a leaking or venting container is empty. We are also not proposing to include time limitations on production because medical gases are generally not expected to expire or degrade. FDA also proposes that, unlike the salvaging requirements under the general drug CGMP regulations, medical gases that have been stored improperly may be salvaged unless their containers have been subjected to adverse conditions that negatively impact the identity, strength, quality, or purity of the product or the integrity of the product's container closure.

3. Certification Provisions

FDA proposes regulations regarding the certification process for designated medical gases that are intended to codify the certification process and

[1] Section 576(a)(3)(A)(i) of the FD&C Act provides that ''[a] designated medical gas for which a certification is granted under paragraph (2) is deemed, alone or in combination, as medically appropriate, with another designated medical gas or gases for which a certification or certifications have been granted, to have in effect an approved application under section 505 or 512, subject to all applicable postapproval requirements,'' for certain indications for use. FDA interprets the term ''combination'' in this section to mean two or more distinct designated medical gases that are mixed together. For example, a mixture of oxygen and nitrous oxide that each meet the standards set forth in an official compendium could constitute a medically appropriate combination of designated medical gases. However, the addition of oxygen to a container that already contains oxygen would not result in a medically appropriate combination of designated medical gases because only one kind of designated medical gas would be present in the container.

provide additional clarity where necessary. These proposed requirements would govern the process for applicants to file a certification request and supplements as well as the contents of such a request. The regulations would set forth requirements concerning the transfer of ownership of a certification from one entity to another.

We are proposing to require the submission of a streamlined annual report, including the required contents and timing for submission.

These proposed regulations would set forth requirements that are similar to the recommendations described in the November 2015 draft guidance for industry ''Certification Process for Designated Medical Gases'' (November 25, 2015, 80 FR 73771) (Ref. 1).

4. Postmarketing Safety Reporting Provisions

FDA is proposing new postmarketing safety reporting regulations for designated medical gases and general safety reporting requirements for all certified designated medical gases.

We also propose adverse event reporting requirements related to the use of designated medical gases in humans and animals. For designated medical gases that are certified for human use and deemed to have in effect an approved application under section 505 of the FD&C Act (21 U.S.C. 355), we are proposing that applicants and nonapplicants be required to report serious adverse events within 15 calendar days from when the applicant or nonapplicant has both met certain reporting criteria and acquired certain minimum data.

We are also proposing requirements for the contents and format of submissions, including an electronic submission requirement, the process for requesting a waiver of the electronic submission requirement, recordkeeping requirements, written procedures requirements, and patient privacy provisions.

For designated medical gases that are certified for animal use and deemed to have in effect an approved application under section 512 of the FD&C Act (21 U.S.C. 360b), we are proposing that applicants and nonapplicants be required to submit serious adverse event reports to FDA within 15 calendar days from when the applicant or nonapplicant has met certain reporting criteria and that recordkeeping requirements related to adverse events are maintained.

C. Legal Authority

Sections 501, 502, 505, 512, 575, 576, and 704 of the FD&C Act (21 U.S.C. 351, 352, 355, 360b, 360ddd, 360ddd–1, and 374), in conjunction with our general rulemaking authority in section 701(a) of the FD&C Act (21 U.S.C. 371(a)) serve as our principal legal authority for this proposed rule.

D. Costs and Benefits

The costs of this proposed rule, if finalized, would be primarily driven by new labeling requirements, regulatory clarification leading to firms becoming compliant with existing requirements, and added CGMP requirements including a requirement for portable cryogenic containers to have a working gauge. The cost savings of this proposed rule, if finalized, would be primarily driven by removing CGMP requirements that would not apply to medical gases, such as removing certain building and facility requirements, or modifying CGMP requirements so that they would be more well-tailored to medical gases, which may streamline inspections. The annualized benefits are estimated to be $3.24 million at a 7 percent discount rate over 10 years. The annualized costs are estimated to be $3.03 million at a 7 percent discount rate over 10 years.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
API	Active Pharmaceutical Ingredient.
CDER	Center for Drug Evaluation and Research.
CFR	Code of Federal Regulations.
CGMP	Current Good Manufacturing Practice.
COA	Certificate of Analysis.
CVM	Center for Veterinary Medicine.
FAR	Field Alert Report.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDA or Agency	Food and Drug Administration.
FDASIA	Food and Drug Administration Safety and Innovation Act.
FR	Federal Register.
ICSR	Individual Case Safety Report.
NDA	New Drug Application.
NADA	New Animal Drug Application.
NF	National Formulary.
OMB	Office of Management and Budget.
PRIA	Preliminary Regulatory Impact Analysis.
USP	United States Pharmacopeia.

III. Background

A. Introduction

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA, Pub. L. 112–144) was signed into law, establishing a new marketing pathway and specific requirements for the regulation of designated medical gases. Section 756 of the Consolidated Appropriations Act, 2017, required FDA to issue final regulations revising the Federal drug regulations with respect to medical gases by July 15, 2017.

The Agency has engaged with stakeholders and Congress to evaluate the need for changes to regulatory requirements for medical gases. This proposed rule is being published to address the areas for which FDA has determined regulatory changes are needed.

B. Need for the Regulation

Medical gases have historically been manufactured, labeled, and distributed in a manner different than most other drugs. Under section 576 of the FD&C Act, the process for obtaining marketing authorization for a designated medical gas also differs from the process for obtaining marketing authorization for other human and animal drugs. Moreover, because of these differences, sponsors of designated medical gases do

not generate the same safety information that sponsors of new drug applications (NDAs) and new animal drug applications (NADAs) would typically generate, including, for example, an understanding of expected adverse events based on clinical trial data. Thus, some existing regulations are not well-tailored to addressing designated medical gases and other medical gases. FDA is undertaking this rulemaking to address these differences, and to decrease regulatory burden where appropriate.

C. FDA's Current Regulatory Framework

Section 1111 of FDASIA established sections 575 through 577 of the FD&C Act (21 U.S.C. 360ddd through 360ddd–2) for medical gases. Section 575(2) of the FD&C Act defines a medical gas as a drug that is manufactured or stored in a liquefied, nonliquefied, or cryogenic state and administered as a gas. Section 575(1) of the FD&C Act defines a designated medical gas as any of the following gases that meet the standards set forth in an official compendium: Oxygen, nitrogen, nitrous oxide, carbon dioxide, helium, carbon monoxide, and medical air. Designated medical gases are also defined to include any other medical gas deemed appropriate by the Secretary of the Department of Health and Human Services (Secretary),[2] after taking into account any investigational new drug application or investigational new animal drug file [3] for the same medical gas submitted in accordance with applicable regulations, unless any period of exclusivity for a new drug under section 505(c)(3)(E)(ii) or (j)(5)(F)(ii) of the FD&C Act, or the extension of any such period under section 505A of the FD&C Act (21 U.S.C. 355a), or any period of exclusivity for a new animal drug under section 512(c)(2)(F) of the FD&C Act, applicable to such medical gas has not expired (section 575(1)(H) of the FD&C Act).

Any person who seeks to initially introduce or deliver for introduction into interstate commerce a designated medical gas may file with the Secretary a request for certification of a medical gas as a designated medical gas (FD&C Act section 576(a)(1)). Any such request shall contain a description of the medical gas, the sponsor's name and address, the name and address of the facility or facilities where the medical gas is or will be manufactured, and any other information the Secretary deems appropriate to determine whether the medical gas is a designated medical gas (Id.). The certification requested under section 576(a)(1) of the FD&C Act is deemed to be granted unless, within 60 days of filing of the request, the Secretary finds that the medical gas subject to the certification is not a designated medical gas, the request does not contain the information required under section 576(a)(1) of the FD&C Act or otherwise lacks sufficient information to permit the Secretary to determine that the medical gas is a designated medical gas, or denying the request is necessary to protect the public health (FD&C Act section 576(a)(2)). FDA interprets the period of 60 days in section 576(a)(2) to mean a period of 60 calendar days.

Section 576(a)(3)(A)(i) of the FD&C Act provides that a designated medical gas for which a certification is granted is deemed, alone or in combination, as medically appropriate, with another designated medical gas or gases for which a certification or certifications have been granted, to have in effect an approved application under section 505 or 512 of the FD&C Act, subject to all applicable postapproval requirements. The deemed approval is for certain indications specified in the statute or for any other indication for use for a designated medical gas or combination of designated medical gases deemed appropriate by the Secretary, unless any period of exclusivity under section 505(c)(3)(E)(iii) or (iv), 505(j)(5)(F)(iii) or (iv), or 527 of the FD&C Act (21 U.S.C. 360cc), or the extension of any such period under section 505A of the FD&C Act, applicable to such indication for use for such gas or combination of gases has not expired. Under section 576(a)(3)(A)(ii) of the FD&C Act, designated medical gases are deemed to have met the requirements of section 503(b)(4) of the FD&C Act (21 U.S.C. 353(b)(4); concerning the labeling of drugs with the symbol ''Rx only'') and section 502(f) of the FD&C Act (concerning the labeling of drugs with adequate directions for use and adequate warnings against certain uses) if the labeling on the final use container bears:

- The information required by section 503(b)(4) of the FD&C Act;
- A warning statement concerning the use of the medical gas as determined by the Secretary by regulation; and
- Appropriate directions and warnings concerning storage and handling.

Designated medical gases that are deemed to have in effect an approved application under section 576(a)(3)(A)(i) of the FD&C Act are not eligible for any period of exclusivity for a new drug under section 505(c) or (j), or 527 of the FD&C Act, or the extension of any such period under section 505A of the FD&C Act, on the basis of such deemed approval (FD&C Act section 576(a)(3)(B)(i)). In addition, no period of exclusivity under section 505(c), 505(j), or 527 of the FD&C Act, or the extension of any such period under section 505A of the FD&C Act, with respect to an application for a drug product, shall prohibit, limit, or otherwise affect the submission, grant, or effect of a designated medical gas certification, except as provided in sections 575(1)(H) and 576(a)(3)(A)(i)(VIII) of the FD&C Act (FD&C Act 576(a)(3)(B)(ii)).

Section 576(a)(4)(A) of the FD&C Act affirms the Secretary's authority to withdraw or suspend approval of a drug product, including a designated medical gas deemed to have in effect an approved application under section 505 or 512 of the FD&C Act. The Secretary under section 576(a)(4)(B) of the FD&C Act may revoke the grant of a designated medical gas certification upon the determination that the certification request contains any material omission or falsification.

Under section 576(b)(1) of the FD&C Act, designated medical gases are subject to the requirements under section 503(b)(1) of the FD&C Act (concerning the dispensing of certain human drugs only pursuant to a prescription) except under the following circumstances:

- The Secretary exercises the authority provided in section 503(b)(3) of the FD&C Act to remove the designated medical gas from the requirements of section 503(b)(1) of the FD&C Act;
- The gas is approved for use without a prescription pursuant to an application under section 505 or 512 of the FD&C Act; or
- The use in question is authorized pursuant to another provision in the FD&C Act relating to the use of medical products in emergencies.

Notwithstanding section 576(b)(1), section 576(b)(2)(A) of the FD&C Act provides that oxygen may be provided without a prescription for use in the event of depressurization or other environmental oxygen deficiency, or for oxygen deficiency or for use in emergency resuscitation when administered by properly trained personnel. For oxygen provided without a prescription, section 576(b)(2)(B) provides that the requirements of section 503(b)(4) (concerning labeling of drugs with the symbol ''Rx only'') are

[2] The functions of the Secretary described herein have been delegated to FDA.

[3] We interpret the term ''investigational new animal drug application'' in FD&C Act section 575(1)(H) to refer to an ''investigational new animal drug file'' to reflect CVM's current administrative process for receiving data and information related to a new animal drug for investigational use. See 21 CFR part 511.

deemed to have been met if its labeling bears a warning that it can only be used for emergency use, and that for all other medical applications a prescription is required.

Pursuant to section 577 of the FD&C Act, a designated medical gas, alone or in a medically appropriate combination with another designated medical gas or gases deemed under section 576 to have in effect an approved application, shall not be assessed prescription drug user fees under section 736(a) of the FD&C Act (21 U.S.C. 379h(a)) or animal drug user fees under section 740(a) of the FD&C Act (21 U.S.C. 379j–12(a)) on the basis of such deemed approval.

FDA's drug regulations also include several requirements specific to medical gases. FDA labeling regulations under part 201 (21 CFR part 201) that currently address the labeling of medical gases include the following:

- Section 201.25(b)(1)(i)(D), which exempts medical gases from bar code label requirements that otherwise apply to human prescription drug products;
- Section 201.161, which exempts certain medical gases from specified requirements if, among other things, applicable warning statements and information concerning storage and handling are included in the labeling; and
- Section 201.328, which describes certain labeling requirements for portable cryogenic medical gas containers and high-pressure medical gas cylinders, including a color coding system.

FDA's CGMP regulations under parts 210 and 211 that currently specifically address the manufacturing, labeling, and containers and closures for medical gases include the following:

- Section 211.94(e), which provides container and closure requirements for medical gases, including gas-specific outlet connections and label and coloring requirements;
- Section 211.125(c), which waives labeling reconciliation requirements for 360° wraparound labels on portable cryogenic medical gas containers;
- Section 211.170(b), which exempts compressed medical gases from the requirement to retain reserve samples; and
- Section 211.196, which exempts compressed medical gas products from the requirement that distribution records contain lot or control numbers.

D. History of the Rulemaking

In developing this proposed rule, FDA held three public workshops (Ref. 2), on December 15, 2017, February 9, 2018, and May 11, 2018, and opened a docket for public comment (FDA–2018–N–1214).[4] The Agency received several comments from interested stakeholders during the public workshops and received more than a dozen comments through the docket. Additionally, FDA received one comment in relation to its regulatory reform efforts associated with Executive Orders 13771 and 13777 (FDA–2017–N–5093).[5] Comments were submitted by industry groups, individual manufacturers, and private citizens. FDA has considered these comments in developing this proposed rule.

FDA received comments recommending revisions to requirements that commenters believe are not well-tailored to medical gases. Other comments addressed safety and handling concerns for medical gases. Multiple comments discussed whether FDA should add additional gases to the list of designated medical gases. Finally, some comments addressed other uses for certain medical gases.

IV. Legal Authority

Sections 501, 502, 505, 512, 575, 576, 701, and 704 of the FD&C Act provide the principal legal authority for this proposed rule. Medical gases are generally regulated as prescription drugs under sections 201(g)(1) and 503(b)(1) of the FD&C Act (though oxygen may be provided without a prescription for certain uses specified at section 576(b)(2) of the FD&C Act).

Section 501 of the FD&C Act describes the circumstances under which a drug is deemed to be adulterated. Under section 501(a)(2)(B) of the FD&C Act, a drug is deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice. For purposes of section 501(a)(2)(B), ''current good manufacturing practice'' includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products. Section 502 of the FD&C Act describes the circumstances under which a drug is deemed to be misbranded. Under section 502(f) of the FD&C Act, a drug is deemed to be misbranded unless its labeling bears adequate directions for use and such adequate warnings against use where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form, as are necessary for the protection of users. Under section 704 of the FD&C Act, FDA is authorized to inspect, among other things, records in any establishment in which prescription drugs or nonprescription drugs intended for human use are manufactured, processed, packed, or held bearing on whether such products are in violation of the FD&C Act.

Section 576 of the FD&C Act describes the certification process for designated medical gases (as defined in section 575 of the FD&C Act) and the effect of certification, the applicability of FDA's prescription requirements, and certain labeling requirements. Under section 576(a)(3)(A)(i), a certified designated medical gas is subject to all applicable postapproval requirements. Under section 505(k) of the FD&C Act, FDA has the authority to establish certain postmarketing safety reporting regulations for human drugs to enable FDA to determine or facilitate a determination as to whether there are or may be grounds to invoke section 505(e) of the FD&C Act, which concerns the withdrawal or suspension of approval of an NDA or abbreviated new drug application (ANDA). Section 512(l) of the FD&C Act authorizes FDA to establish postmarketing safety reporting regulations for new animal drugs to enable FDA to determine or facilitate a determination as to whether there are or may be grounds to withdraw approval of an application pursuant to section 512(e) or 512(m)(4) of the FD&C Act.

Thus, sections 501, 502, 505, 512, 575, 576, and 704 of the FD&C Act, in conjunction with our general authority in section 701(a) of the FD&C Act to promulgate regulations for the efficient enforcement of the FD&C Act, serve as our principal legal authority for this proposed rule.

V. Description of the Proposed Rule

We are proposing to establish new parts 213 and 230 (21 CFR parts 213 and 230) and amend parts 4, 16, 201, 210, 211, 314, and 514 (21 CFR parts 4, 16, 201, 210, 211, 314, and 514). The proposed rule would:

- Revise the labeling regulations specific to medical gases;
- Establish CGMP requirements specific to medical gases;
- Establish regulations governing the designated medical gas certification

[4] The announcement for the first two workshops referenced Docket No. FDA–2017–N–0001 (82 FR 54353, November 17, 2017). In the announcement for the third workshop, FDA announced that the docket number would change to FDA–2018–N–1214 and that all comments submitted to the first docket would be transferred to the new docket number (83 FR 13440, March 29, 2018).

[5] These Executive Orders were revoked by Executive Order 13992.

process under section 576 of the FD&C Act, including certain postapproval requirements; and

• Establish postmarketing safety reporting requirements specific to designated medical gases.

A. Proposed Labeling Provisions

FDA proposes revisions to the labeling regulations in part 201 related to medical gases.

1. Definitions

Proposed § 201.161(c)(1) defines the term ''designated medical gas.'' This definition refers to the statutory definition found in section 575(1) of the FD&C Act and is intended to apply to the same gases described in section 575(1) of the FD&C Act.

The term ''final use container'' is defined in proposed § 201.161(c)(2) to mean a container that is for direct use or access by a patient or healthcare provider to administer a designated medical gas or medically appropriate combination of designated medical gases. The following would not be included in the proposed definition of ''final use container'':

• Bulk or transport containers, or

• containers described in § 868.5655 (21 CFR 868.5655).

The Agency specifically requests comment on the scope of the proposed definition of ''final use container'' and how it relates to current labeling practice.

The term ''bulk or transport container'' is defined in proposed § 201.161(c)(3) to mean a container used to transport or store designated medical gases or medically appropriate combinations of designated medical gases and that is not used directly to administer such gases to a patient. This definition would cover storage tanks, storage banks, railcars, and tanker trucks. It would also include containers that are connected to medical gas supply systems (for example, cylinders connected to a hospital's oxygen system).

2. Description of Proposed Provisions

In § 201.1(b), FDA proposes to add certain operations that are required to produce a medical gas to the list of operations that are performed by its manufacturer for purposes of section 502(a) and (b)(1) of the FD&C Act and as used in the Agency's labeling regulations in part 201. FDA proposes that fabricating a medical gas by chemical reaction, physical separation, compression of atmospheric air, purification (*e.g.,* reprocessing an industrial gas into a medical gas), by combining two or more distinct medical gases, or by other process, would constitute an operation performed by a manufacturer. Medical gases are produced via several different processes, including air separation, chemical synthesis, and compression, and FDA believes the proposed language would address all such processes. However, under the proposed language, repacking or filling operations in which a finished medical gas is transferred from one container to another, including a container that contains the same medical gas (sometimes referred to as transfilling or ''curbside filling'' activities at the point of use), would not be considered an operation performed by a manufacturer for purposes of the labeling regulations in part 201 (note that transfilling would be considered a manufacturing activity for purposes of the proposed CGMP regulations under part 213), so long as those operations are limited to transferring finished gas from one container to another without any change or transformation of the gas. FDA also notes that this provision refers to ''medical gas'' instead of ''designated medical gas'' because the processes used to produce designated medical gases and other types of medical gases generally fit within the broad categories of processes described in the proposed language. The Agency believes that clarification is needed for all medical gases, and as such, FDA proposes to list operations that are required to produce a medical gas as operations that are performed by its manufacturer, regardless of whether the medical gas is a designated medical gas.

FDA proposes to revise § 201.10(d)(2) to specify the format for a statement of ingredients for designated medical gases. FDA proposes that the statement of the percentage of a designated medical gas in a drug product be expressed in percent volume/volume. The intent of this provision is to better clarify and consistently display the amount of each designated medical gas present in a container.

FDA proposes to revise § 201.51, which requires the label of a prescription drug in package form to bear a declaration of net quantity of contents. In paragraph (a), FDA proposes to clarify that the statement of quantity of designated medical gases and medically appropriate combinations thereof in a gaseous state shall be in terms of volume measure. In paragraph (b), FDA proposes to clarify that the statement of liquid measure currently described in the regulation would not apply to designated medical gases or medically appropriate combinations thereof. Rather, FDA proposes separate requirements for the declaration of net quantity in the labels of designated medical gases or medically appropriate combinations thereof in a:

• Gaseous state in a high-pressure container;

• Liquefied compressed gas state in a high-pressure container; or

• Liquefied state in a portable cryogenic container.

FDA recognizes that some reasonable level of product loss due to venting or evaporation is expected during manufacture; thus, minor deviations between the stated net quantity and the actual net quantity that result from normal venting over time would not cause the product to be misbranded. FDA believes that the information in 201.51(b)(1) through (3) can be included on a separate sticker or decal on the container, and need not be contiguous with other portions of required labeling. Under proposed § 201.51(b)(4), labeling for net quantity of contents is not required for bulk or transport containers, as defined in § 201.161(c)(3). Examples of such containers include storage tanks, storage banks, railcars, and tanker trucks.

FDA proposes that designated medical gases and medically appropriate combinations for animal use utilize the same labeling information as designated medical gases and medically appropriate combinations for human use. Accordingly, FDA proposes to amend § 201.105 to exempt designated medical gases and medically appropriate combinations from the misbranding requirements of section 502(f)(1) of the FD&C Act if they are in compliance with the labeling requirements of § 201.161. This proposal is intended to allow manufacturers to have one set of labeling that can be utilized for both human and animal use of their designated medical gases. Manufacturers will not necessarily know at the time of manufacture, filling, or distribution how their gas will be used. Additionally, FDA expects that requiring two separate sets of labeling would create a significant burden on industry with little or no benefit to product safety or patient outcomes. Because FDA is not aware of any reason to require different information for animal use, the Agency believes utilization of the same labeling for both human and animal use is appropriate.

FDA proposes several revisions to § 201.161 in addition to the proposed definitions described above. Under proposed paragraph (a), the requirements of section 503(b)(4) (concerning when a drug's label must bear the symbol ''Rx only'') and 502(f)

(requiring a drug's labeling to bear adequate directions for use and certain adequate warnings) of the FD&C Act are deemed to have been met for a designated medical gas or a medically appropriate combination of designated medical gases if the labeling on its final use container bears certain information depending on the specific gas or gases it contains. Each of the proposed revisions is described in turn below.

FDA proposes revisions to the statement describing the effect of compliance with this section. FDA proposes this revision to more closely align with section 576(a)(3)(A)(ii) of the FD&C Act. FDA does not believe it is necessary for § 201.161(a) to include exemptions from 21 CFR 201.100(b)(2), (3), and (c)(1), given that section 576(a)(3)(A)(ii) of the FD&C Act provides a separate way of satisfying the requirements of section 502(f) for designated medical gases.

FDA proposes to remove the list of gases in § 201.161(a) and instead refer to ''designated medical gas.'' FDA proposes these revisions to § 201.161 for consistency with section 576(a)(3)(A)(ii) of the FD&C Act. The proposed revisions would bring medical air and carbon monoxide that meet the definition of ''designated medical gas'' within the scope of § 201.161; these gases are not included in the list of gases in § 201.161 currently but are designated medical gases for which a certification can be granted under section 576 of the FD&C Act. Instead of adding medical air and carbon monoxide to the list of gases, FDA proposes to revise the first sentence to clarify that all designated medical gases and medically appropriate combinations thereof are within the scope of § 201.161(a). Should other medical gases be added to the definition of ''designated medical gas'' pursuant to section 575(1)(H) of the FD&C Act in the future, this proposed revision would make the provisions of § 201.161 applicable to such gases without the need to amend this regulation further. This proposed revision would also ensure that all designated medical gases other than oxygen, including medical air and carbon monoxide, and medically appropriate combinations of designated medical gases are required to bear the label statements in proposed § 201.161(a)(2) in order for sections 503(b)(4) and 502(f) to be deemed to be met for such gas or gases.

FDA proposes to remove the language in § 201.161 referencing §§ 201.328 and 211.94(e)(2). FDA believes it is unnecessary for § 201.161 to reference compliance with §§ 201.328 and 211.94(e)(2) as a condition for sections 503(b)(4) and 502(f) to be deemed to be met.

Additionally, FDA proposes to revise paragraph (a) to require that the final use container of a designated medical gas or medically appropriate combination of gases must bear the required information in order for sections 503(b)(4) and 502(f) to be deemed to be met for such gas or gases. This proposed revision is intended to clarify that the warnings, directions, and other information in § 201.161(a) must appear in the labeling of the final use container of a designated medical gas or medically appropriate combination of designated medical gases in order for the requirements of sections 503(b)(4) and 502(f) of the FD&C Act to be deemed to be met for such gas or gases, consistent with the requirements in section 576(a)(3)(A)(ii) of the FD&C Act.

In the case of oxygen, FDA proposes to require the final use container to bear a warning statement providing the following (§ 201.161(a)(1)(i)):

- Uninterrupted use of high concentrations of oxygen over a long duration, without monitoring its effect on oxygen content of arterial blood, may be harmful;
- oxygen should not be used on patients who have stopped breathing unless used in conjunction with resuscitative equipment; and
- in the case of oxygen that may be provided without a prescription for use in the event of depressurization or other environmental oxygen deficiency, or for oxygen deficiency or for use in emergency resuscitation when administered by properly trained personnel, a warning that the oxygen can be used for emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation, and that for all other medical applications a prescription is required.

This is the same information currently required in § 201.161(a)(1)(i) for oxygen. FDA believes this information is important to convey the risks of using oxygen and is consistent with the requirements in section 576(a)(3)(A)(ii) and (b)(2) of the FD&C Act.

FDA proposes § 201.161(a)(1)(ii), which would require clear and prominent ''no smoking'' and ''no vaping'' warning statements and a graphic warning symbol on the label of oxygen final use containers indicating that smoking, vaping, and open flames near oxygen are dangerous. Such a graphic symbol may be based on those created by standards development organizations. FDA is aware of numerous instances of fires related to the medical use of oxygen, most often related to individuals smoking in the vicinity of an oxygen tank in operation. Additionally, FDA has become aware of some reports that vaping products [6] have been linked to medical oxygen fires and explosions (Refs. 3 to 6). These events can cause death and serious injury to the patient, as well as cohabitants, neighbors, and first responders. Oxygen cylinders generally contain warnings regarding keeping oil, grease, combustibles, heat, sparks, and flame away from the product (though language varies from cylinder to cylinder). However, this language is generally in very fine print, is not expressed in a manner that is clear to lay users, and does not mention smoking or vaping directly. The purpose of this proposed provision is to include in product labeling a plain-language warning against smoking, vaping, or using open flames near an operating oxygen tank. Because many patients on oxygen therapy have smoking-related illnesses, and because some patients may continue to smoke or vape during treatment, FDA believes that the proposed warning will help mitigate the risk of fires during the administration of oxygen. The proposed ''no smoking'' and ''no vaping'' warning statements and graphic symbol may appear on a separate sticker or decal displaying the information on the container or be painted directly on the container. The Agency will continue to consider other risks of combustion as well.

In the case of all designated medical gases other than oxygen, and in the case of medically appropriate combinations of designated medical gases, FDA proposes to require the final use container to bear the following information (§ 201.161(a)(2)(i) and (ii)):

- A warning statement providing that the administration of the gas or gas combination (as applicable) may be hazardous or contraindicated; and
- a warning statement providing that the gas or gas combination (as applicable) should be used only by or under the supervision of a licensed practitioner who is experienced in the use and administration of the gas or gas combination (as applicable) and is familiar with the indications, effects, dosages, methods, and frequency and duration of administration, and with the hazards, contraindications, and side effects and the precautions to be taken.

This is the same information currently required in § 201.161(a)(1)(ii) for the listed gases other than oxygen, as well

[6] The term ''vaping products'' includes vapes or vape pens, personal vaporizers, e-cigarettes, cigalikes, e-pens, e-hookahs, e-cigars, e-pipes and other battery-operated tobacco products in addition to other non-nicotine vape products.

as for medically appropriate combinations of the listed gases. In addition, FDA proposes to require that the labeling on the final use container of designated medical gases other than oxygen and medically appropriate combinations of designated medical gases bear the symbol ''Rx only.'' FDA believes this information is important to convey the risks of using these gases and is consistent with the requirements in section 576(a)(3)(A)(ii) and (b)(1) of the FD&C Act.

Under proposed § 201.161(a)(3), the labeling on the final use container for all designated medical gases and medically appropriate combinations thereof would be required to bear appropriate directions and warnings concerning storage and handling. FDA believes this proposed revision is consistent with the current requirement in § 201.161(a)(2). The Agency proposes this revision to reflect the language in section 576(a)(3)(A)(ii)(III) of the FD&C Act on this issue.

The Agency has received comments recommending that it issue a separate warning statement requirement for medical air that states that medical air may be used without a prescription for breathing support when administered by properly trained personnel. FDA has decided not to propose a warning statement for medical air that is different from the warning statement proposed for designated medical gases other than oxygen, nor does FDA otherwise propose to exercise its authority under section 503(b)(3) of the FD&C Act to remove medical air from the requirements of section 503(b)(1). In the 2016 final rule entitled ''Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements,'' FDA responded to comments asserting that certain non-prescription uses of medical air are medically appropriate by deciding not to finalize its proposal to add medical air to the list of gases at § 201.161(a) and stating that it would continue to consider what would constitute an appropriate warning statement for medical air (81 FR 81685 at 81689; November 18, 2016). Since the publication of the 2016 final rule, FDA has continued to consider this issue, and the Agency remains unaware of any uses for medical air that would be appropriate for nonprescription use, and no new information supporting such uses has been provided since the Agency last addressed this issue in a citizen petition response to the Compressed Gas Association (Ref. 7). FDA believes that medical air intended for use by properly trained personnel in a healthcare setting should remain a prescription use subject to the requirements of section 503(b)(1) of the FD&C Act. The Agency specifically requests comment on this issue.

Proposed new § 201.161(b) would create separate labeling requirements for bulk or transport containers used for designated medical gases or medically appropriate combinations of designated medical gases. FDA proposes to require that such containers be identified with the name of the product contained therein and be accompanied by documentation identifying the product as meeting applicable compendial standards. As discussed in this section, bulk or transport containers are excluded from the proposed definition of final use containers. Because these large containers are generally removed from the point of care and are not expected to be used directly to administer a designated medical gas or medically appropriate combination of designated medical gases to a patient, FDA does not believe that such containers need to bear the information that would be required under proposed § 201.161(a). However, it is essential that the identity of the gas or gases inside such containers is evident to individuals handling and transporting the containers in order to prevent mix-ups. Many firms in the supply chain for medical gases, including those firms downstream from the manufacturers that initially produce the gas, receive and distribute gases for medical and non-medical use, and some non-medical gases may not meet compendial standards applicable to designated medical gases. Therefore, this proposal would require that a bulk or transport container bears the name of the designated medical gas or medically appropriate combination of designated medical gases contained therein, and that the accompanying documentation identifies that the product meets applicable compendial standards. These proposed requirements are expected to help prevent mix-ups and ensure that recipients of designated medical gases or medically appropriate combinations thereof in bulk or transport containers are provided information indicating that such gases meet applicable compendial standards.

In § 201.328(a)(1), FDA proposes technical changes to reflect that the requirements in § 211.94(e)(2) are proposed to be moved to § 213.94(e)(3). See section V.B.1 for more information on this proposed revision.

Proposed new § 201.328(d) would provide that the owner of a designated medical gas container or a container of a medically appropriate combination of designated medical gases may be identified on the container. This statement may appear on a separate sticker or decal on the container and need not be contiguous with other labeling on the container, but if the container owner is not the manufacturer, packer, or distributor of the gas, that shall be clearly stated. FDA recognizes the complex distribution system for designated medical gases and medically appropriate combinations of designated medical gases and the importance of allowing container owners to be clearly identified so that patients and healthcare professionals can contact the container owners if necessary. This provision is intended to help ensure that appropriate entities can be contacted regarding quality issues or adverse events. It is additionally intended to facilitate the return of cylinders to owners that may not also be medical gas manufacturers. The proposed inclusion of the container owner's information would not cause the container owner to be a ''relabeler'' for purposes of FDA's registration and listing requirements.

B. Proposed Current Good Manufacturing Practice Provisions

FDA proposes the establishment of part 213, which would contain the CGMP requirements for preparation of medical gases, including designated medical gases, for administration to humans or animals. If finalized as proposed, medical gases proposed to be subject to part 213 would no longer be subject to part 211. FDA also proposes conforming edits to part 210 so that applicable provisions would reflect the new CGMP regulations for medical gases in part 213. As proposed, part 213 would apply to the entity that initially produces a medical gas and also to any downstream firms that manufacture, process, pack, or hold medical gases, including firms that combine, commingle, refill, or distribute designated medical gases and medically appropriate combinations thereof. Part 213 is not intended to apply to entities further upstream in the supply chain from the entity that initially produces a medical gas. FDA seeks comment on the scope of these requirements, including the stage of product development at which they would apply and the entities that would be subject to the requirements. In this section, FDA will first describe proposed revisions to parts 210 and 211. Then FDA will describe the proposed requirements in part 213, including how they would differ from the requirements in part 211. Lastly, FDA will describe certain groups of CGMP requirements under part 211 that FDA is not proposing in part 213.

1. Proposed Revisions to Parts 210 and 211

FDA proposes conforming edits to parts 210 and 211 to account for the proposed new part 213. In part 210, FDA proposes to add references to part 213 in § 210.1(a) and (b) and in § 210.2(a) and (b) so that applicable provisions in part 210 would reflect the new CGMP regulations for medical gases in part 213.

In § 211.1(a), FDA proposes to add ''medical gases as defined in § 213.3(b)(12)'' to the parenthetical that currently excludes positron emission tomography drugs from part 211. Proposed part 213 would contain the CGMP requirements for medical gases.

FDA also proposes to delete § 211.94(e). Instead, proposed § 213.94 would contain updated requirements for medical gas containers and closures that are generally consistent with the current requirements in § 211.94(e), with some additional provisions. More information is in section V.B.6 of this document.

FDA proposes to delete the last sentence of § 211.125(c), which waives labeling reconciliation requirements for 360° wraparound labels on portable cryogenic medical gas containers because labeling reconciliation for medical gases would be addressed by proposed § 213.125(b).

FDA proposes to delete the reference to ''containers of compressed medical oxygen'' in § 211.132(c)(1), which is in a parenthetical that excludes certain products from the requirement for each retail package of an over-the-counter drug product covered by § 211.132 to bear a particular statement regarding its tamper-evident features. This reference would no longer be relevant if this proposed rule is finalized because medical gases (including compressed medical oxygen) would no longer be subject to part 211.

FDA proposes to delete the statement in § 211.170(b) that reserve samples of compressed medical gases need not be retained. Under the proposed rule, medical gases would be subject to proposed part 213, which would not include reserve sample requirements.

FDA proposes to delete the exception in § 211.196 that distribution records for compressed medical gas products are not required to contain lot or control numbers because distribution records requirements for medical gases would be addressed by proposed § 213.196.

2. General Provisions

Section 213.1 explains the scope of FDA's proposed CGMP requirements for medical gases. Proposed part 213 would contain the minimum CGMP requirements for preparation of all medical gases for administration to humans or animals, including designated medical gases, medically appropriate combinations of designated medical gases, medical gases that are approved under an application that was submitted to FDA under section 505 or 512 of the FD&C Act, and any marketed unapproved drugs that are medical gases. Because designated medical gases and other kinds of medical gases share many of the same physical characteristics and are manufactured, processed, packed, and held using similar operations and control strategies, FDA believes that continuing to have a single set of CGMP requirements for all medical gases is appropriate.

FDA does not consider the process of mixing or combining gases by a hospital or healthcare provider at the point of care and as part of the ordinary practice of treating individual patients to be activities subject to part 213.

Part 213 applies to all designated medical gases and medically appropriate combinations thereof, regardless of whether they are intended for use in humans, animals, or both.

Proposed § 213.3 includes several definitions that generally track those in part 210, some of which have been revised to tailor them more specifically to medical gases. Proposed § 213.3 also contains new definitions that are relevant to the manufacture, processing, packing, and holding of medical gases. Proposed paragraph (a) would generally apply the definitions and interpretations in section 201 of the FD&C Act to such terms when used in proposed part 213. Proposed paragraph (b) contains additional definitions as follows:

- The term ''acceptance criteria'' is proposed to be defined in § 213.3(b)(1) to mean the product specifications and acceptance/rejection criteria, such as acceptable quality level and unacceptable quality level, with an associated sampling plan, that are necessary for making a decision to accept or reject a lot or batch (or any other convenient subgroups of manufactured units). This is identical to the definition of the same term in part 210. The Agency believes that establishing clear product specifications and acceptance/rejection criteria for determining whether a lot or batch is acceptable will help ensure the identity, strength, quality, and purity of medical gases.
- Proposed § 213.3(b)(2) would define the term ''batch'' to mean ''a specific quantity of a medical gas or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.'' This is generally consistent with the definition of the same term in part 210. The Agency believes this definition would allow for significant flexibility in defining a batch to address considerations raised by different types of firms and different manufacturing, processing, packing, and holding activities.
- The term ''commingling or commingled'' is proposed to be defined in § 213.3(b)(3) to refer to the act of combining one lot of designated medical gas or component with another lot or lots of the same designated medical gas or component. This is primarily intended to reflect the industry practice of combining designated medical gases of the same identity (*e.g.,* nitrogen and nitrogen) from multiple original manufacturers or lots, all of which meet compendial standards. This definition would be new in part 213.
- In proposed § 213.3(b)(4), the term ''component'' is revised. Compared to the definition in § 210.3(b)(2) it means any ingredient intended for use in the manufacture of a medical gas, including those that may not appear in such gas. The term does not include incoming designated medical gases. Different proposed requirements in part 213 would apply to components and incoming designated medical gases. These proposed requirements are described further in section V.B.6 of this proposed rule.
- Proposed § 213.3(b)(5) defines the term ''designated medical gas.'' This definition refers to the statutory definition found in section 575(1) of the FD&C Act and is intended to apply to the gases described in section 575(1) of the FD&C Act.
- FDA also proposes to add a definition of the term ''FDA'' in § 213.3(b)(6) to mean the Food and Drug Administration. This is consistent with other Agency regulations that contain a definition of FDA.
- Proposed § 213.3(b)(7) defines the term ''in-process material'' to mean ''any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and used in, the preparation of the medical gas.'' This is generally consistent with the definition of the same term in part 210.
- FDA proposes in § 213.3(b)(8) to define ''incoming designated medical gas'' to mean a designated medical gas received from one source that is commingled with the same gas from another source, used in a medically appropriate combination of designated medical gases or in the production of

another medical gas, or further distributed. This definition is intended to cover designated medical gases that downstream entities receive from original manufacturers and other sources. However, incoming gases that are not designated medical gases but that are intended for use in the manufacture of a medical gas would be considered components. As described above, FDA proposes different requirements for components and incoming designated medical gases. This definition would be new in part 213.

• In proposed § 213.3(b)(9), the term ''lot'' is defined to mean a batch, or a specific identified portion of a batch, having uniform character and quality within specified limits. In the case of a medical gas produced by continuous process, the term means a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits. This is generally consistent with the definition of the same term in part 210.

• FDA proposes to define ''lot number, control number, or batch number'' in § 213.3(b)(10) to mean ''any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of medical gas or other material can be determined'' (§ 213.3(b)(11)). This is generally consistent with the definition of the same term in part 210.

• In proposed § 213.3(b)(11), the term ''manufacture, processing, packing, or holding'' is defined to include packaging and labeling operations, testing, and quality control of medical gases. This is generally consistent with the definition of the same term in part 210 because many provisions refer to these actions, and FDA intends that they have the same meaning as in part 210. FDA considers packaging in the context of these proposed requirements to include filling a container with a medical gas.

• FDA proposes in § 213.3(b)(12) that the term ''medical gas'' has the meaning given the term in section 575(2) of the FD&C Act. This would include designated medical gases, medically appropriate combinations of designated medical gases, medical gases that are approved under an application that was submitted to FDA under section 505 or 512 of the FD&C Act, and any marketed unapproved drugs that are medical gases. This term would not include gases that are used as excipients in drug products that are not medical gases (*e.g.,* propellants in inhalation drugs).

• FDA proposes to define ''original manufacturer'' in § 213.3(b)(13) to include persons or entities that initially produce a designated medical gas by chemical reaction, physical separation, compression of atmospheric air, purification of a gas, or other means. FDA's intent is to capture the various methods by which firms produce designated medical gases. A person who refills a designated medical gas into a new container, either for further distribution or at the delivery site, would not be considered an original manufacturer. Additionally, a person who creates a medically appropriate combination of designated medical gases would not be considered an original manufacturer. This proposed definition would be new in part 213.

• FDA's proposed definition of ''quality unit'' in § 213.3(b)(14) is any person or persons designated with the authority and responsibility for overall quality management and other responsibilities as defined in § 213.22. Under proposed part 213, the quality unit's responsibilities would include oversight of quality throughout the entire manufacturing process. We are proposing to use the term ''quality unit'' because the Agency believes this term more appropriately reflects current terminology. As FDA has previously noted, the Agency considers ''quality control unit'' (defined in § 210.3(b)(15)) and ''quality unit'' to be synonymous. FDA proposes an updated definition for part 213 that focuses on ''overall quality management'' rather than quality control. The Agency believes that this definition would better reflect industry practice and the Agency's understanding of the responsibilities of the quality unit.

• FDA's proposed definition of ''strength'' in § 213.3(b)(15) is generally consistent with the definition in part 210, and contains two parts: (1) The concentration of the medical gas (for example, weight/weight, weight/volume, or unit dose/volume basis), and/or (2) the potency, that is, the therapeutic activity of the medical gas as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data (expressed, for example, in terms of units by reference to a standard).

FDA seeks comment on whether there are other terms, including those that are used in this proposed rule or in parts 210 and 211, that the Agency should define in part 213.

3. Organization and Personnel

Proposed § 213.22 describes the responsibilities of the quality unit and is similar in scope to § 211.22. Proposed paragraphs (a) through (d) are generally consistent with paragraphs (a) through (d) in § 211.22, with one notable change: FDA proposes to use the term ''quality unit'' instead of ''quality control unit.'' Paragraph (a) would require that there be a quality unit with the responsibility and authority to approve or reject all components, medical gas containers and closures, in-process materials, packaging material, labeling, and medical gases, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. Additionally, the quality unit would be responsible for approving or rejecting medical gases manufactured, processed, packed, or held under contract by another company. The Agency believes that assigning dedicated staff to these quality responsibilities is critical to ensuring the identity, strength, quality, and purity of the medical gas.

Paragraph (b) would require that there be made available to the quality unit adequate laboratory facilities for the testing and approval (or rejection) of components, medical gas containers and closures, packaging materials, in-process materials, and medical gases. The availability of such facilities would help the quality unit perform its functions.

Under paragraph (c), the quality unit would have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the medical gas. The Agency believes this provision would provide clarity regarding these responsibilities and that the quality unit is best positioned to determine whether these procedures and specifications are appropriate.

Paragraph (d) would state that the responsibilities and procedures applicable to the quality unit shall be in writing and shall be followed. The Agency believes this would help provide additional assurance for reliable continuation of established policies and procedures regarding product quality.

Paragraph (e) would clarify that quality unit personnel may perform other functions if there are appropriate written controls in place to ensure such other functions are performed separately from quality unit responsibilities and such other functions do not interfere with the quality unit's responsibilities or subordinate the quality unit's responsibilities to any other unit. Small

firms that manufacture, process, pack, or hold a drug, including medical gases, have limited personnel who may have multiple roles within the firm. So long as there are appropriate written controls in place to ensure that other functions do not interfere with the quality unit's responsibilities or subordinate the quality unit's responsibilities to any other unit, FDA considers it acceptable for quality unit personnel to perform these other functions.

Proposed § 213.25 addresses personnel qualifications and responsibilities. Paragraph (a) would contain requirements for personnel education, training, and experience that are generally consistent with those contained in § 211.25, except as described below. Under proposed § 213.25(a), persons engaged in the manufacture, processing, packing, or holding of a medical gas would be required to have the education, training, and experience (or any combination thereof) to enable them to perform assigned functions. Training would have to be in the employee's particular operations and in CGMP (including in the applicable CGMP regulations and written procedures required thereunder). Training in CGMP would have to be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them. FDA proposes to specify in § 213.25(a) that written documentation must be maintained demonstrating employees' completion of training, including the date, type of training, and results of any completion criteria, such as test results. The Agency believes that these requirements would be sufficient to allow firms to maintain properly trained staff capable of accomplishing all required tasks. This paragraph would apply to all personnel engaged in the manufacture, processing, packing, or holding of a medical gas, including supervisors and subordinates. Therefore, we are not proposing a separate requirement similar to § 211.25(b) regarding supervisor responsibilities in this proposed rule.

Paragraph (b) would require that there be an adequate number of qualified personnel to perform manufacturing, processing, packing, and holding activities for each medical gas. The scope of this proposed requirement is the same as in § 211.25(c). This proposed requirement is important to ensure that all steps related to manufacturing, processing, packing, and holding are performed or monitored appropriately. What would constitute ''adequate'' personnel would depend in part on the size and complexity of the operations being performed.

Paragraph (c) would restrict access to ''limited-access areas'' to authorized personnel only. This proposed requirement is the same as § 211.28(c) and is important for medical gases because of the danger associated with mishandling medical gases and the risks to patients if such gases are improperly manufactured.

In § 213.34, FDA proposes requirements regarding consultants that are generally consistent with requirements that currently apply to medical gases under § 211.34. FDA does not see a need for different training and experience requirements for consultants advising on medical gases compared to other drug products. Consultants would be required to have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Further, records would be required to be maintained that state the name, address, and qualifications of any consultants and the type of service they provide.

4. Buildings and Facilities

FDA proposes a more limited set of building and facilities requirements for the manufacture, processing, packing, or holding of medical gases compared to part 211. FDA's primary concern regarding buildings and facilities used for these products is the risk of mix-ups because multiple gases are often produced at these buildings and facilities, and a gas mix-up could lead to patient harm. Additionally, while the risk of contamination is diminished for medical gases because they are generally manufactured in a closed, sealed system, periodic cleaning and maintenance is necessary for all buildings and facilities, so buildings and facilities must be designed to facilitate such cleaning and maintenance. The proposed requirements in this subpart are intended to address these risks, taking into account the unique manufacturing processes for medical gases.

Proposed § 213.42(a) would require that buildings and facilities used in the manufacture, processing, packing, or holding of a medical gas be of adequate design, including adequate space, for the orderly placement of equipment and materials to prevent mix-ups and allow for adequate cleaning, maintenance, and proper operations. Specifically, buildings and facilities would be required to be of adequate design to prevent mix-ups between components, incoming designated medical gases, medical gas containers and closures, labeling, in-process materials, or medical gases. FDA proposes to specify ''buildings and facilities'' in this section and elsewhere because some medical gas operations, including storage, can be performed outdoors without affecting the safety, identity, strength, quality, and purity of the product. FDA expects that there will be multiple ways of achieving adequate design and adequate space for all manufacturing operations that prevent mix-ups and allow for necessary cleaning and maintenance. Multiple gases are often manufactured at the same facility, and a mix-up could result in a patient receiving the wrong gas, which could be fatal. Therefore, it is essential that buildings and facilities be designed to enable personnel to clearly identify which equipment and materials are being used for which gas, to avoid such mix-ups. Moreover, while contaminants such as ordinary dust and dirt are unlikely to enter a closed system, such contamination can still occur, for example, at the point at which a gas is transferred from one container to another.

Proposed § 213.42(b) would require that operations be performed within specifically defined areas of adequate size, with separated or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination or mix-ups during the following procedures:

- Receipt, identification, storage, and withholding from use of components or incoming designated medical gases, medical gas containers and closures, and labeling, pending the appropriate sampling, testing, or examination by the quality unit before release for manufacturing or packaging;
- Holding rejected components, incoming designated medical gases, medical gas containers and closures, and labeling before disposition;
- Storage of released components, incoming designated medical gases, medical gas containers and closures, and labeling;
- Storage of in-process materials;
- Manufacturing and processing operations;
- Packaging and labeling operations;
- Quarantine storage before release of medical gases;
- Storage of medical gases after release; and
- Control and laboratory operations.

Where multiple gases are being produced at the same facility, it is important for staff to be able to easily determine which gas is being manufactured in each area of the facility. These requirements will also help personnel distinguish between received, in-process, and finished product. FDA anticipates that firms can

meet this requirement with physical barriers, signage, or both, though firms may use other appropriate means. Proposed § 213.42(b) would further require that the flow of components, incoming designated medical gases, containers, closures, labeling, in-process materials, and medical gases be designed to prevent contamination and mix-ups.

Under proposed § 213.42(c), any building or facility used in the manufacture, processing, packing or holding of a medical gas shall be maintained in a clean condition so as to assure the safety, identity, strength, quality, and purity of the gas. Additionally, § 213.42(c) would require that written procedures applicable to the maintenance and cleaning of buildings and facilities be established and followed. FDA believes this proposed requirement is more limited than the sanitation requirement in § 211.56(a), and that it is better tailored to medical gas production, which involves a generally lower risk of contamination than other drug products. The condition of buildings and facilities that would be considered clean for medical gas production is expected to be different from the condition of buildings and facilities that would be considered clean for production of other drug products, where greater risks of contamination generally exist.

5. Equipment

Subpart D contains proposed requirements for equipment. Proposed § 213.63 would require that equipment be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. FDA expects that the design of the facility and equipment will allow for appropriate cleaning and maintenance (for example, personnel can access all equipment that must be cleaned). FDA expects that firms will ensure that pigtails, valves, hoses, and similar connectors are kept clean and maintained.

Proposed § 213.65 addresses equipment construction and is similar to § 211.65. Paragraph (a) would require that equipment be constructed so that surfaces that contact components, in-process materials, or medical gases are not reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the medical gas beyond the official or other established requirements. Paragraph (b) would require that substances required for operations, such as lubricants or coolants, shall not come into contact with components, containers, closures, in-process materials, or medical gases so as to alter the safety, identity, strength, quality or purity of the medical gas beyond the official or other established requirements.

FDA proposes equipment maintenance and cleaning requirements under § 213.67. These proposed requirements differ from those that currently apply to medical gases under § 211.67 and reflect the differences in appropriate practices for routine cleaning of equipment associated with the manufacturing, processing, packing, and holding of medical gases. Paragraph (a) would require that written procedures be established, maintained, and followed for adequate cleaning and maintenance of equipment. Procedures would be required to include the following:

- Assignment of responsibility for cleaning and maintaining equipment;
- maintenance and cleaning schedules, including, where appropriate, sanitizing schedules;
- a sufficiently detailed description of the methods, equipment, and materials used in cleaning and maintenance, as well as the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance;
- removal or obliteration of previous batch identification;
- protection of clean equipment from contamination prior to use; and
- inspection of equipment for cleanliness immediately before use.

FDA anticipates that these procedures would address, among other things: Cleaning, or verifying as clean, equipment and product contact surfaces prior to initial use, after potential exposure to a contaminant, or as part of maintenance if such maintenance may expose the product contact surfaces to potential contamination; maintaining equipment at appropriate intervals to prevent malfunctions or contamination; and inspecting or testing systems prior to returning to service, to assure that no residual cleaning agents are present.

Proposed paragraph (b) specifies that such procedures shall not alter the safety, identity, strength, quality, or purity of the medical gas beyond established requirements.

Paragraph (c) would require that records be kept of cleaning, maintenance, and inspection as specified in § 213.180.

Proposed § 213.68 addresses requirements for automatic, mechanical, and electronic equipment used in the manufacture of medical gases. Paragraph (a) would require that such automatic, mechanical, and electronic equipment be routinely calibrated, inspected, and checked, according to a written program designed to ensure proper performance, and that written procedures and records of calibration, inspections, and checks be maintained. Ensuring that automated, mechanical, and electronic equipment is properly functioning is critical to ensuring the safety, strength, identity, quality, and purity of a gas. Without such checks, firms could manufacture gases that fail to meet compendial standards, or that are not appropriate for the ultimate patients' needs.

Paragraph (b) would require validation of computerized systems that record, store, or use data. The validation necessary would depend on how the computerized system is used in the manufacturing process.

In paragraph (c), FDA would require the maintenance of backup files of data entered into computer systems, though such backups would not be required where certain data, such as calculations, are eliminated by computerization or other automated processes.

Paragraph (d) would require that appropriate change control be used whenever modifications are made to computerized systems to assure that any changes do not adversely affect data integrity or product quality. FDA expects that this will include that manufacturers evaluate proposed changes with affected departments, that the proposed changes are assessed for revalidation where appropriate, and that activities are documented. Records would also be required to be maintained of such modifications.

6. Control of Incoming Designated Medical Gas, Components, and Medical Gas Containers and Closures

Subpart E contains proposed requirements for control of incoming designated medical gases, components, and medical gas containers and closures. Proposed § 213.80(a) and (b) are similar to paragraphs (a) and (b) of § 211.80, though the proposed requirements would also apply expressly to incoming designated medical gases. Paragraph (a) would require sufficiently detailed written procedures to be developed and followed describing the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components, incoming designated medical gases, and medical gas containers and closures. Paragraph (b) would require that components, incoming designated medical gases, and medical gas containers and closures be handled and stored in a manner to prevent contamination and mix-ups. As previously mentioned, medical gases are

generally manufactured in a closed, pressurized system, and gas mix-ups generally pose a more significant risk than contamination, considering previous incidents in which patients were administered the wrong gas (Ref. 8). However, while contamination poses a lower risk, there still exists the possibility for contamination. FDA believes that different controls would likely be appropriate for medical gas manufacturers to prevent contamination than would be expected for producers of other drugs.

Proposed paragraph (c) would require that lots of incoming designated medical gases or components be assigned a unique identification number, regardless of whether the incoming lot is used directly as supply or commingled with an existing supply. This would help facilitate the tracing of product once it enters distribution.

FDA is not proposing that part 213 include the requirements described in paragraphs (c) and (d) in § 211.80. FDA believes it is unnecessary to include the requirement in § 211.80(c) that product be stored off the floor and suitably spaced to permit cleaning and inspection. Sealed medical gas containers are designed to protect gases from contamination and external conditions, and their size and weight make storage off the floor impracticable in many settings. FDA also is not proposing to include in part 213 the requirement in § 211.80(d) that each container or grouping of containers for components or drug product containers, or closures be identified with a distinctive code for each lot in each shipment received. Gas containers are reused, and inspection of containers prior to reuse would be required under proposed § 213.84(a). Thus, FDA believes that other lot identification requirements in proposed part 213 are sufficient to track product.

Proposed § 213.82 addresses the receipt and storage of incoming designated medical gases. The proposed requirements differ from currently applicable requirements in § 211.82 to better reflect the use of incoming designated medical gases in further manufacturing. Under proposed paragraph (a), a firm would have to verify and record upon receipt of a designated medical gas that the shipment contains a signed certificate of analysis (COA) from the supplier, and that the COA contains the following:

- The supplier's name;
- the name of the incoming designated medical gas;
- the lot number or another unique identification number;
- the actual analytical result obtained for strength, as well as the results of other tests performed (FDA expects these tests would include tests sufficient to demonstrate conformance with compendial standards);
- identification of the test method(s) used for analysis;
- the NDA and/or NADA number of the incoming designated medical gas; and
- the supplier representative's signature and the date of signature.

If the incoming designated medical gas is obtained from a supplier other than the original manufacturer, the shipment would also have to include complete information from the original manufacturer's COA. The firm would also be required to establish and maintain a program to ensure the reliability of the supplier's capabilities through appropriate assessment and testing procedures. This is essential to ensuring that the information in the COA is accurate, and thus that the incoming designated medical gas meets relevant standards.

Proposed paragraph (b) would require that an identity test be conducted on incoming designated medical gases upon receipt. FDA understands that this is consistent with current industry practice (Ref. 2), and because designated medical gas manufacturers supplying the gas will conduct full compendial testing, and the firm receiving the incoming designated medical gas would conduct full compendial testing prior to release (see proposed § 213.165), FDA believes this is an appropriate level of review.

FDA proposes § 213.84 regarding testing and approval or rejection of components, containers, and closures. Paragraph (a) would require that components, containers, and closures (including valves) be examined for conformance with appropriate written procedures and specifications, and approved or rejected, prior to the manufacturing or filling process. Firms can meet this proposed requirement by testing for conformance with written specifications. In lieu of such examination by the firm, a statement of verification that the component, container, or closure meets specifications may be accepted from the supplier, provided that the firm establishes and maintains a program to ensure the reliability of the supplier's capabilities through appropriate assessment and testing provisions. This requirement would be satisfied with an auditing system. This type of evaluation system is intended to ensure the integrity of components, containers, and closures for the entire period of use. Rejected items would need to be handled in accordance with § 213.89.

Under proposed paragraph (b), firms would be required to take appropriate actions to protect against container and closure leaks. This would include performing leak tests on containers and closures at the time of fill and after fill but prior to release. FDA has evaluated inspectional findings from 2003 to 2021 and identified numerous instances of leaking or empty containers reported by customers and patients, following release by the manufacturer (Ref. 9). Because of the location and delayed timing of these defects, it appears some are likely not detectable prior to release. Therefore, additional controls may be needed to further protect against container and closure leaks to provide sufficient assurance of the durability of the container closure system throughout its period of use. For example, the inclusion of representative leak tests at additional intervals, such as upon pick-up or receipt of the container by the manufacturer, may be an additional adequate control. FDA seeks comment, with related data and explanation, from manufacturers, distributors, and end users of medical gases and other interested parties on whether leak testing at the time of fill and after fill but prior to release would sufficiently ensure the integrity of the container closure system for the period of use, and whether additional periodic leak tests would enhance the ability to correct and prevent container closure defects that are only detectable after they leave the manufacturer.

Proposed paragraph (c) would require that components be sampled, tested, and approved or rejected as appropriate prior to use. Firms would be able to meet this proposed requirement by performing testing for conformance with written specifications or by an identity test on the component accompanied by an acceptable COA from the supplier, provided that the firm establishes and maintains a program to ensure the reliability of the supplier's capabilities through appropriate assessment and testing procedures. Components are not always used in the manufacture of designated medical gases, but when they are used, FDA believes these proposed requirements are reasonable.

Proposed § 213.89 is similar to the requirements in § 211.89 in that rejected components, containers, and closures would need to be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable, but proposed § 213.89 would also apply to incoming designated medical gases.

Such a quarantine system need not include physical quarantining, as other methods can adequately ensure that unsuitable products are not used. FDA proposes to add a requirement that rejected components, incoming designated medical gases, and medical gas containers and closures be documented and assessed. This additional proposed requirement would help to ensure that any trends that warrant further investigation can be identified.

Proposed § 213.94 would contain additional requirements for medical gas containers and closures. Paragraph (a) is generally consistent with the requirements in § 211.94(a) and would require that containers and closures not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the medical gas beyond the official or established requirements.

Under paragraph (b), container closure systems would be required to provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the medical gas. This is generally consistent with the requirements in § 211.94(b).

Paragraph (c) would require that medical gas containers and closures be clean to assure that they are suitable for their intended use. This is generally consistent with § 211.94(c), but FDA does not propose to include the requirements related to sterilization or removal of pyrogenic properties, as those are not relevant to medical gases.

Under proposed paragraph (d), standards or specifications, methods of testing, and, where indicated, methods of cleaning shall be written and followed for medical gas containers and closures. This is generally consistent with § 211.94(d), but FDA does not propose to include the requirements related to sterilization or removal of pyrogenic properties, as those are not relevant to medical gases.

Proposed paragraph (e) is a revised version of § 211.94(e) and would contain requirements for medical gas containers and closures. In paragraph (e)(1), FDA proposes that portable cryogenic medical gas containers that are not manufactured with permanent gas use outlet connections (*e.g.,* those that have been silver-brazed) must have gas-specific use outlet connections that are attached to the valve body so that they cannot be readily removed or replaced (without making the valve inoperable and preventing the container's use) except by the manufacturer. Proposed § 213.94(e)(1) is consistent with § 211.94(e)(1). Consistent with § 211.94(e)(1), FDA proposes to define ''manufacturer'' for purposes of § 213.94(e)(1) to include any individual or firm that fills high-pressure medical gas cylinders or cryogenic medical gas containers. The Agency believes only such manufacturers should be able to remove or replace gas-specific use outlet connections that are attached to the valve body. Also, consistent with § 211.94(e)(1), FDA proposes to define ''portable cryogenic medical gas container'' for purposes of § 213.94(e)(1) as one that is capable of being transported and is intended to be attached to a medical gas supply system within a hospital, healthcare entity, nursing home, other facility, or home healthcare setting, or is a base unit used to fill small cryogenic gas containers for use by individual patients. The term would not include cryogenic containers that are not designed to be connected to a medical gas supply system, *e.g.,* tank trucks, trailers, rail cars, or small cryogenic gas containers for use by individual patients (including portable liquid oxygen units as defined at § 868.5655). The Agency believes all portable cryogenic medical gas containers should have gas-specific use outlet connections that are attached to the valve body in order to prevent gas mix-ups. FDA seeks comment regarding whether the scope of the exception to the term ''portable cryogenic medical gas container'' is appropriate, especially as the exception would include small cryogenic containers for use by individual patients.

Under paragraph (e)(2), FDA proposes to add the requirement that portable cryogenic medical gas containers as defined in proposed § 213.94(e)(1) as well as small cryogenic gas containers for use by individual patients (including portable liquid oxygen units as defined in § 868.5655) have a working gauge sufficient to indicate whether the container has an adequate supply of medical gas for continued use. This is intended to enable end users, such as healthcare practitioners, patients, and caretakers, to monitor the gas remaining in the container. Without such a gauge, end users may not be able to determine when the container needs to be refilled or replaced. Additionally, if a container is stored for a long period of time before use and, during that time, slowly vents or leaks, the end user will be able to determine with a working gauge whether there is still gas in the container. FDA believes that the term ''working gauge'' would allow for flexibility, so that firms may use the type of gauge appropriate to measure the remaining volume or weight of medical gas, in liquid or gaseous form, as appropriate. FDA believes that the proposed requirement to have a working gauge would help to assure the safety, identity, strength, quality, and purity of medical gases in portable cryogenic containers and small cryogenic containers for use by individual patients throughout their period of use.

Paragraph (e)(3) would contain the label and coloring requirements that currently apply to medical gases under § 211.94(e)(2), except that it would not include the requirement that the labeling not be susceptible to becoming worn or inadvertently detached during normal use. Because medical gas containers are reused and distributed among multiple entities, FDA believes that labeling inspection requirements proposed in this rulemaking would be sufficient to assure that labeling that enters into distribution is complete, accurate, durable, and readable, and that unsuitable labeling is replaced.

7. Production and Process Controls

Subpart F contains FDA's proposed requirements for production and process controls for medical gases. The proposed requirements in § 213.100(a) and (b) are generally consistent with the currently applicable requirements in § 211.100. Proposed paragraph (a) would require written procedures for production and process controls designed to assure that medical gases have the identity, strength, quality, and purity they purport or are represented to have. The procedures would need to include all requirements in subpart F. Further, the procedures, including any changes, would need to be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality unit. Paragraph (b) would require that written production and process control procedures be followed in the execution of the various production and process control functions and documented at the time of performance, and that deviations be recorded and justified. FDA believes that the existing requirements for developing and following written procedures for production and process controls are appropriate for medical gases because they would help ensure consistent compliance with a firm's established procedures for production of medical gases.

In § 213.101, FDA proposes different requirements for charge-in of components and incoming designated medical gases than those in § 211.101. Proposed paragraph (a) would require that, except when a monograph or

formulary specifies a range, the batch be formulated with the intent to provide 100 percent of the labeled or established amount of each medical gas. Where a monograph or formulary specifies a range for the contents of a medical gas, the medical gas would be required to be formulated with the intent to provide an amount within that specified range. Because medical gases are often manufactured continuously in a closed system, weighing, measuring, and subdividing components is generally not performed. Paragraph (b) would require that components and incoming designated medical gases added to in-process supply or final product containers be weighed or measured as appropriate. Final product and in-process supply containers would also be required to identify the name of the component or designated medical gas or the name and percentage of each component or designated medical gas if they contain multiple components or designated medical gases, as well as the unique lot number assigned.

Proposed § 213.110 would include a more limited set of sampling and testing requirements than the existing requirements in § 211.110, which contain several testing requirements that are inapplicable to medical gases (including tablet or capsule weight variation, disintegration time, and dissolution time and rate). Paragraph (a) would require that in-process materials be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality unit during the production process. Under paragraph (b), written procedures would be required to be established and followed describing the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch. Such control procedures would need to be established to monitor the output and to validate the performance of those manufacturing processes. This is important for assuring batch uniformity and the integrity of drug products. Paragraph (c) would require that rejected in-process materials be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable. FDA believes that these proposed requirements would be sufficient to help ensure that medical gases are manufactured according to specifications and prevent mix-ups or the accidental use of rejected or quarantined product.

8. Packaging and Labeling Control

Proposed subpart G would contain packaging and labeling control requirements. FDA proposes packaging and labeling materials examination and usage criteria in § 213.122. The proposed requirements in paragraphs (a) through (e) are generally consistent with the current requirements in paragraphs (a) through (e) in § 211.122. Paragraph (a) would require that there be sufficiently detailed written procedures describing the receipt, identification, storage, handling, sampling, examination and/or testing of labeling and packaging materials and that such procedures be followed. Further, paragraph (a) would require that labeling and packaging materials be representatively sampled, and examined or tested upon receipt and before use in packaging or labeling of a medical gas. Paragraph (b) would state that labeling or packaging materials may be approved and released for use if they meet appropriate written specifications, and that they must be rejected if they do not meet such specifications to prevent their use in operations for which they are unsuitable. Paragraph (c) would require that records be maintained for each shipment of each different labeling and packaging material indicating receipt, examination, and whether the materials were accepted or rejected. Paragraph (d) would require that labels and other labeling materials for each different medical gas, strength, or quantity of contents be stored with suitable identification to avoid mix-ups. Further, access to storage would need to be limited to authorized personnel. Paragraph (e) would require the destruction of obsolete and outdated materials, as well as materials that do not meet applicable requirements.

Under paragraph (f), FDA would require one of three special control procedures for packaging and labeling operations: Dedicated labeling and packaging lines for each strength of each medical gas; use of appropriate electronic or electromechanical equipment to conduct a 100 percent examination for correct labeling during or after completion of finishing operations; or use of visual inspection to conduct a 100 percent examination for correct labeling during or after completion of labeling operations for hand-applied labeling (which would need to be performed by one person and independently verified by a second person). The Agency believes that utilizing one of these procedures is critical to preventing mix-ups. Paragraph (g) would require monitoring of printing devices on, or associated with, manufacturing lines used to imprint labeling upon the unit label or case to assure that all imprinting conforms to the print specified in the batch production record. Finally, paragraph (h) would allow the reuse of labels if they are legible, properly affixed to the container, and otherwise meet all applicable requirements. Unlike most drug containers, medical gas containers are reused many times and made of extremely durable materials. FDA believes that the proposed requirements in this section would be sufficient to ensure the quality and legibility of medical gas labels.

In proposed § 213.125, FDA would establish requirements for issuing labeling. Paragraph (a) would require that labeling and packaging operations be controlled to prevent labeling and product mix-ups, and that procedures be written and followed describing in sufficient detail the control procedures employed for the issuance of labeling. Proposed paragraph (b) would require use of procedures to reconcile the quantities of labeling issued, used, and returned, and would require evaluation of discrepancies found between the quantity of medical gas and the quantity of labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. Such discrepancies would need to be investigated in accordance with proposed § 213.192.

Labeling reconciliation is proposed to be waived for cut or roll labeling if a 100 percent examination for correct labeling is performed in accordance with proposed § 213.122(f)(2) (100 percent electronic or electromechanical examination of labeling). Labeling reconciliation would also be waived for 360° wraparound labels on portable cryogenic medical gas containers. FDA is proposing to retain the label reconciliation requirement for medical gases except in the circumstances in which it would be waived, consistent with § 211.125, because label reuse may introduce risk into the labeling process that would not be present with unlabeled containers. While reuse of cylinder labels and 100 percent verification of hand-applied labels on medical gas cylinders through visual inspection provides some assurance of correct labeling, such examination does not preclude the need for quality assurance steps, such as label reconciliation, to be built into the labeling process. The periodic replacement of cylinder labels that are worn, damaged or missing introduces variability and subjectivity into the determination of which and how many containers need new labels, potentially

increasing the risk of mislabeling. The Agency considers label reconciliation procedures, designed commensurate with the risk, to be essential to the overall control of labels to minimize the potential for mix-ups.

Paragraph (c) would require that excess lot number stickers or decals bearing lot or control numbers be discarded. FDA expects that this will help prevent product mix-ups or the inclusion of incorrect lot information on a gas container. Finally, paragraph (d) would exempt bulk or transport containers (as defined in proposed § 201.161(c)(3)) from § 213.125. FDA believes that it is not necessary for this provision to apply to bulk or transport containers because end users are generally not expected to handle or use these containers to directly administer the gas to patients.

Proposed § 213.130 would require that written procedures be developed and followed to assure that the correct labels, labeling, and packaging materials are used for medical gases, similar to the requirements in § 211.130. These procedures would be required to incorporate the following features. Paragraph (a) would require physical or spatial separation from operations on other products. FDA expects this proposed requirement would help to prevent mix-ups. Additionally, FDA proposes to use the term ''other products'' because some firms that manufacture medical gases may also manufacture gases for non-medical purposes, such as for industrial use. Paragraph (b) would require that filled, unlabeled containers of medical gases that are set aside be identified and handled for future labeling operations to preclude mislabeling of individual containers, lots, or portions of lots. It would not be necessary to apply identification directly to each individual container, but the firm would need to be able to identify the name, strength, quantity of contents, and lot or control number of such containers. For example, this could be done through signage in the area in which the containers are stored.

FDA proposes in paragraph (c) that the medical gas be identified with a lot or control number that permits determination of the history of the manufacture and control of the batch. The lot or control number of the medical gas could be identified by use of a separate identification sticker or decal and would not need to be contiguous with other labeling information. Paragraph (d) would require, like the existing requirement in § 211.130(d), that packaging and labeling materials be examined for suitability and correctness before packaging operations, and that such examination be documented in the batch production record. FDA proposes to add a provision allowing product labels, including 360° wraparound labels, to be reused if they meet all applicable labeling requirements, all information on the label is legible, and the label is in good condition.

Paragraph (e) proposes the same requirements as those that currently apply under existing § 211.130(e). Under this proposal, firms would be required to inspect packaging and labeling facilities immediately before use to assure that all medical gases have been removed from previous operations. Moreover, this proposal would require inspection to assure that packaging and labeling materials unsuitable for subsequent operations have been removed, and the results of such inspection have been documented in the batch production records.

FDA proposes paragraph (f), which would exempt bulk or transport containers (as defined in proposed § 201.161(c)(3)) from the requirements of § 213.130, provided they are identified with the name of the product contained therein and accompanied by documentation identifying the product as meeting applicable compendial standards. It is unnecessary for bulk and transport containers to bear the information required by this section because patients and healthcare providers are not expected to utilize them directly to administer a gas.

9. Holding and Distribution

Subpart H would establish holding and distribution requirements. Proposed § 213.150 would contain requirements for warehousing and distribution procedures. Paragraph (a) would require that written procedures be established and followed describing the distribution of medical gases. Such procedures would be required to include a system by which the distribution of each lot can be readily determined to facilitate any necessary recalls. FDA believes that the requirement in § 211.150(a) to distribute the oldest approved stock of a drug product first (often called the ''first-in, first-out'' requirement) is unnecessary to include in this proposed rule, as medical gases are generally not expected to expire or degrade under ordinary storage conditions. Paragraph (b) would require that written procedures be established and followed regarding warehousing of medical gases, similar to the requirements in § 211.142(a). These procedures would be required to include procedures for the quarantine of such gases before release by the quality unit. Unlike the current requirements in § 211.142(b), the proposed requirements would not include procedures regarding the conditions of drug storage because sealed, closed containers are generally expected to protect the gas inside from a wide range of environmental conditions. Moreover, the Agency believes the requirements in proposed §§ 213.42 and 213.80 would sufficiently address storage and handling.

10. Laboratory Controls

Subpart I proposes requirements for laboratory controls. In proposed § 213.160, FDA would incorporate the existing requirements in § 211.160, with one difference in § 213.160(b)(4). Proposed paragraph (a) would require that the establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by subpart I, including any changes, be drafted by the appropriate organizational unit and reviewed and approved by the quality unit. Such requirements would have to be followed and documented at the time of performance, and deviations recorded and justified.

Under proposed paragraph (b), laboratory controls would be required to include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, medical gas containers, closures, in-process materials, labeling, and medical gases conform to appropriate standards of identity, strength, quality, and purity, and include the following four elements:

- Determination of conformity to applicable written specifications for the acceptance of each lot within each shipment of components, medical gas containers and closures, and labeling used in the manufacture, processing, packing, or holding of a medical gas. The specifications would be required to include a description of the sampling and testing procedures used. Samples would need to be representative and adequately identified. Such procedures would also need to require appropriate retesting of any component, medical gas container, or closure that is subject to deterioration. See § 213.160(b)(1).
- Determination of conformance to written specifications and a description of sampling and testing procedures for in-process materials. Such samples would need to be representative and properly identified. See § 213.160(b)(2).
- Determination of conformance to written descriptions of sampling procedures and appropriate

specifications for medical gases. Such samples would need to be representative and properly identified. See § 213.160(b)(3).

• The calibration of instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met, or verification of such calibration. Instruments, apparatus, gauges, and recording devices not meeting established specifications would not be able to be used. See § 213.160(b)(4). This differs from § 211.160(b)(4) in that FDA proposes to require calibration or verification of calibration of instruments, apparatus, gauges, and recording devices. In the medical gas industry, some downstream entities may not conduct their own calibration. FDA believes that verification of calibration is necessary if the entity does not conduct its own calibration.

Proposed § 213.165 would contain requirements for testing and release of medical gases for distribution. Paragraph (a) would require that there be appropriate laboratory determination of satisfactory conformance to final specifications for each batch, including the identity and strength, prior to release. The Agency omitted the requirements in § 211.165(b) from its proposal because generally there is less risk of microbial contamination for medical gases.

Section 213.165(b) would require that any sampling and testing plans be described in written procedures, and that such written procedures be followed. Such plans would need to include the method of sampling, the number of units per batch, and acceptance criteria. FDA believes it is unnecessary to incorporate in proposed § 213.165(b) the more detailed requirements regarding acceptance criteria described in § 211.165(d).

Proposed § 213.165(c) would require that the accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm be validated and documented. This may be done in accordance with proposed § 213.194(a)(2). Further, the suitability of all testing methods would need to be verified under actual conditions of use.

FDA proposes § 213.165(d), which would require rejection of medical gases that fail to meet established standards or specifications and any other relevant quality criteria. This proposal is generally consistent with the requirements described in § 211.165(f), but FDA is not proposing to include the provision stating that reprocessing may be performed or the requirements for using reprocessed material. The Agency is not aware of reprocessing that occurs for medical gases. However, we welcome comment on this issue, including any example scenarios in which such gases are reprocessed.

Finally, FDA would clarify in § 213.165(e) that the proposed requirements in § 213.165 would not apply to the filling of a designated medical gas or medically appropriate combination via liquid to liquid into a container at a delivery site, often referred to by industry as ''curbside filling.'' Because such filling operations are not expected to result in any material change in the gas being filled (for example, oxygen continues to be oxygen after filling), the gas is not expected to fall out of conformance with the requirements in § 213.165 if it is in conformance earlier in the distribution chain and stored under proper conditions.

FDA proposes in § 213.166 stability testing and expiration dating requirements for medical gases marketed under applications submitted under section 505 or 512 of the FD&C Act. Under proposed paragraph (a), any stability testing performed and any expiration date established for medical gases marketed under applications submitted under section 505 or 512 of the FD&C Act would need to be in accordance with the proposed requirements described in subsection (b), subject to the conditions established in their approved applications, if any. Under this proposed rule, stability testing and expiration dating would not be required for all medical gases. However, stability testing, expiration dating, or both would be required for some medical gases (for example, these would be necessary when required by an approved application for the safe and effective use of the drug, or stability testing would be necessary when an applicant chooses to label its product with an expiration date regardless of whether one is needed for safe and effective use under an approved application). FDA believes that this proposed requirement would allow for flexibility in determining whether stability testing, expiration dating, or both are necessary for a particular gas. Furthermore, specific stability testing requirements may vary depending on the particular gas.

Proposed paragraph (b) would contain requirements to assure that the medical gas meets applicable standards of identity, strength, quality, and purity at the time of use:

• The stability testing program would need to be designed to assess the stability characteristics of the medical gas and its container closure system. The results of stability testing would need to be used in determining appropriate storage conditions and any expiration dates included on the label. The stability program shall include the appropriate sample size, test intervals, container closure systems, and storage conditions for samples retained for testing.

• Any expiration dates included on the label would be required to appear in accordance with § 201.17.

• Stability would need to be evaluated periodically to ensure that the medical gas continues to meet the standards for identity, strength, quality, and purity stated on the labeling to support the expiration date.

FDA is not proposing stability testing or expiration dating requirements for designated medical gases, as they are not expected to expire or degrade. Additionally, the proposed leak testing and working gauge requirements in this proposed rule are expected to address concerns regarding the container closure system's ability to prevent leakage. If a designated medical gas manufacturer chooses to include an expiration date on its container, FDA expects that such a date would be determined by appropriate stability testing that reflects the stability of the gas and the integrity of the container closure system.

11. Records

Proposed subpart J would contain requirements for records. Because FDA is not proposing to require the labeling of medical gases to bear expiration dates, except as proposed in § 213.166, the proposed requirements in § 213.180 differ from the requirements in § 211.180. Paragraph (a) would provide that all records that would be required under part 213, or copies of such records, be readily available for authorized inspection during the retention period and are subject to copying as part of such an inspection. The records would be able to be kept at either the establishment where the activities described in such records occurred or at another location from which the records can be immediately retrieved. Retrieval via computer or other electronic means would meet this requirement. Per paragraph (b), all records would have to be legible, stored to prevent deterioration or loss, and either original or accurate reproductions of original records. Paragraph (c) would require that all records that would be required to be maintained in compliance with part 213 be maintained

for at least 3 years from the date the batch of medical gas is distributed, except where otherwise provided. This timeframe is the same as that used in § 211.180(a) for over-the-counter drugs lacking expiration dating.

Paragraph (d) would require that written records required under part 213 be maintained so that their data can be used for evaluating, at least annually, the quality standards of each medical gas to determine the need for changes in specifications or manufacturing or control procedures. Written procedures would also have to be established and followed for such evaluations. The procedures would also be required to include provisions for a review of a representative number of batches, whether approved or rejected, and, where applicable, records associated with the batch, and a review of complaints, recalls, returned or salvaged medical gases, and investigations conducted under § 213.192 for each gas. Under paragraph (e), firms would be required to develop written procedures for notifying responsible firm officials of any recalls, reports of inspectional observations by FDA, regulatory actions related to good manufacturing practice taken by FDA, or any investigations resulting from adverse event complaints.

Proposed § 213.182 would require that there be a written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use. These records would be required, as part of individual equipment logs, to show the date, time, product, and lot number of each batch processed. Individual equipment logs would not be required for equipment dedicated to one product, but lots or batches would have to follow in numerical order and be manufactured in numerical sequence in such a case. Also, where dedicated equipment is employed, the records of cleaning, maintenance, and use would be required to be part of the batch record. The individuals performing and double-checking the cleaning and maintenance (or, if the cleaning and maintenance is performed using automated equipment under § 213.68, just the person verifying such cleaning and maintenance) would have to date and sign or initial the log indicating the work was performed. Entries in the log would be required to be in chronological order. While FDA recognizes that cleaning of a closed, pressurized system is not always appropriate, when it is applicable, it is essential to maintain adequate records of such cleaning.

FDA proposes in § 213.184 a more limited set of recordkeeping requirements for components, medical gas containers and closures, and labeling than those described in § 211.184. The records would include the results of any test or examination performed (including those performed pursuant to §§ 213.84 and 213.122) and the conclusions derived from the test or examination; documentation of the examination and review of labels and labeling for conformity with established specifications in accordance with §§ 213.122 and 213.130; and the disposition of rejected components, containers, closures, and labeling. Medical gas containers are generally reused many times before they are taken out of service. FDA believes that the proposed requirements in §§ 213.84, 213.122, and 213.130 to evaluate containers and labeling are appropriate and sufficient to assure the quality of containers and the accuracy and legibility of their labels.

In § 213.186, FDA proposes master production and control recordkeeping requirements that are more tailored to medical gases than the current requirements in § 211.186. Paragraph (a) would require that master production and control records for each medical gas be prepared, dated, and signed to assure uniformity from batch to batch. Paragraph (a) would also require that the preparation of such records be described in a written procedure, and that such written procedure be followed. Paragraph (b) proposes to require certain information for each master production and control record. The records would be required to include: The product name and strength; a list of all components and any incoming designated medical gases used in manufacturing designated by names or codes sufficiently specific to indicate any special quality characteristics; a description of the containers, closures, and packaging materials and labels; and complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed.

These proposed requirements differ from the requirements in § 211.186 because of the differences in manufacturing and distribution of medical gases. For example, because medical gas manufacturing generally includes some venting of gas, measuring calculated excess of component, theoretical weight, and theoretical yield is infeasible.

In lieu of the requirements found in § 211.188, FDA proposes § 213.189, which would impose batch production and control recordkeeping requirements for each batch of medical gas produced. Paragraph (a) would require batch production and control records to be prepared for each batch of medical gas produced. Paragraph (b) would require that batch production and control records include documentation that each significant step in the manufacturing, processing, packing, and holding process was accomplished, including:

- Dates and times of each significant step, including in-process and laboratory tests as applicable. This documentation would include any prefill, filling, or post-filling inspections, which are essential to assuring product meets applicable standards.
- A description of the container for the medical gas, including the number and size of the containers filled as applicable. The containers used in manufacturing and filling operations can vary significantly, so documenting the containers is important for tracking purposes.
- Specific identification of each component and its source or in-process material used as applicable.
- Measures of components used in the course of processing as applicable.
- Testing results, including any in-process test results and finished product test results.
- Dated signature or initials of the persons performing and directly supervising or checking each significant event in the operation.
- Inspection of the packaging and labeling area before and after use.
- Complete labeling control records, including specimens or copies of all labeling used and label application and reconciliation records as appropriate. Because labeling does not always need to be applied due to the reuse of labels, documentation of these labeling control activities is important to help prevent mix-ups and the incorrect application of labeling.
- Any investigation made according to § 213.192.

Proposed § 213.192 would contain production record review requirements for medical gases. Under paragraph (a), manufacturing production and control records, including those for packaging and labeling, would need to be reviewed and approved by the quality unit to determine compliance with all established, approved written procedures before release or distribution of a batch. The quality unit would also be required to review production records to determine whether errors or unexplained discrepancies have occurred prior to batch release. If any

errors or unexplained discrepancies have occurred, or a batch or any component of the batch fails to meet specifications, the firm would be required to conduct thorough investigations and take appropriate corrective actions. FDA further proposes to require a written record of the investigation, including the conclusions and followup. However, for entities that fill at a delivery site, paragraph (b) would require that production and control records be reviewed and approved by the quality unit to determine compliance with all established, approved written procedures within 1 business day after fill. FDA believes this additional time is needed for reviewing such records associated with filling at a delivery site because delivery personnel typically conduct such filling at multiple locations. As such, it is impractical for the quality unit to be present at the time of filling, and the characteristics of the gas are not expected to change during the filling process. Therefore, the Agency believes it is appropriate for the quality unit to review production and control records shortly after delivery is completed.

FDA recognizes that, because containers and labels are reused many times for medical gases, firms are generally unable to trace the history of a cylinder's use or identify the root cause of a cylinder-related problem. Nevertheless, if an error or unexplained discrepancy associated with a cylinder is identified, or if a cylinder is found not to meet any of its specifications, FDA believes it is necessary for the firm to conduct a thorough investigation to identify the problem and take appropriate corrective action, such as taking a faulty cylinder out of circulation. FDA believes this proposal would establish production record review requirements that would assure that medical gases meet the requirements of the FD&C Act as to safety and have the identity, strength, quality, and purity they are purported or represented to possess.

FDA is also proposing § 213.194, which would impose laboratory recordkeeping requirements. Paragraph (a) would require that laboratory records related to the manufacture of a medical gas include complete data derived from all tests necessary to ensure compliance with established specifications and standards, including examinations and assays. Laboratories would have to keep a complete record of all data created in the course of each test, including the records described in paragraphs (a)(1) through (4), as follows:

- A description of the sample, the batch or lot number to be tested, the date the sample was taken, and the date the sample was tested.
- The test method used, the test result, how the results compare with established standards of identity, strength, quality, and purity for the component, container, in-process materials (as applicable), and medical gas tested, a record of any calculations performed and any calculated results, and the unit of measurement of the result. It would not be necessary to provide the actual calculation where the result is evident through use of simple addition and subtraction (for example $100 - 0.1 = 99.9$).
- Where applicable, any graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific component, in-process material, or medical gas for each lot tested.
- The initials or signature of the person performing the test as well as a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards.

Paragraph (b) would require that complete records be maintained of any modification of an established test method. These records would need to include the reason for the modification and data to verify that the modification produced results that are at least as accurate and reliable for the material being tested as the established method. Paragraph (c) would require that complete records be maintained of any testing and standardization of laboratory reference standards, reagents, and standard solutions. These requirements are the same as those that currently apply to medical gases under § 211.194(b) and (c).

Paragraph (d) would require that complete records be maintained of the periodic calibration or verification of calibration of laboratory instruments, apparatus, gauges, and recording devices that would be required by § 213.160(b)(4). This paragraph differs from § 211.194(d) in that it would allow for verification of calibration. It is FDA's understanding that it is common for some medical gas equipment to be calibrated by a supplier or other entity prior to arrival at the laboratory.

Paragraph (e) would require that complete records be maintained of all stability testing performed in accordance with proposed § 213.166. This requirement is consistent with the current requirement in § 211.194(e). As described above, only a subset of medical gases are expected to be subject to stability testing requirements, but for such gases, documentation of stability testing is essential to ensuring that the gas will maintain its stability for the expected timeframe.

Under proposed § 213.196, distribution records would be required to contain the name of the product, the lot or batch number, the consignee's contact information, and the date and quantity shipped. FDA believes that including the lot or batch number is essential to properly tracking and tracing product in the event a safety issue is discovered. Information about the dosage form, as required in § 211.196, is not necessary for medical gases because the dosage form is always ''gas.'' For medical air and medically appropriate combinations of designated medical gases, the distribution record would also need to include the percentage of each gas. FDA believes that this information is essential to prevent mix-ups because the concentration of each component would be clearly determined.

Proposed § 213.198 contains proposed requirements for complaint files that are similar to those requirements that currently apply to medical gases under § 211.198. Paragraph (a) would require that written procedures be established and followed for the receipt and handling of all written and oral complaints concerning a medical gas. These procedures would have to include a quality unit review of any complaint involving the possible failure of a medical gas to meet its specification as well as an investigation to determine the cause of the failure. An out-of-specification medical gas (for example, a combination containing higher quantities of oxygen than intended) could result in serious patient harm if administered. These procedures would also be required to include provisions for determining the need for an investigation under § 213.192 and determining whether the complaint represents an event that would need to be reported under proposed part 230.

Paragraph (b) would require that a written record of each complaint be maintained. This record would have to include the name of the medical gas, the lot or batch number, the name of the complainant, the date the complaint was received, the nature of the complaint, and the response to the complaint. It would also be required to include the findings of any investigation and followup. If an investigation is not conducted, the record would need to include the reason that an investigation was found not to be necessary and the name of the responsible person making such a determination.

Paragraph (c) would require the maintenance of complaint files in a manner such that they would be readily available for inspection by the firm or by FDA during an inspection. Complaint files would be required to be maintained for at least 1 year after the date that the complaint was received or for at least 3 years after distribution of the medical gas, whichever is longer. This proposed record retention period is the same as that used in § 211.180(a) for certain over-the-counter drugs lacking expiration dating and would facilitate review and evaluation by the firm of information that is received after the event, thus facilitating the firm's ability to observe trends over time.

12. Returned and Salvaged Medical Gases

Subpart K contains proposed requirements for returned and salvaged medical gases. FDA proposes in § 213.204 to require that returned medical gases be identified as such and held. Moreover, if the conditions under which the returned gases have been held, stored, or shipped before or during their return, or if the condition of the gas, its container, carton, or labeling, as a result of storage or shipping, cast doubt on its safety, identity, strength, quality, or purity, the returned medical gas would need to be destroyed unless examination, testing, or other investigations prove the gas meets appropriate standards of safety, identity, strength, quality, or purity. These requirements would apply to situations in which a distributed medical gas is sent back to a firm due to a quality issue. Firms would need to maintain certain records of returned medical gases. Further, if the reason for a medical gas being returned implicates associated batches, an appropriate investigation pursuant to proposed § 213.192 would need to be conducted. Procedures for holding, testing, and use of returned medical gases would need to be in writing and followed. Proposed § 213.204 would not apply to the routine refilling of a cryogenic medical gas containers in the normal course of business unless the container was returned for a quality issue.

Proposed section 213.204 is largely the same as current § 211.204, with an added provision regarding routine refilling. FDA believes that the current requirements for returned drug product are appropriate for medical gases. However, the proposed routine refilling provision would be essential to address the fact that small amounts of gas are expected to remain in a returned container that will be reused. This situation is uncommon for other types of drug products, but medical gas containers are generally reusable, and complete purging of a container is impracticable. Another notable difference compared to § 211.204 is the omission of reprocessing requirements, as it is FDA's understanding that reprocessing of returned medical gases does not occur. Generally, gases are reused if they meet specifications; otherwise, they are vented. FDA requests comment on this issue.

Section 213.208 would allow the salvaging of medical gases that have been subjected to improper storage conditions unless the gas's container has been subjected to adverse conditions that impact the identity, strength, quality, and purity of the medical gas, or the integrity of the container closure. These requirements would apply to situations in which a medical gas has been subject to improper storage conditions under the control of a firm responsible for the manufacture, processing, packing, or holding of the gas. Scenarios in which this may arise include natural disasters, facility structural damage (such as a building collapse), or exposure to smoke in the event of a fire. If there is a question whether the medical gas has been subjected to improper storage conditions, salvaging would only be permitted if there is evidence from laboratory tests that the gas meets all applicable standards of identity, strength, quality and purity, and the closure is not compromised. Section 213.208 also would require that firms maintain and follow written procedures for the holding, testing, and use of salvaged medical gases. While medical gases in sealed containers are generally considered unlikely to be affected by adverse conditions, such as natural disasters or significant changes in temperature, humidity, or pressure, a medical gas container could be damaged by such circumstances. Therefore, it is essential for firms to evaluate any containers potentially affected by adverse conditions.

13. Notable Part 211 Provisions FDA Does Not Propose To Include in Part 213

In this section, FDA discusses existing CGMP provisions of note that the Agency has not proposed for inclusion in part 213. In the proposed CGMP requirements described above in this section, FDA addressed some individual requirements in part 211 that the Agency has not proposed for inclusion in part 213, but this section addresses some other sets of requirements that are outside the scope of the above discussion. We specifically request public comment on these areas.

The requirements in § 211.28(a), (b), and (d) regarding personnel responsibilities are not included in this proposed rule. Medical gases are generally manufactured, stored, combined, and distributed under pressure in closed systems. Therefore, the risk of contamination is generally lower than for other drugs. FDA believes that the other requirements that would be established by this proposed rule would sufficiently address the risk of contamination in medical gases.

FDA is not proposing to include certain buildings and facilities requirements from part 211, subpart C, in proposed part 213, subpart C (specifically §§ 211.44 through 211.58) because they are not relevant to the manufacture, processing, packing, and holding of medical gases, or because the proposed requirements in § 213.42 sufficiently address these issues. For example, FDA believes that specific lighting requirements are not necessary because the risk of lightbulbs breaking and contaminating the gas inside a closed manufacturing system is remote. Moreover, FDA believes that the level of lighting at a facility would be sufficiently addressed by the requirements in § 213.42 to ensure that the design, space, and placement of equipment in a facility help protect against mix-ups (for example, we interpret this to mean that, among other things, employees have sufficient light to read labels). Similarly, specific ventilation requirements are not necessary because the closed manufacturing system for medical gases is generally unaffected by external factors such as air quality in the facility. Other specific requirements in part 211 regarding plumbing, sewage, and sanitation are also unnecessary because the risk of contamination is extremely low and because the proposed requirements in part 213 would adequately address these concerns.

The current requirements for filters in § 211.72 are also not included in this proposed rule. Because medical gases are not administered as injectable drugs, the requirements in § 211.72 are not relevant. FDA seeks comment on the need for filter requirements.

Because medical gases are generally not expected to expire or degrade under ordinary storage conditions, FDA does not believe it is necessary to include in this proposed rule the requirements in § 211.86 regarding using the oldest approved stock first or § 211.87 regarding retesting product that has been stored for long periods of time or whose containers have been exposed to air.

FDA is not proposing to include a calculation of yield requirement similar to § 211.103. Gas loss is expected during manufacturing and can be variable even under normal operating conditions. The requirements proposed in part 213 would be sufficient to determine that the medical gas in the container is the amount and type indicated by the label and required by the final product specifications. Therefore, such a requirement would not provide useful information to firms or FDA.

FDA is not proposing to include an equipment identification requirement similar to § 211.105. Because equipment used for medical gas manufacturing is expected to be specific to the gas being manufactured, there is typically no changeover of machinery for firms to track. Accordingly, FDA does not believe such a requirement is necessary to assure the safety, identity, strength, quality, and purity of medical gases.

FDA is not proposing to include time limitations on production similar to § 211.111 because medical gases are generally not expected to expire or degrade under ordinary storage conditions. FDA also is not proposing to include requirements regarding the control of microbiological contamination similar to § 211.113 because the risk of contamination is extremely low for these products.

FDA is not proposing to include a requirement similar to § 211.115, which establishes requirements for reprocessing. The Agency is not aware that reprocessing occurs for medical gases. Rather, it is FDA's understanding that gases not meeting specifications generally would be vented. However, as mentioned above, we welcome comment on this issue, including any example scenarios in which medical gases are reprocessed.

FDA is not proposing to include the drug product inspection requirements in § 211.134. Because cylinders are reused many times, FDA believes that the labeling inspection provisions in proposed § 213.122(f) would assure proper product labeling.

FDA is not proposing to include the reserve sampling requirements in § 211.170 because the requirements in § 211.170 are not appropriate for medical gases. The proposed sampling requirements elsewhere in part 213 would be sufficient to address sampling for in-process and finished medical gases.

14. Proposed Revisions to 21 CFR Part 4 CGMP Requirements

FDA recognizes that some medical gases are marketed as part of a combination product. For example, a medical gas may be marketed with a device constituent part (for example, a portable liquid oxygen unit or a pressure regulator). However, a gas cylinder with a simple on/off valve (*i.e.,* without a pressure regulator) would generally not be considered a device. Combination products are subject to part 4, subpart A (21 CFR part 4, subpart A), which clarifies the application of CGMP regulations to combination products and provides a streamlined approach to demonstrate CGMP compliance for facilities that manufacture co-packaged or single-entity combination products.

FDA intends to amend part 4, subpart A to reflect the new requirements for medical gases under part 213 and clarify how to comply with part 4, as amended. FDA proposes to include in 21 CFR 4.2 a definition of the term ''medical gas'' consistent with the definition in proposed part 213, as well as a definition of ''medical gas CGMPs'' that refers to part 213.

FDA also proposes to revise § 4.3(a) (21 CFR 4.3(a)) to account for combination products that contain a medical gas. For such products, part 213 would apply rather than parts 210 and 211, as described in proposed new § 4.3(e).

FDA proposes to include in § 4.4(b) (21 CFR 4.4(b)) specific provisions for combination products that include a medical gas as a drug constituent part to enable use of a streamlined approach for designing and implementing a CGMP operating system that complies with CGMP requirements for medical gas-device combination products akin to the streamlined approaches available for other drug-device combination products. FDA believes that when a manufacturer of a medical gas-device combination product demonstrates that its CGMP operating system complies with part 213 in full, the provisions from part 820 (21 CFR part 820), with which manufacturers must demonstrate compliance, should be the same as those currently listed in § 4.4(b)(1) because part 213 covers the same general areas as part 211, and FDA is not aware of device characteristics that would necessitate a different approach. If a medical gas-device combination product manufacturer demonstrates that its CGMP operating system complies with part 820 in full, FDA believes that the following proposed requirements from part 213 would be appropriate to ensure that critical aspects of medical gas production are addressed:

- Section 213.84. Testing and approval or rejection of components, containers, and closures.
- Section 213.94. Medical gas containers and closures.
- Section 213.122. Materials examination and usage criteria.
- Section 213.165. Testing and release for distribution.
- Section 213.166. Stability testing and expiration dating for medical gases marketed under applications submitted under section 505 or 512 of the FD&C Act.
- Section 213.204. Returned medical gases.
- Section 213.208. Salvaging of medical gases.

FDA proposes to make other conforming edits as needed, such as revising § 4.4(e) to include a reference to part 213, and to clarify (where appropriate) throughout part 4, subpart A the requirements for medical gases.

FDA specifically seeks comment on this proposal, including: (1) Which part 213 provisions should be included in the list of provisions for combination products containing a medical gas as a drug constituent part for which the CGMP operating system has been shown to comply with part 820; (2) whether the part 820 provisions listed in § 4.4(b)(1) should be revised for combination products containing a medical gas as a drug constituent part to include other 820 requirements or to remove certain existing references to part 820 call-outs; and (3) whether it is appropriate to permit manufacturers to have the option of choosing to demonstrate compliance with part 213 in full along with the part 820 call-out provisions or compliance with part 820 in full along with the part 213 call-out provisions.

The Agency believes that part 4, subpart A helps ensure appropriate implementation of CGMP requirements for combination products while avoiding unnecessary redundancy in CGMP operating systems for these products, and that, given the benefits of the approach in part 4, subpart A, it should include combination products that contain a medical gas. FDA expects that sponsors of medical gases submitted under section 505 of the FD&C Act with a delivery system are already aware that they are producing a combination product, and as such should already be familiar with the requirements in part 4, subpart A. For firms that combine a designated medical gas or medically appropriate combination of designated medical gases with a finished, off-the-shelf device, FDA expects that the burden for complying with the device CGMP requirements would be relatively low. In some cases, firms may be able to leverage information from their device supplier to demonstrate compliance

with device call-outs. Additionally, some device provisions are not expected to apply in all cases; some class I devices are exempt from the design control requirements in 21 CFR 820.30, and the installation and servicing requirements in 21 CFR 820.170 and 820.200, respectively, are not applicable to all devices.

C. Proposed Certification and Annual Reporting Provisions

The proposed rule would establish, within new part 230, regulations setting forth the requirements for obtaining certification of a designated medical gas pursuant to section 576 of the FD&C Act. Since the passage of FDASIA, many applicants have sought marketing authorization for a designated medical gas under section 576 of the FD&C Act, and this proposed rule would codify that process in FDA's regulations while also providing additional clarity where necessary. As proposed, part 230 would contain the requirements for filing a certification request for a designated medical gas for human use, animal use, or both. FDA is also proposing to make certain provisions in parts 314 and 514 inapplicable to designated medical gases, given that part 230 would apply instead.

Sections 575 and 576 of the FD&C Act also authorize FDA to deem certain medical gases not listed in section 575(1)(A) through (G) to be designated medical gases (FD&C Act section 575(1)(H)) and to certify designated medical gases or medically appropriate combinations of such gases for certain indications for use not listed in section 576(a)(3)(A)(i)(I) through (VII) (FD&C Act section 576(a)(3)(A)(i)(VIII)). The Agency is not proposing regulations implementing these provisions as part of this rulemaking because the Agency does not expect to deem additional medical gases to be designated medical gases at this time. In addition, the Agency does not expect to certify designated medical gases for indications beyond those currently described in section 576 of the FD&C Act at this time. If, in the future, FDA decides it would be appropriate to deem additional medical gases to be designated medical gases or to certify designated medical gases or medically appropriate combinations of such gases for additional indications for use, FDA expects to undertake such actions without the need for further rulemaking.

FDA also notes that section 575(1)(F) of the FD&C Act provides that carbon monoxide is a designated medical gas if it ''meets the standards set forth in an official compendium.'' Section 201(j) of the FD&C Act defines ''official compendium'' to include the U.S. Pharmacopeia (USP), the official Homeopathic Pharmacopeia of the United States (HPUS), the official National Formulary (NF), or any supplement to any of them. There is currently no monograph in the USP or NF for carbon monoxide. There is a HPUS monograph for carbon monoxide, though it is inapplicable to carbon monoxide as a designated medical gas for use in lung diffusion testing. FDA does not intend to object to the marketing of carbon monoxide for use in lung diffusion testing as long as the product conforms to one of the alternatives in the Center for Drug Evaluation and Research's Manual of Policies and Procedures 5310.7 Rev. 1, *Acceptability of Standards from Alternative Compendia (BP/EP/JP)* (Ref. 10). This proposed approach is consistent with the draft policy described in the draft guidance for industry entitled ''Certification Process for Designated Medical Gases'' (Ref. 1). If and when a monograph entitled ''Carbon Monoxide'' is added to the USP or NF, FDA expects original manufacturers that wish to continue marketing carbon monoxide to promptly submit a certification request.

1. Definitions

Proposed § 230.3(b)(2) defines the term ''applicant.'' An applicant is proposed to be defined as any person or entity who submits a certification request for a designated medical gas under part 230, including supplements. This is generally the original manufacturer. An applicant would also include any person or entity who owns a granted certification for a designated medical gas under part 230. This definition is generally consistent with FDA's use of the term ''applicant'' with regard to NDAs and ANDAs (see 21 CFR 314.3(b)), as well as NADAs and ANADAs (see 21 CFR 514.3).

FDA also proposes to define ''certification request'' as a submission under section 576 of the FD&C Act requesting certification of a medical gas as a designated medical gas. After a certification request is deemed to be granted, a designated medical gas is deemed, alone or in combination, as medically appropriate, with another designated medical gas or gases for which a certification or certifications have been granted, to have in effect an approved application under section 505 or 512 of the FD&C Act, subject to all applicable postapproval requirements, for the applicable indications for use described in section 576(a)(3)(A)(i)(I) through (VIII) of the FD&C Act.

FDA proposes to define ''FDA or Agency'' to mean the Food and Drug Administration, consistent with other Agency regulations.

2. General Requirements for All Certification Submission Types

Proposed § 230.50 would establish the general requirements related to designated medical gas certification requests. The requirements would apply to all submission types. Proposed § 230.50(a)(1) would provide that the certification process described in part 230, subpart B applies to designated medical gases for the indications described in section 576(a)(3)(A)(i) of the FD&C Act. Currently, manufacturers who intend to market medical gases that do not meet the definition of designated medical gas, or who intend to market designated medical gases for indications not described in section 576(a)(3)(A)(i) of the FD&C Act, must obtain approval of that medical gas under part 314 or part 514, or both, as applicable. For example, if an applicant intends to market nitrous oxide for a use other than analgesia (see section 576(a)(3)(A)(i)(III) of the FD&C Act), the certification process in proposed part 230 would not be available for that drug product at this time. If FDA deems additional indications for use appropriate under section 576(a)(3)(A)(i)(VIII) of the FD&C Act, the certification process could extend to designated medical gases for those uses. However, as of the date of this proposed rule, FDA has not deemed any additional indications for use to be appropriate for any designated medical gases.

Also in § 230.50(a)(1), FDA proposes to require any person who seeks to initially introduce or deliver for introduction a designated medical gas into interstate commerce to file a request for certification. An applicant would be required to identify its intention to market their designated medical gas for human use, animal use, or both. If a certification is deemed to be granted, a designated medical gas, alone or in combination, as medically appropriate, with another designated medical gas or other designated medical gases for which a certification or certifications have been granted, would be deemed to have in effect, for the uses described in section 576(a)(3)(A)(i) of the FD&C Act:

- An approved application under section 505 of the FD&C Act, if the applicant requested certification solely for human use;
- an approved application under section 512 of the FD&C Act, if the

applicant requested certification solely for animal use; or

• approved applications under sections 505 and 512 of the FD&C Act, if the applicant requested certification for both human and animal use.

(See section 576(a)(3)(A)(i); see also proposed § 230.105.) Applicants should submit one request per designated medical gas, regardless of how many of their facilities manufacture or will manufacture that designated medical gas. Persons who receive a designated medical gas from an applicant or another person and fill the gas into containers, including via liquid to liquid at a delivery site, are not expected to submit certification requests under part 230 because the gas they are handling should be the subject of a granted certification held by another entity. (See also proposed § 213.82.)

Proposed § 230.50(a)(2) would describe the relationship between the proposed certification requirements in part 230 and parts 314 and 514. Proposed § 230.50(a)(2) would provide that any person that proposes to market a medical gas that is a new drug for human use must obtain approval under part 314, and any person that proposes to market a medical gas that is a new animal drug for animal use must obtain approval under part 514, unless the medical gas meets the definition of a designated medical gas, and the medical gas is proposed to be marketed, alone or in combination (as medically appropriate), with another designated medical gas or gases for which a certification or certifications have been granted, for a use described under section 576(a)(3)(A)(i) of the FD&C Act. ''New drug'' and ''new animal drug'' are defined in section 201(p) and (v) of the FD&C Act.

Proposed § 230.50(b) would outline the information that must be submitted in a certification request. In addition, though not a proposed requirement in this proposed rule, FDA recommends that the applicant include a cover letter describing the purpose of the submission (*e.g.,* original certification, amendment to supply additional information requested by FDA). Such cover letters often provide context and information that would be helpful to the Agency as it processes certification requests. Under § 230.50(b)(1), the certification request would need to include the name, address, telephone number, and email address of the person or entity requesting certification. If the address of the entity requesting certification is not in the United States, the certification request would need to contain the name and address of, and be countersigned by, an attorney, agent, or other authorized official who resides or maintains a place of business within the United States. Under § 230.50(b)(2), the certification request would also need to identify the type of submission as one of the following:

• *Original certification request:* An initial request for certification by an applicant for certification of a medical gas as a designated medical gas.

• *Amendment to a pending submission:* A submission related to a pending submission that revises existing information or provides additional information, including responses to Information Request Letters.

• *Resubmission:* A complete submission that has been revised and submitted again following a previous denial (if the applicant chooses to resubmit its submission, it would need to provide a written response to all deficiencies identified in FDA's denial letter, along with other information required for certification requests; this would help assure that past deficiencies are addressed before applicants resubmit, thus promoting the efficient use of Agency resources)

• *Supplement to a granted certification:* Any submission that contains a change to a certification that was previously granted.

• *Other:* Any submission that does not fit into one of the other categories described in this list.

Under § 230.50(b)(3), the applicant would also need to include a description of the designated medical gas. Each designated medical gas certification request would need to include the name of the gas, as well as a certification statement that the designated medical gas meets the appropriate compendial standard. FDA intends to develop a designated medical gas certification form which would include a certification statement. The Agency anticipates the form would have OMB approval prior to the finalization of any proposed rule.

Under § 230.50(b)(4), applicants would also be required to include certain facility information in the certification request, including the name and address of the facility or facilities where the designated medical gas will be initially produced. FDA uses the term ''facility'' in this proposed provision to be consistent with the terminology in section 576(a)(1)(C) of the FD&C Act, which requires that a certification request include ''[t]he name and address of the facility or facilities where the medical gas is or will be manufactured.'' For purposes of this proposed regulation, the term ''facility'' would be synonymous with the term ''establishment'' as it is used in part 207 (21 CFR part 207). Other facilities that only perform subsequent activities such as transfilling, mixing, or filling at a delivery site would not be considered ''facilities'' for purposes of this proposed regulation. Applicants would also need to include a brief description of the manufacturing or processing activities performed at each facility listed in the certification, which would include chemical reaction, physical separation, compression of atmospheric air, purification of a gas, or other activities to produce a designated medical gas. Applicants would also need to include an FDA Establishment Identifier (FEI), if one exists, and a Unique Facility Identifier (UFI) in accordance with the requirements of part 207 and section 510 of the FD&C Act (21 U.S.C. 360). If an applicant intends to open a new facility to manufacture the designated medical gas, FDA recognizes that the applicant may not have an FEI at the time of the certification request, as FEIs are generally assigned upon registration of a new establishment. However, for existing facilities, including the FEI in the certification request will assist FDA in monitoring its establishment inventory. Regarding the UFI, inclusion of this information will assist the Agency in linking certification requests to registration information required by section 510(b)(1) of the FD&C Act and 21 CFR 207.25(e). FDA's preferred UFI is the Data Universal Numbering System (DUNS) number (Ref. 11). Firms can acquire a DUNS number at no cost. For amendments and supplements, only changes to the list of facilities would need to be submitted.

Under proposed § 230.50(b)(5), the applicant would be required to certify in its certification request that its methods, facilities, and controls used in manufacturing, processing, packing, and holding of the designated medical gas, as applicable, are adequate to ensure the gas's safety, identity, strength, quality, and purity. This certification would be met by completing a field on the certification form referenced above. This information is critical to determining whether the medical gas manufactured at the facility is a designated medical gas because it meets applicable compendial standards (FD&C Act section 576(a)(1)(D)). Designated medical gases generally have narrow compendial standards, and requiring an applicant to certify that it employs appropriate methods, facilities, and controls would help ensure consistent, quality manufacture of a gas that meets such standards.

Lastly, under § 230.50(b)(6), if the Agency deems any other information

appropriate to determine whether the gas meets the definition of a designated medical gas, the applicant would be required to provide that additional information as well. This would generally be in the form of a written request by FDA for the additional information. The applicant may also provide other information that the applicant believes will assist the Secretary in evaluating the request.

Though FDA is not proposing changes to its registration and listing regulations as they apply to designated medical gases, FDA notes that firms must also comply with applicable registration and listing requirements in section 510 of the FD&C Act and part 207. For example, firms must register establishments and list designated medical gases, or update existing registration and listing information, pursuant to part 207, subparts B and D.

Proposed § 230.50(c) would describe the requirements for submitting a certification request. Applicants would be required to submit a signed, completed request for certification either in an electronic format that FDA can process, review, and archive, or in hard copy by submitting two paper copies to the Center for Drug Evaluation and Research (CDER) Central Document Room. FDA encourages submission of certification requests through the NextGen Portal at *https://edm.fda.gov*. FDA intends to assign an NDA or NADA number (or both, if the applicant has expressed its intent to market the medical gas for human and animal use) for reference purposes when an original certification request is filed. If certification is granted, the applicant should use these application numbers in all further submissions to the Agency. If certification is not granted, and the applicant resubmits their certification request in the future, the previously assigned NDA and/or NADA number would continue to be the relevant application number(s).

Section 230.65 would allow applicants to withdraw a certification request that has not been deemed granted. An applicant could notify FDA that it withdraws its certification request at any time prior to the certification being deemed granted. Withdrawal of a certification request would not preclude refiling. If a certification request is withdrawn, FDA would retain the certification request, and if the applicant requests a copy via Freedom of Information Act (FOIA) request, FDA would provide it pursuant to the fee schedule in FDA's public information regulations.

3. Supplements and Other Changes to a Granted Certification

Section 230.70(a) of the proposed rule would require an applicant to submit a supplement if any information in the certification request has changed after the request has been deemed granted, including, but not limited to, the addition of a new facility manufacturing the designated medical gas, a change in contact information, or a change in the corporate name. FDA anticipates these are the most common types of information in the request that might change after certification has been deemed granted.

Under proposed § 230.70(b), the supplement would need to include a signed, completed request for certification form with the updated information in compliance with the requirements of § 230.50, and would need to be submitted no later than 30 calendar days after the date the change occurred. FDA proposes that supplements may be submitted after the fact because the Agency does not anticipate that the types of changes submitted in a supplement would need to be approved before the change occurs.

4. Change in Ownership of a Certification That Has Been Granted

Proposed § 230.72 would address situations in which a designated medical gas certification that has been granted undergoes a change in ownership, for example, due to a merger or acquisition. Proposed § 230.72 would expressly allow for the transfer of ownership of such a certification. When a transfer occurs, both the new and former owners would be required to submit certain information to FDA. Under proposed paragraph (a), the former owner would be required to submit a letter or other document explaining that all rights to the certification have been transferred to the new owner. Under proposed paragraph (b), the new owner would be required to submit a supplement under § 230.70 signed by the new owner describing any changes in the conditions in the granted certification, and a letter or other document identifying the date the transfer of ownership is effective.

5. Annual Report

Proposed § 230.80(a) would require applicants to submit an annual report each year within 60 calendar days of the anniversary of the date the certification was deemed granted. Section 576(a)(2) of the FD&C Act provides that a certification request is deemed to be granted unless, within 60 days of its filing, FDA denies the request based on certain findings; FDA interprets the period of 60 days in this provision to mean a period of 60 calendar days. The applicant would be required to submit a signed, completed annual report form either in an electronic format that FDA can process, review, and archive, or in hard copy by submitting two paper copies to CDER's Central Document Room. The annual report would be required to contain the following information from the prior 12 months, pursuant to proposed § 230.80(b):

- A summary of any significant new information that might affect the safety, effectiveness, or labeling of the designated medical gas. The applicant would also be required to include any actions it has taken or intends to take as a result of this information.
- The applicant would need to include the National Drug Code (NDC) numbers, the quantities distributed for domestic use, and the quantities distributed for foreign use. The disclosure of financial or pricing data would not be required.
- Any changes to the applicant's name or contact information. This information would need to be submitted in a supplement no later than 30 calendar days after the change occurred pursuant to proposed § 230.70, but the Agency believes that receiving all current information consolidated in an annual report will help FDA keep track of applicants and ensure that the Agency has current information.
- The applicant would need to include a list of current facilities, and a list of facilities that were used since the previous annual report (or since the certification was deemed granted) but are no longer in use.

This information would be critical to allow FDA to evaluate all changes to the product and its manufacturing since the most recent report and determine whether any changes have the potential to alter the identity of the gas such that it no longer meets the applicable compendial standard or the definition of a designated medical gas.

6. FDA Review of Certification Submissions

Under proposed § 230.100(a), as part of its review, FDA would consider information submitted with the certification submission along with any other available, relevant information of which FDA becomes aware. Such information could include information obtained from State or Federal officials, FDA inspection reports, or any other source. Per § 230.100(b), FDA proposes the following grounds for denying a submission:

• The medical gas that is the subject of the submission is not a designated medical gas. For example, FDA currently would deny a certification request for oxygen that fails to meet the standards for Oxygen, USP.

• The submission does not contain the required information or otherwise appears to lack sufficient information to determine that the medical gas is a designated medical gas. This may occur if the applicant fails to certify that the medical gas meets the applicable compendial standards, or if FDA obtains evidence that the medical gas fails to meet applicable compendial standards.

• The applicant's methods, facilities, and controls used for the manufacture, processing, and handling of the designated medical gas, as applicable, are not adequate to ensure its safety, identity, strength, quality, and purity, or

• Denying the request is otherwise necessary to protect the public health.

Under proposed § 230.100(c), within 60 calendar days of filing of a certification submission, FDA could contact the applicant to request additional information regarding the submission if it determines that the submission is missing required information, that FDA needs such information to determine whether the medical gas is a designated medical gas, or that FDA determines such information is necessary to protect the public health. This proposed provision would help applicants correct or complete their submission, or decide to withdraw, in a timely and efficient manner. Section 576(a)(2) of the FD&C Act provides that a certification request is deemed to be granted unless, within 60 days of its filing, FDA denies the request based on certain findings; FDA interprets the date of filing under this provision to mean the date that the certification request is received by the Agency. Upon receipt of an amendment to a pending certification request, this 60-day period would restart to allow FDA sufficient time to review new information received. FDA may find that the submission lacks sufficient information if, within the 60-day review period, FDA is unable to contact the applicant to obtain and evaluate the missing information or if FDA is able to contact the applicant but is not provided with the additional information within the 60-day review period.

Proposed § 230.100(d) would provide that, within 60 calendar days of filing of a submission, if FDA makes one of the findings described in proposed § 230.100(b), FDA will notify the applicant in writing that the submission is denied and provide the basis for FDA's determination.

7. When a Certification Submission Is Deemed Granted

Proposed § 230.105 would provide that, unless FDA makes one of the findings described in § 230.100(b) and notifies the applicant within 60 calendar days of filing that the submission is denied, certification is deemed to be granted and the designated medical gas will be deemed to have in effect an approved application under section 505 or 512 of the FD&C Act, or both, for the indications specified in section 576(a)(3)(A)(i) of the FD&C Act. FDA would notify the applicant in writing and intends to post the letter on the Agency's website. The designated medical gas for which a certification is deemed granted would be subject to all applicable postapproval requirements. If, however, FDA has not responded during the 60-day review time period, the applicant may begin marketing their designated medical gas unless and until FDA withdraws or revokes approval.

8. Withdrawal or Revocation of Approval of an Application for a Designated Medical Gas

Proposed § 230.150 describes requirements concerning withdrawal or revocation of approval of an application for a designated medical gas. Proposed paragraph (a) addresses withdrawal of approval. FDA proposes that it will notify the applicant and afford an opportunity for a hearing on a proposal to withdraw approval of the application under the procedure in § 314.200 (21 CFR 314.200), § 514.200 (21 CFR 514.200), or both, as applicable, for any of the grounds listed in proposed paragraph (a)(1). FDA proposes that if the Secretary of the Department of Health and Human Services has suspended approval on a finding that there is an imminent hazard to public health, FDA will initiate the withdrawal process. Additionally, FDA proposes that it will initiate the withdrawal process if it makes any of the following findings:

• Clinical or other experience, tests, or other scientific data show that the designated medical gas is unsafe for use under the conditions of use upon the basis of which the application was approved;

• New evidence of clinical experience not available to FDA until after the application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when the application was approved, evaluated together with the evidence available when the application was approved, reveal that the designated medical gas is not shown to be safe for use under the conditions of use upon the basis of which the application was approved;

• Upon the basis of new information before FDA with respect to the designated medical gas, evaluated together with the evidence available when the application was approved, that there is a lack of substantial evidence from adequate and well-controlled investigations as defined in 21 CFR 314.126, that the designated medical gas will have the effect it is purported or represented to have under the conditions of use prescribed, recommended, or suggested in its labeling; or

• The application contains any untrue statement of a material fact.

In § 230.150(a)(2), FDA proposes that it may notify the applicant and afford an opportunity for a hearing on a proposal to withdraw approval of the application under the procedure in § 314.200, § 514.200, or both, as applicable, if FDA makes any of the following findings:

• The applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain required records or to make required reports applicable to designated medical gases, including under sections 505(k) and 512(l) of the FD&C Act, part 230, and part 213, or that the applicant has refused to permit access to, or copying or verification of, its records;

• On the basis of new information before FDA, evaluated together with the evidence available when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the designated medical gas are inadequate to ensure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Agency;

• On the basis of new information before FDA, evaluated together with the evidence available when the application was approved, the labeling of the designated medical gas, based on a fair evaluation of all material facts, is false or misleading in any particular, and the labeling was not corrected by the applicant within a reasonable time after receipt of written notice from the Agency; or

• The applicant has failed to comply with the notice requirements of section 510(j)(2) of the FD&C Act (pertaining to the requirements regarding product listing updates).

Section 576(a)(4)(A) of the FD&C Act makes clear that the authority to

withdraw or suspend approval under section 505(e) applies to designated medical gases that are deemed to have in effect approved applications under section 505 or 512. FDA believes the grounds proposed in § 230.150(a)(1) and (2) are consistent with the bases for withdrawing an application under section 505(e) of the FD&C Act.

Under proposed § 230.150(a)(3), FDA would also withdraw approval if the applicant requests its withdrawal because the designated medical gas subject to the application is no longer being marketed, provided none of the conditions listed in proposed paragraphs (a)(1) or (a)(2) applies. FDA proposes to consider such a written request for withdrawal to be a waiver of an opportunity for hearing otherwise provided for in this section. Such withdrawal, when requested by the applicant, would be without prejudice to refiling.

Under proposed paragraph (a)(4), FDA could notify an applicant that it believes a potential problem associated with a designated medical gas is sufficiently serious that the designated medical gas should be removed from the market and may ask the applicant to waive the opportunity for hearing otherwise provided under this section, to permit FDA to withdraw approval, and to remove voluntarily the product from the market. If the applicant agrees, FDA would not make a finding under paragraph (a), but would withdraw approval in a notice published in the **Federal Register** that contains a brief summary of FDA's and the applicant's views of the reasons for withdrawal.

Proposed paragraph (a)(5) provides that, if FDA withdraws an approval, the Agency will publish a notice in the **Federal Register** announcing the withdrawal of approval. This is consistent with the Agency's current practice to announce withdrawn approvals.

Under proposed paragraph (b), FDA could revoke the grant of a certification if FDA determines, after providing the applicant with notice and opportunity for an informal hearing in accordance with 21 CFR part 16, that the request for certification contains any material omission or falsification. This is intended to implement section 576(a)(4)(B) of the FD&C Act. FDA proposes corresponding edits to 21 CFR 16.1(b)(2) to include reference to this provision.

9. Proposed Changes to Part 314

FDA proposes carving out designated medical gases from certain provisions in part 314 for which a corresponding provision specific to designated medical gases is proposed to be added to part 230. FDA also proposes carving out designated medical gases from certain provisions of part 314 that are not relevant to designated medical gases. Proposed new § 314.1(c) (21 CFR 314.1(c)) would list the provisions that FDA proposes no longer apply to designated medical gases.

A number of provisions in part 314 would continue to apply to designated medical gases.[7] Section 314.80(g) (21 CFR 314.80(g)), regarding the electronic submission of safety reports, would continue to apply. FDA anticipates that the electronic format for submission of human drug individual case safety reports (ICSRs) will be the same as for other human drugs, and that existing guidance will be appropriate for human designated medical gas ICSRs.

The following provisions in § 314.81 (21 CFR 314.81) also would continue to apply:

- § 314.81(b)(3), which addresses submission of advertisements and promotional labeling, special reports upon written request from the Agency, notification of permanent discontinuance or an interruption in manufacturing, and the requirements for withdrawing an approved drug product from sale;
- § 314.81(c), which addresses submitting information related to multiple applications and patient identification requirements; and
- § 314.81(d), which authorizes FDA to withdraw approval of an application for failure to make reports required under § 314.81.

FDA is not aware of any reason to exempt applicants from these requirements, though the Agency requests comment on the burden associated with complying with these provisions.

Subparts E and G of part 314 would also continue to apply. FDA has not identified any reason to establish different requirements and procedures for hearings, imports and exports, drug master files, or public disclosure of Agency records related to designated medical gases.

10. Proposed Changes to Part 514

Similarly, FDA proposes carving out designated medical gases from provisions in part 514 for which a provision specific to designated medical gases is proposed to be added to part 230. FDA also proposes carving out provisions that do not apply to certification requests for designated medical gases. Proposed revisions to § 514.1(a) list the provisions that FDA proposes no longer apply to designated medical gases. FDA proposes that the data confidentiality requirements, hearing procedures, and judicial review process would continue to apply because FDA has not identified any reason to establish different procedures for designated medical gases. Within § 514.80, FDA proposes revisions to the table and to paragraph (a) to further explain that NADAs for designated medical gases are not subject to the reporting requirements in § 514.80 and are instead subject to part 230.

D. Proposed Postmarketing Quality and Safety Reporting Provisions

Also within part 230, FDA proposes new postmarketing safety reporting requirements for designated medical gases.

1. Definitions

Proposed § 230.3(a) would incorporate relevant definitions from sections 201 and 575 of the FD&C Act. Additionally, FDA proposes several additional definitions in § 230.3(b) related to postmarketing safety reports along with the definitions described in section V.C. above. FDA proposes to define ''adverse event'' to mean any untoward medical occurrence associated with the use of a designated medical gas in humans or animals, whether or not it is considered related to the designated medical gas. This would include adverse events occurring in the course of the use of a designated medical gas, adverse events occurring from overdose (whether accidental or intentional), adverse events occurring from abuse, adverse events occurring from discontinuation (such as physiological withdrawal), and any failure of expected pharmacological action.

The proposed definitions of ''ICSR'' and ''ICSR attachments'' would be generally consistent with the definitions of those terms in § 314.80(a). FDA proposes to define ''ICSR'' to mean a description of an adverse event related to an individual patient or subject. The Agency proposes to define ''ICSR attachment'' to mean documents related to the adverse event described in an ICSR, such as medical records, hospital discharge summaries, or other documentation.

FDA proposes to define ''life-threatening adverse event'' to mean any

[7] FDA has described its intention to issue a proposed rule that, among other things, would amend part 314 to modernize postmarketing safety reporting requirements for drugs (see RIN 0910–AI61 on Fall 2021 Unified Agenda of Regulatory and Deregulatory Actions), and FDA intends to update proposed § 314.1(c) to address any new or modified provisions added by that rulemaking that would not apply to designated medical gases.

adverse event that places the patient, in the view of the initial reporter, at *immediate* risk of death from the adverse event as it occurred. This term would not include an adverse event that, had it occurred in a more severe form, might have caused death.

The proposed definition of ''minimum data set for an ICSR for an adverse event'' is generally consistent with the list of minimum data elements for a postmarketing ICSR described in the 2001 draft guidance for industry ''Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines'' (Postmarketing Safety Reporting Draft Guidance) (Ref. 12). FDA proposes that a minimum data set for an ICSR for an adverse event include the following four elements: (1) An identifiable patient, (2) an identifiable reporter, (3) a suspect designated medical gas, and (4) an adverse event.

FDA proposes to define ''nonapplicant'' in a manner that is generally consistent with how the term is described in § 314.80(c)(1)(iii). A nonapplicant would be defined as anyone other than the applicant whose name appears on the label of a designated medical gas container as a manufacturer, packer, or distributor.

FDA proposes to include a definition of ''serious adverse event.'' Under this proposed definition, an adverse event would be considered serious if it results in: Death; a life-threatening adverse event; inpatient hospitalization or prolongation of existing hospitalization; a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or a congenital anomaly/birth defect. Important medical events that may not result in one of the above outcomes may be considered serious adverse events when, based upon appropriate medical judgment, they may jeopardize the patient or study subject and may require medical or surgical intervention to prevent one of the outcomes listed above. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of product dependency or product abuse. Additional examples in animals include severe hypersensitivity reactions or respiratory distress.

2. Field Alert Reports

Section 230.205 contains the proposed requirements for field alert reporting for distributed designated medical gases and articles. Applicants would be required to submit a field alert report (FAR) to the FDA district office that is responsible for their facility concerning (a) information concerning any incident that causes the designated medical gas or its labeling to be mistaken for, or applied to, another article; and (b) information concerning any bacteriological contamination, or significant chemical, physical, or other change or deterioration in the designated medical gas, or failure of one or more distributed batches to meet established specifications. FARs would be required to be submitted within 3 working days of receipt by the applicant. FDA considers working days to be any day from Monday through Friday, excluding U.S. Federal holidays (Ref. 13). The Agency seeks comment on the appropriateness of the 3-day reporting period. FDA would accept receipt of a FAR by telephone or other rapid communication if the applicant promptly follows up in writing. Email is an appropriate method for rapid communication as well as followup. Proposed § 230.205 would also contain requirements for identifying a FAR submission.

Proposed § 230.205 is generally consistent with the FAR requirements in § 314.81(b)(1). FDA proposes to establish § 230.205 to clarify that designated medical gases for both human and animal use would need to follow the same FAR requirements. FDA is not aware of any reason to establish different requirements for designated medical gases for animal use.

3. General Reporting Requirements for Designated Medical Gas Adverse Events

Proposed § 230.210 would contain general requirements for reporting adverse events related to designated medical gases.

Proposed § 230.210(a) would require applicants and nonapplicants to promptly review all safety information that the applicant or nonapplicant receives or otherwise obtains from any source (including both foreign and domestic sources). Examples of such sources would include safety information from commercial marketing experience, reports in the published scientific and medical literature, unpublished scientific papers, and reports from regulatory authorities (this would include domestic and foreign authorities).

As described below in sections V.D.4 and V.D.5, applicants and nonapplicants would be required to submit safety reports for designated medical gases pursuant to §§ 230.220 (for human use) and 230.230 (for animal use). Applicants and nonapplicants for a designated medical gas with both an approved NDA and an approved NADA would be subject to both the human reporting requirements in § 230.220 and the animal reporting requirements in § 230.230. However, both sets of reporting requirements would not apply at the same time for a given event. For example, if an adverse event associated with the use of a designated medical gas in a human patient occurs, the proposed requirements in § 230.220 would apply, but the proposed requirements in § 230.230 would not. Conversely, if an adverse event associated with the use of a designated medical gas in an animal patient occurs, the proposed requirements in § 230.230 would apply, but the proposed requirements in § 230.220 would not. In addition, if an adverse event occurs in a human from exposure during use of the gas in an animal patient, the proposed requirements in § 230.230 would apply, but those in § 230.220 would not. FDA considers an applicant responsible for information known to its employees, affiliates, and contractors. FDA would similarly consider a nonapplicant responsible for information known to its employees, affiliates, and contractors.

Under proposed § 230.210(b)(1), reports or information submitted by applicants or nonapplicants (and any release by FDA of such reports or information) under § 230.220 or 230.230 would not necessarily reflect a conclusion that the report or information constitutes an admission that the designated medical gas caused or contributed to an adverse effect. Additionally, under proposed § 230.210(b)(2), applicants and nonapplicants would not need to admit, and they could deny, that the report or information submitted under § 230.220 or § 230.230 constitutes an admission that the designated medical gas caused or contributed to an adverse effect.

4. Human Designated Medical Gas ICSR Requirements

Proposed § 230.220 would contain requirements for submission of ICSRs associated with the use of a designated medical gas in humans. Under proposed § 230.220(a)(1), both applicants and nonapplicants would be required to submit each ICSR associated with the use of a designated medical gas in humans described in § 230.220(b) to FDA as soon as possible, but no later than 15 calendar days from the date when the applicant or nonapplicant has both met the reporting criteria in paragraph (b) and acquired a minimum data set for an ICSR for that adverse event.

The proposed timeframe for reporting adverse events under § 230.220(a)(1) is

15 calendar days. In contrast to § 314.80(c)(1)(iii), which describes circumstances under which a nonapplicant can elect to submit adverse drug experience reports to the applicant instead of FDA, FDA proposes in § 230.220 to require both applicants and nonapplicants to report adverse events involving designated medical gases directly to FDA. There are a large number of downstream entities that would meet the definition of ''nonapplicant'' and that combine, distribute, and fill designated medical gases, compared to a small number of upstream entities that would meet the definition of ''applicant.'' These downstream nonapplicants may receive designated medical gases from multiple sources, including multiple applicants, and the gases may be commingled within a single tank. Therefore, FDA anticipates that it would be challenging for a downstream nonapplicant to trace the suspect gas to a specific upstream applicant if the nonapplicant becomes aware of a safety issue.

FDA also proposes that the 15-day period would be triggered upon the applicant both meeting the reporting criteria described in proposed § 230.220(b) and acquiring a minimum data set for an ICSR for an adverse event. This proposed requirement would help ensure that a minimum level of information is obtained prior to submission of the report so that the Agency has a more complete picture of the incident. Lastly, FDA is not proposing to include a requirement that an adverse event be unexpected to be subject to the proposed reporting requirement. Because designated medical gases are not required to be studied in clinical trials, which are commonly conducted for other drugs, to be certified under section 576 of the FD&C Act, designated medical gas applicants are not expected to generate the type of labeling information about expected adverse events that sponsors of other types of drugs typically generate during product development. Thus, we expect that the applicants and nonapplicants for designated medical gases that would have reporting obligations under this proposed rule would not be able to determine whether an adverse event was unexpected.

FDA is not proposing a requirement for periodic safety reporting for designated medical gases of the type required under § 314.80(c)(2). This would codify FDA's current approach with regard to the submission of periodic adverse drug experience reports as described in the March 2015 Compliance Program Guidance Manual 7356.002E, (Ref. 14). We do not believe it is necessary to incorporate such a requirement in the proposed postmarket safety reporting regulations that would apply to designated medical gases, but we welcome comment on this issue.

Proposed § 230.220(a)(2) would provide that applicants and nonapplicants should not resubmit ICSRs that they obtained from the FDA Adverse Event Reporting System database or that FDA forwarded to them. This is generally consistent with § 314.80(b). FDA encourages applicants and nonapplicants not to resubmit such ICSRs. Duplicative reports can divert Agency resources away from other safety priorities and, if not identified as duplicates, may obscure signal identification.

Under proposed § 230.220(a)(3), applicants and nonapplicants would be required to submit to FDA new information they receive or otherwise obtain that is related to a previously-submitted ICSR or an ICSR that was sent to the applicant by FDA. Such information would need to be submitted within 15 calendar days after the applicant or nonapplicant receives or otherwise obtains the new information. If an applicant or nonapplicant receives or otherwise obtains new information related to a previously submitted ICSR, they would have to submit the information to FDA under this proposed rule. For example, if a physician submits information to an applicant about an adverse event related to the applicant's designated medical gas, the applicant submits an ICSR based on that information, and the physician updates the applicant in the future, any new information would need to be submitted to FDA as new information within 15 calendar days. This proposed requirement is important to ensure that FDA becomes aware of any new information that arises about the adverse event.

Proposed paragraph (b) would describe two types of ICSRs that must be submitted to FDA. First, applicants and nonapplicants would be required to report serious adverse events received. This would include ICSRs for serious adverse events reported to the applicant or nonapplicant spontaneously (such as reports initiated by patients, consumers, and healthcare professionals) as well as ICSRs for serious adverse events obtained from published scientific and medical journals either as case reports or as the result of a formal clinical trial. Unlike the safety reporting requirements in part 314, FDA is not proposing to include a requirement that the event be unexpected. Designated medical gases do not have traditional product labels that most human drugs and animal drugs bear, and their applicants generally have not conducted traditional clinical trials that would typically generate robust adverse reaction information. Therefore, required serious adverse events must be submitted regardless of expectedness.

In proposed § 230.220(b)(1)(iii), FDA proposes to include one exception to the requirement that serious adverse events be reported within 15 calendar days. ICSRs would not be required for reports of a patient death in cases where the patient was administered oxygen, unless the applicant or nonapplicant is aware of evidence to suggest that the death was caused by the administration of oxygen. FDA recognizes that oxygen is commonly administered during end-of-life care or to patients with a life-threatening disease or who are otherwise in critical condition. Accordingly, FDA believes that unless there is evidence to suggest that the administration of oxygen caused a patient's death, such reports are unlikely to reflect an underlying safety signal.

Second, FDA proposes that, upon notification by FDA, an applicant would be required to submit, in a timeframe established by FDA, ICSRs for any adverse events that would not be required under proposed § 230.220(b)(1). FDA would specify the adverse events to be reported as well as the reason for requiring its reporting to the Agency. For example, FDA might take such action if it identifies a potential safety signal that would not otherwise be reported under § 230.220(b)(1), but the Agency needs additional information to fully evaluate the safety signal, including its seriousness and scope.

Under the proposed requirements in § 230.220, ICSRs would not need to be submitted for fires associated with oxygen use if the patient did not also experience a reportable adverse event. Applicants and nonapplicants who become aware of patients who experience a reportable adverse event associated with a fire related to oxygen use (such as burns or smoke inhalation) would be required to submit an ICSR. Because it is well-known that oxygen accelerates combustion and that smoking near an oxygen source can cause a fire, FDA believes it is unnecessary to receive reports in which the patient does not experience an adverse event.

Proposed paragraph (c) would describe the process for completing and submitting an ICSR. Under paragraph (c)(1), FDA proposes to require submission of ICSRs and ICSR attachments in electronic format that

FDA can process, review, and archive, as described in § 314.80(g)(1). Should this proposed rule be finalized, FDA would incorporate designated medical gases into existing guidances on electronic submission of postmarketing safety reports under § 314.80(g)(1), as designated medical gases would be expected to use the same electronic reporting mechanism. Under § 230.220(c)(1)(ii), applicants and nonapplicants would be able to request in writing a temporary waiver of the requirements in § 230.220(c)(1)(i), as described in § 314.80(g)(2) (see also Ref. 15). Further, FDA would grant such waivers on a limited basis and for good cause shown.

Under proposed paragraph (c)(2), FDA proposes additional reporting requirements. Proposed paragraph (c)(2) would direct applicant and nonapplicants to submit each ICSR only once and would require applicants and nonapplicants to submit a separate ICSR for each patient who experiences an adverse event reportable under paragraph (b). FDA also proposes to require that adverse event terms described in an ICSR be coded using standardized medical terminology (*e.g.,* the Medical Dictionary for Regulatory Activities). The use of standardized medical terminology facilitates sharing of regulatory information internationally for human medical products (Ref. 16). Additionally, the use of standardized medical terminology will facilitate electronic transmission of safety information in a format that FDA can process, review, and archive, as required under § 314.80(g)(1). ICSRs submitted under § 230.220 would be required to contain at least the minimum data set for an ICSR for an adverse event. The applicant or nonapplicant would need to actively seek the minimum data set in a manner consistent with proposed paragraph (f) and document and maintain records of their efforts. Inclusion of the minimum data set would similarly facilitate electronic transmission of safety information in the necessary format for FDA to process, review, and archive. Proposed paragraph (c)(2) would also require that the applicant or nonapplicant complete all known, available elements of an ICSR described in proposed paragraph (d). For adverse events, applicants and nonapplicants would be required to actively seek any information needed to complete all applicable elements, consistent with the written procedures that would be required under proposed paragraph (f), and to document and maintain records of their efforts to obtain the missing information. However, if an adverse event is reportable under proposed § 230.220(b) but the ICSR is missing certain elements listed in paragraph (d) (*i.e.,* elements other than the required minimum data set), FDA would still receive and review the ICSR. Lastly, proposed paragraph (c)(2) would require an applicant or nonapplicant to submit the following types of supporting documentation in an ICSR, if available:

- A copy of the autopsy report if the patient died, or a hospital discharge summary if the patient was hospitalized (to be submitted as an ICSR attachment in the manner specified); and
- A copy of the published article for each ICSR of an adverse event obtained from published scientific and medical literature (to be submitted as an ICSR attachment in the manner specified).

FDA seeks comment on the burden associated with complying with these proposed requirements. These proposed requirements also include required timeframes, translation of foreign language documents, and cross-referencing in the case of multiple ICSRs related to the same article.

Proposed paragraph (d) would describe the information to be included in an ICSR. This is generally the same list as in § 314.80(f), with a few exceptions. First, FDA is not proposing to require that the applicant or nonapplicant state whether the product is a combination product. Second, FDA does not propose to require the submission to include an expiration date because designated medical gases are not generally expected to have an expiration date under proposed part 213. Third, FDA does not propose to require the applicant or nonapplicant to state whether the product is a prescription or nonprescription product. With the exception of oxygen for limited uses identified in section 576(b)(2)(A) of the FD&C Act, all designated medical gases are for prescription use, and the Agency expects that to continue to be the case. Fourth, FDA has proposed to combine the contact information in § 314.80(f)(5)(i) and (ii) into one bullet. Fifth, we propose to clarify in § 230.220(d)(5)(iv) that the applicant or nonapplicant would be required to submit the NDA and/or NADA number for their certification. Lastly, FDA proposes to require that the applicant or nonapplicant state whether the ICSR is an expedited report, rather than stating whether the ICSR is a 15-day alert report.

Proposed paragraph (e) would contain recordkeeping requirements. Applicants and nonapplicants would be required to maintain records of information related to adverse events under proposed § 230.220 for up to 10 years from the initial receipt of information. These records would need to be maintained regardless of whether the information was submitted to FDA. The records would also need to include raw data, correspondence, and any other information relating to the evaluation and reporting of adverse event information that is received or otherwise obtained by the applicant or nonapplicant. These proposed requirements are generally consistent with the requirements in § 314.80(j). FDA also proposes that, upon written notice, the applicant or nonapplicant would need to submit any or all of these records to FDA within 5 calendar days after receipt of the notice. Applicants and nonapplicants would also need to permit authorized FDA employees to access, copy, and verify these established and maintained records, at reasonable times. These proposed requirements will help facilitate the review of new and emergent safety issues, including of potential safety signals that may be associated with nonserious adverse events, which would not be required to be reported to FDA under proposed paragraph (b)(1).

Proposed paragraph (f) would require that applicants and nonapplicants develop written procedures to fulfill their obligations under proposed § 230.220 for the surveillance, receipt, evaluation, and reporting of adverse event information. This proposed requirement is generally consistent with existing requirements in § 314.80(b) and is appropriate for designated medical gases. Additionally, we propose to specify that these procedures would need to address employee training and the obtaining and processing of adverse event information from other applicants and nonapplicants. Employee training is important to ensure that all personnel who may receive or handle adverse event information on the company's behalf fully understand their responsibilities. Processing adverse event information from other parties is also critical because of the many layers of distribution typical for designated medical gases.

Proposed paragraph (g) would contain proposed patient privacy provisions. Rather than including patient names and addresses in reports under proposed § 230.220, proposed paragraph (g) would recommend that applicants and nonapplicants assign a unique code to identify patients. Proposed paragraph (g) would recommend that applicants and nonapplicants include the name of the reporter from whom the information was received as part of the initial reporter information, even if the patient

is the reporter. As set forth in FDA's public information regulations in part 20, FDA generally may not disclose the names of patients, individual reporters, healthcare professionals, hospitals, and geographical identifiers submitted to FDA in adverse event reports. This is similar to the patient privacy provisions for other drugs in § 314.80(i), though FDA proposes to expand these requirements to nonapplicants.

5. Animal Designated Medical Gas Adverse Event Reporting Requirements

Proposed § 230.230 would contain requirements for submission of adverse event reports related to the use of a designated medical gas in animals. Proposed § 230.230(a) would govern the types of reports that would be required to be submitted to FDA.

Under proposed § 230.230(a)(1), applicants and nonapplicants must submit adverse event reports to FDA as soon as possible but no later than within 15 calendar days of first receiving the information. Reports are required for serious adverse events the applicant or nonapplicant receives from others as well as reports from published literature, regardless of whether the applicant or nonapplicant believes the event is related to the designated medical gas. FDA proposes an exception to the reporting requirements for the death of an animal that was administered oxygen, unless the applicant or nonapplicant becomes aware of evidence to suggest that the administration of oxygen caused the death. As is the case with human use of oxygen, FDA expects that oxygen will be administered to animals that are in critical condition. For such animals, death is expected to be a common outcome, so unless evidence suggests a causal relationship between oxygen and the death, FDA does not believe that adverse event reporting in that instance will shed new light on the safety of oxygen.

Proposed § 230.230(a)(2) would require that applicants and nonapplicants report adverse events that do not qualify for serious adverse event reporting under paragraph (a)(1) if notified by FDA to do so. This proposed requirement would allow FDA to obtain information regarding other safety signals if the Agency determines additional information is necessary to help protect animal or public health.

As is the case for designated medical gases for human use, FDA would like to clarify that the proposed rule would not require submission of reports for fires associated with oxygen use if the animal patient did not experience an adverse event. Fires associated with oxygen use would be required to be reported if the animal patient experiences an adverse event. Because it is known that oxygen accelerates combustion and that smoking or open flames near an oxygen source can cause a fire, FDA believes it is not necessary to receive reports in which the animal patient did not experience a serious adverse event.

Proposed § 230.230(a)(3) would state that applicants and nonapplicants should not resubmit any adverse event reports obtained from FDA's adverse event reporting database or that FDA forwards to the applicant or nonapplicant, in order to minimize duplication.

The format of adverse event reporting for animal use is addressed in proposed § 230.230(b). FDA proposes to require submission in an electronic format, and that data in electronic submissions conform to the data elements in Form FDA 1932 and the Agency's technical documents on how to provide electronic submissions (*e.g.,* method of transmission and processing, media, file formats, preparation and organization of files). The proposed rule would allow FDA to issue updated technical documents, as necessary. The most current information on submitting postmarketing safety reports to the Center for Veterinary Medicine (CVM) in electronic format can be found on CVM's web page at *https://www.fda.gov/IndustryReportAnimalAE* (see, *e.g.,* ''Instructions for Electronic Submission of Mandatory Adverse Event Reports to FDA CVM'') (Ref. 17). As in the corresponding provision for designated medical gases for human use, under proposed 230.230(b)(2), applicants and nonapplicants would be able to request in writing a temporary waiver of the electronic reporting requirements.

Proposed paragraph (c) contains recordkeeping requirements. Applicants and nonapplicants must maintain records of information related to adverse event reports for up to 5 years from the initial receipt of information. These records must be maintained regardless of whether the information was submitted to FDA. The records must also include raw data, correspondence, and any other information relating to the evaluation and reporting of such information that is received or otherwise obtained by the applicant or nonapplicant. These proposed requirements are generally consistent with the requirements in proposed 230.220(e), though FDA proposes a retention period of 5 years, consistent with other animal safety reporting requirements. FDA also proposes to require that, upon written notice, the applicant or nonapplicant must submit these records to FDA within 5 calendar days after receipt of the notice. Because applicants and nonapplicants would not be required to submit nonserious adverse event reports, retaining the ability to collect records not submitted to the Agency would help FDA address questions that arise as FDA evaluates safety signals. Applicants and nonapplicants must also permit authorized FDA employees to access, copy, and verify these established and maintained records, at reasonable times. These proposed requirements will help facilitate the review of new and emergent safety issues.

6. Part 4 Postmarketing Safety Reporting Requirements

As mentioned above, some medical gases are marketed as part of a combination product. The Agency believes some clarification is needed regarding the applicability of the postmarketing safety reporting requirements in part 4, subpart B to such medical gases.

Because proposed part 230 would only apply to designated medical gases, medical gases under applications submitted under section 505 of the FD&C Act would continue to be subject to the postmarketing safety reporting requirements in part 314. Additionally, if the medical gas is part of a combination product that received marketing authorization (*e.g.,* under an application submitted under section 505 of the FD&C Act), the requirements in part 4, subpart B currently apply. FDA proposes no changes for such products with regard to safety reporting requirements.

As proposed in this section, new part 230 would apply to applicants and nonapplicants of designated medical gases subject to the certification requirements in section 576 of the FD&C Act. As explained in 21 CFR 4.100, part 4, subpart B does not apply to combination products that have not received marketing authorization. Therefore, part 4, subpart B would not apply to designated medical gases that are part of a combination product that did not receive marketing authorization. However, other reporting requirements may apply, *e.g.,* the medical device reporting requirements in 21 CFR part 803 if such combination product includes a device constituent part. Further, if proposed part 230 is finalized, the safety reporting requirements therein would apply to such combination product that includes a designated medical gas.

VI. Proposed Effective Date

FDA proposes that any final rule based on this proposal become effective 18 months after publication in the **Federal Register**. The Agency anticipates that some proposed requirements will result in changes to cylinders as they are returned from service, and that it may take some time for firms to make required changes to all cylinders. We believe that 18 months is an appropriate amount of time to enable firms to make such changes. FDA solicits comment on this proposed compliance date.

VII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule would more specifically tailor the current good manufacturing practice requirements for medical gases, add new oxygen labeling requirements, clarify the medical gas certification process, and clarify adverse event reporting requirements, this rule would create small net cost savings for small entities, and we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

This proposed rule, if finalized, would establish, within part 213, CGMP regulations specific to medical gases. These proposed regulations include many of the same categories of requirements as the general drug CGMP regulations but are tailored to reflect differences in how medical gases are manufactured, packaged, labeled, stored, and distributed. This proposed rule, if finalized, would make limited changes to the labeling requirements of part 201 including requiring that a ''no smoking'' statement, a ''no vaping'' statement, and graphic warning symbol be added to oxygen designated medical gas containers to reduce the risk of fire. This proposed rule, if finalized, would codify and clarify the process for obtaining a certification to market designated medical gases. Recommendations for how to request a certification for designated medical gases are currently included in a draft guidance. This proposed rule, if finalized, would establish new postmarketing safety reporting regulations for designated medical gases that would address human and animal use and more specifically reflect the development, manufacturing, and distribution of designated medical gases.

The costs of this proposed rule, if finalized, would be primarily driven by new labeling requirements, regulatory clarification leading to firms becoming compliant with existing requirements, and added CGMP requirements including a requirement for portable cryogenic containers to have a working gauge.

The cost savings of this proposed rule, if finalized, would be primarily driven by removing CGMP requirements that would not apply to medical gases, such as removing certain building and facility requirements, or modifying CGMP requirements so that they would be more well-tailored to medical gases, which may streamline inspections.

Table 1 summarizes the estimated benefits and costs of the proposed rule, if finalized. The annualized benefits would range from $0.00 million to $6.48 million with a primary estimate of $3.24 million over a 10-year span at a 7 percent discount rate. Annualized at a 3 percent discount rate these benefits would range from $0.00 million to $6.86 million with a primary estimate of $3.43 million. The annualized costs would range from $1.38 million to $4.95 million with a primary estimate of $3.03 million at a 7 percent discount rate. Annualized at a 3 percent discount rate these costs would range from $1.23 million to $4.77 million with a primary estimate of $2.88 million.

The present value of the estimated benefits would range from $0.00 million to $51.98 million with a primary estimate of $26.02 million at a 7 percent discount rate and from $0.00 million to $65.37 million with a primary estimate of $32.73 million at a 3 percent discount rate. The present value of the estimated costs would range from $11.06 million to $39.71 million with a primary estimate of $24.33 million at a 7 percent discount rate and from $11.74 million to $45.49 million with a primary estimate of $27.49 million at a 3 percent discount rate.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized $millions/year	$3.24 3.43	$0.00 0.00	$6.43 6.86	2020 2020	7 3	10 10	Most benefits are cost savings to industry while the remaining are cost savings for FDA due to a more streamlined inspection process.
Annualized Quantified	.....	.....	.....	.....	7 3	.....	
Qualitative	.....	.....	.....	.....	.....	.....	

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Costs:							
Annualized Monetized $millions/year	3.03	1.38	4.95	2020	7	10	
	2.88	1.23	4.77	2020	3	10	
Annualized Quantified	.....	.....	.....	.....	7	.....	
	.....	.....	.....	.....	3	.....	
Qualitative	.....	.....	.....	.....	.....	.....	
Transfers:							
Federal Annualized Monetized $millions/year	.....	.....	.....	.....	7	.....	
	.....	.....	.....	.....	3	.....	
From/To	From:			To:			
Other Annualized Monetized $millions/year	.....	.....	.....	.....	7	.....	
	.....	.....	.....	.....	3	.....	
From/To	From:			To:			
Effects: State, Local or Tribal Government: None. Small Business: Not significant. Wages: None. Growth: None.							

FDA conducted a regulatory flexibility analysis of the impact of the proposed rule on small entities. Approximately 41 percent of domestic entities that would be affected by the proposed rule are small according to Small Business Administration (SBA) size standards. We estimate that the highest single year cost for a firm could be as high as 0.788 percent while the average costs to receipts ratio is 0.007 percent. Therefore, our analysis of the impact of the proposed rule on small entities suggests that small firms will not be significantly affected by the proposed regulation, if finalized.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 18) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h), (j), and (k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). A description of these provisions is given in the *Description* section of this document with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Current Good Manufacturing Practice, Certification, Postmarketing Safety Reporting, and Labeling Requirements for Certain Medical Gases.

Description: This rulemaking is amending existing regulations and establishing new regulatory requirements pertaining to medical gases.

Description of Respondents: Respondents to this information collection are entities who manufacture, process, pack, label, or distribute certain medical gases.

1. Product Jurisdiction and Combination Products; OMB Control No. 0910–0523—Revision

FDA recognizes that some medical gases are marketed as part of a combination product. For example, a medical gas may be marketed with a device constituent part (for example, a portable liquid oxygen unit or a pressure regulator). Combination products are subject to information collection provisions found in 21 CFR parts 3 and 4, which prescribe content and format requirements associated with marketing applications, together with applicable recordkeeping and reporting requirements.

FDA proposes to revise provisions in part 4 to account for combination products that contain a medical gas, as FDA proposes medical gases to be subject to proposed part 213, and to clarify (where appropriate) applicable medical gases requirements throughout part 4. We believe that the revisions impose no new burden associated with information collection currently approved under OMB control number 0910–0523 and invite comment on our assumptions.

2. Labeling Requirements for Prescription Drugs; OMB Control No. 0910–0572—Revision

We estimate the burden of the information collection as follows:

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; proposed CFR section	Number of respondents	Number of disclosures per respondent [2]	Total annual disclosures [2]	Average burden per disclosure	Total hours
Labeling of bulk or transport containers used to hold designated medical gases; § 201.161(b).	1,696	2.36	4,000	0.1 (6 minutes)	400
On the container label, identify the owner of a designated medical gas container or a container of a medically appropriate combination of designated medical gases. If the container owner is not the manufacturer, packer, or distributor of the gas, identify that information on the label; § 201.328(d).	1,696	2.36	4,000	0.1 (6 minutes)	400
Total			8,000		800

[1] There are no capital costs or operating and maintenance costs associated with the information collection.
[2] Totals have been rounded to the nearest whole number.

Regulations in part 201 govern the statement of ingredients and declaration of net quantity of contents with regard to prescription drug product labeling.

The proposed revisions to the regulations would require that firms identify bulk or transport containers with the name of the product contained therein and that containers be accompanied by documentation that identifies the product as meeting applicable compendial standards. Bulk or transport containers are excluded from the proposed definition of final use containers. Because these large containers are removed from the point of care and we do not expect that patients and healthcare practitioners will use them directly to administer designated medical gas, FDA does not believe that firms' bulk or transport containers need to bear the information that we would require under proposed § 201.161(a). However, to prevent mix-ups, it is essential that the identity of the gas inside such containers is evident to individuals who handle and transport the containers. FDA expects that these proposed requirements will help prevent mix-ups and ensure that recipients of medical gases in bulk or transport containers are provided information indicating that such gases meet applicable compendial standards.

Based on our experience with similar information collection, we estimate that 1,696 firms will label 4,000 containers and assume firms will expend 6 minutes (0.1 hours) to identify the containers with the name of the product and place documentation that identifies the product as meeting applicable compendial standards, totaling 400 hours annually.

Proposed § 201.328(d) would provide that the owner of a designated medical gas container or a container of a medically appropriate combination of designated medical gases may be identified on the container. This statement may appear on a separate sticker or decal on the container (that is, it need not be contiguous with other labeling on the container), but if the container owner is not the manufacturer, packer, or distributor of the gas, that information shall be clearly stated. FDA recognizes the complex distribution system for designated medical gases and medically appropriate combinations of designated medical gases and the importance of each entity in the distribution chain being clearly identified so that patients and healthcare professionals can contact the appropriate entity if necessary. We intend for this provision to help ensure that appropriate entities can be contacted about quality issues or adverse events. In addition, the proposed labeling requirement would facilitate the return of cylinders to owners who may not also be medical gas manufacturers. FDA proposes that including the container owner's information will not cause the container owner to be a ''relabeler'' for purposes of FDA's registration and listing requirements.

Based on our experience with similar information collection, we estimate that 1,696 firms will identify on a designated medical gas container or a container of a medically appropriate combination of designated medical gases the name of the container owner who may not also be the manufacturer, packer, or distributor of the gas. We assume firms would include this label on 4,000 containers and will expend 6 minutes (0.1 hours) to perform this activity, totaling 400 hours annually.

3. Current Good Manufacturing Practice for Medical Gases; OMB Control No. 0910–NEW

We estimate the burden of the information collection as follows:

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; proposed CFR section	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records [2]	Average burden per recordkeeping	Total hours
New Start Up SOP; § 213.42	1,696	1	1,696	13	22,048
SOP Maintenance; § 213.42	1,696	1	1,696	0.65 (39 minutes)	1,102
New Start Up SOP; § 213.208	1,696	1	1,696	13	22,048
SOP Maintenance § 213.208	1,696	1	1,696	0.65 (39 minutes)	1,102
Documentation of completion of training; § 213.25(a)	1,696	10	16,960	0.083 (5 minutes)	1,408
Consultants' records of sufficient education, training, and experience, or any combination thereof; § 213.34.	1,696	0.336	571	0.5 (30 minutes)	286
Firms' records of equipment maintenance and cleaning; § 213.67(c)	1,696	43.7676	74,230	0.25 (15 minutes)	18,557
Maintain records for modifications to automatic, mechanical, and electronic equipment; § 213.68(d).	1,696	6.734	11,420	0.25 (15 minutes)	2,855

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity; proposed CFR section	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records [2]	Average burden per recordkeeping	Total hours
Receipt and storage of incoming designated medical gases; § 213.82(a).	1,380	417	575,460	0.25 (15 minutes)	143,865
Records of rejected components; § 213.89	1,380	24.2	33,400	0.083 (5 minutes)	2,772
Maintain records for each shipment received of each different labeling and packaging material indicating receipt, examination, and whether accepted or rejected; § 213.122(c).	1,696	43.7676	74,230	0.25 (15 minutes)	18,558
Document results of inspections in the batch production records; § 213.130(e).	1,696	67.334	114,200	0.25 (15 minutes)	28,550
Maintain written records so that data therein can be used for evaluating, at least annually, the quality standards of each medical gas to determine the need for changes in specifications or manufacturing or control procedures; § 213.180(d).	1,696	0.27	457	0.25 (15 minutes)	114
Maintain record of equipment cleaning and use log maintenance; § 213.182.	1,696	1.76	2,969	0.16 (10 minutes)	475
Maintain records for components, medical gas containers and closures, and labeling; § 213.184.	1,696	2.626	4,454	0.33 (19.8 minutes)	1,470
Maintain master production and control records; § 213.186	1,696	13.467	22,840	2	45,680
Maintain batch production and control records; § 213.189	1,696	21.883	37,115	1.3 (78 minutes)	48,250
Maintain record of the investigation; § 213.192(a)	1,696	2.69	4,568	1	4,568
Maintain laboratory records; § 213.194(b) through (e)	1,696	33.667	57,100	0.5 (30 minutes)	28,550
Maintain distribution records; § 213.196	1,696	33.667	57,100	0.25 (15 minutes)	14,275
Maintain written records of each complaint; § 213.198(b)	1,696	6.733	11,420	1	11,420
Total			1,105,278		417,953

[1] There are no capital costs or operating and maintenance costs associated with the information collection.
[2] Totals have been rounded to the nearest whole number.

FDA proposes to establish part 213 setting forth CGMP requirements applicable to medical gases. If finalized, part 213 would apply to firms that manufacture a medical gas and would also establish requirements applicable to firms that subsequently combine, commingle, refill, or distribute medical gases.

The proposed regulations include recordkeeping requirements pertaining to personnel qualifications and responsibilities of persons who are engaged in the manufacturing, processing, packing, or holding of a medical gas.

Provisions under proposed § 213.42(c) include recordkeeping to document the development and implementation of written procedures to ensure that firms maintain a clean condition for any building used to manufacture, process, pack, or hold a medical gas so as to ensure the safety, identity, strength, quality, and purity of the gas. Firms would need to develop written procedures that apply to maintaining and cleaning buildings. Based on available data, we estimate 1,696 firms will each develop and implement written procedures to maintain and clean buildings. We assume it will take 13 hours to perform this activity, totaling 22,048 hours annually. Firms would also maintain these procedures. Based on available data, we estimate 1,696 firms would each maintain written procedures to maintain and clean buildings. We assume it will take 39 minutes (0.65 hours) to perform this activity, totaling 1,102 hours annually.

Similarly, under proposed § 213.208, firms would be required to develop and implement written procedures for the holding, testing, and use of salvaged medical gases. Based on available data, we estimate 1,696 firms will develop and implement written procedures for the holding, testing, and use of salvaged medical gases. We assume it will take 13 hours for firms to perform this activity, totaling 22,048 hours annually. Based on available data, 1,696 firms will prepare written procedures (1 procedure each) for the holding, testing, and use of salvaged medical gases. We assume it takes 0.65 hours to perform this activity, totaling 1,102 hours annually.

The proposed regulations would provide that employee training be included in the firm operations. Recordkeeping would be established to demonstrate that qualified individuals conduct training on a continuing basis and with sufficient frequency to allow employees to remain familiar with applicable requirements. Based on available data, we estimate that 1,696 firms will prepare written documentation pertaining to employee training. We assume 10 employees per firm will create 16,960 records (10 records per firm) and that it will take 5 minutes (0.083 hours) to prepare the records, for a total of 1,408 hours annually.

Under proposed § 213.34, records demonstrating that consultants have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained will be required. Based on available data, we estimate that 1,696 firms will maintain 571 records of consultants' education, training, and experience, or any combination thereof and assume it will take 30 minutes (0.5 hours) to perform this activity, totaling 286 hours annually.

Based on available data, we estimate that 1,696 firms will maintain 74,230 records of equipment maintenance and cleaning and assume it will take 15 minutes (0.25 hours) to perform this activity, totaling 18,557 hours annually.

Based on available data, we estimate 1,696 firms will develop and implement 11,420 written procedures for automatic, mechanical, and electronic equipment and assume firms will expend 15 minutes (0.25 hours) to perform this activity, totaling 2,855 hours annually.

As provided for in the proposed regulations, if an incoming designated medical gas is obtained from a supplier other than the original manufacturer, the shipment would also need to include specific information. To ensure the reliability of appropriate assessment and testing, firms will be required to establish and maintain a program to ensure the reliability of the supplier's capabilities through appropriate assessment and testing procedures. Based on assumptions found in our Preliminary Regulatory Impact Analysis (PRIA), we estimate that 1,380 firms would verify and document records upon receipt of a designated medical gas. We assume firms will maintain

575,460 records (417 records each (1 delivery per week of oxygen for 1 year (52 deliveries) plus 1 delivery per night of nitrogen for 1 year (365 deliveries)). We further assume firms will expend 15 minutes (0.25 hours) each (104 hours in total for each firm) to perform this activity, totaling approximately 143,865 hours annually.

Proposed § 213.89 would require that firms identify and control rejected components, containers, and closures under a quarantine system designed to prevent their use in operations for which they are unsuitable. Proposed § 213.89 also applies to incoming designated medical gases. Quarantine systems would not need to include physical quarantining because other methods can adequately ensure that unsuitable products are not used. Based on assumptions found in section II.F.4.b of the PRIA, we estimate that 1,380 downstream firms would need to assess and document 33.4 million medical gas components, containers, and closures annually. We assume that firms would reject 0 to 0.1 percent of all containers. These firms will maintain a total of 33,400 records of rejected components and we assume will expend 5 minutes (0.083 hours) to perform this activity, totaling 2,772 hours annually.

Under proposed § 213.122(c), firms would need to maintain records for each shipment received of each different labeling and packaging material indicating receipt, examination, and whether accepted or rejected. Based on available data, we estimate 1,696 firms will prepare 74,230 records to document each shipment received of each different labeling and packaging material indicating receipt, examination, and whether accepted or rejected. We assume it will take 15 minutes (0.25 hours) to perform this activity, totaling 18,558 hours annually.

Under proposed 213.130(e), firms would need to document results of inspections concerning packaging and labeling in the batch production records. Based on available data, we estimate 1,696 firms will document results of inspections in the batch production records in approximately 114,200 records. We assume it will take 15 minutes (0.25 hours) per record to perform this activity, totaling 28,550 hours annually.

As described in section V.B.11 of this document and proposed § 213.180(d), firms would need to maintain written records so that data therein can be used for evaluating, at least annually, the quality standards of each medical gas to determine the need for changes in specifications or manufacturing or control procedures. Based on available data, we estimate 1,696 firms will prepare 457 records. We assume it will take 15 minutes (0.25 hours) to perform this activity, totaling 114 hours annually.

Under proposed § 213.182 and as described in section V.B.11 of this document, firms would need to maintain a written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use. Based on available data, we estimate 1,696 firms will prepare 2,969 records documenting major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use. We assume it will take 10 minutes (0.16 hours) to perform this activity, totaling 475 hours annually.

As described in section V.B.11 of this document and under proposed § 213.184, firms would need to maintain certain records concerning components, medical gas containers and closures, and labeling. Based on assumptions found in our PRIA, we estimate 1,696 firms will prepare 4,454 records for components, medical gas containers and closures, and labeling. We assume firms will expend 19.8 minutes (0.33 hours) to perform this activity, totaling 1,470 hours annually.

As discussed in section V.B.11 of this document and estimates for the number of firms calculated throughout the PRIA, under proposed § 213.186, to ensure uniformity from batch to batch, firms would need to prepare, date, and sign master production and control records for each medical gas. Based on data from existing information collection requests and estimates for the number of firms calculated throughout the PRIA, we estimate 1,696 firms will prepare and maintain approximately 22,840 master production and control records and assume it will require 2 hours for firms to perform this activity, totaling 45,680 hours annually.

Under proposed § 213.189 and as described in section V.B.11 of this document, firms would need to maintain batch production and control records. These records would need to include documentation that the firm has accomplished each significant step in the manufacturing, processing, packing, or holding of the medical gas produced. Based on data from existing information collection requests and estimates for the number of firms calculated throughout the PRIA, we estimate 1,696 firms will prepare and maintain 37,115 batch production and control records. We assume it will require 78 minutes (1.3 hours) for firms to perform this activity, totaling 48,250 hours annually.

Section V.B.11 of this document and proposed § 213.192(a) describe production record review. Per paragraph (a), firms would need to maintain a written record of the investigation and include the conclusions and followup. Based on data from existing information collection requests and estimates for the number of firms calculated throughout the PRIA, we estimate 1,696 firms will prepare and maintain 4,568 laboratory records and that it will require 1 hour for firms to perform this activity, totaling 4,568 hours annually.

Under proposed § 213.194(b) through (e) and as described in section V.B.11 of this document, firms would need to maintain certain laboratory records. Based on available data, we estimate 1,696 firms will prepare and maintain 57,100 laboratory records and assume it will require 30 minutes (0.5 hours) for firms to perform this activity, totaling 28,550 hours annually.

As described in section V.B.11 of this document, proposed § 213.196 describes certain proposed requirements for distribution records. Based on available data, we estimate 1,696 firms will prepare and maintain 57,100 distribution records and assume it will require 15 minutes (0.25 hours) for firms to perform this activity, totaling 14,275 hours annually.

As discussed under proposed § 213.198(b), firms would be required to maintain written records of each complaint regarding medical gases. Our full discussion is shown in section V.B.11 of this document. Based on assumptions found in our PRIA, we estimate 1,696 firms will maintain 11,420 records of complaints. We assume it will require approximately 1 hour for firms to perform this activity, totaling 11,420 hours annually.

4. Certification Process and Postmarketing Quality and Safety Reporting; OMB Control No. 0910–NEW

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; proposed CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of certification requests and certification form that includes any resubmissions and amendments to pending requests; § 230.50	5	1	5	3	15
Submission of supplements to certification requests and other changes; § 230.70	4	1	4	3	12
Submission of requests to transfer ownership of certification, including new address and the owner's submission of any change in the conditions in the granted certification; § 230.72	2	2	4	2	8
Annual reports; § 230.80	50	2.16	108	2	216
Field alert reports; § 230.205	1,380	0.002	3	8	24
CDER: Submission of ICSRs (§ 230.220(a) through (d))	1,430	0.12	172	6	1,032
CDER's maintenance of records for human designated medical gas ICSR requirements (§ 230.220(e))	1,430	0.48	686	16	10,976
CVM's recordkeeping requirements related to adverse event reports (§ 230.230(c))	1,696	0.0044	7.5	5	37.5
CVM: Submission of adverse event reports; § 230.230	1,696	0.0044	7.5	5	37.5
CVM: Waiver request from electronic submission requirement; § 230.230	1,696	0.0044	7.5	5	37.5
Total			1,004.5		12,395.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals have been rounded to the nearest whole number.

Proposed § 230.50 (see section V.C.2 of this document) would establish the general requirements for requesting a designated medical gas certification for all submission types and would outline the information that must be included in certification request submissions.

The proposed regulations would require applicants to include facility information in certification requests. Such information would include, among others, name and address of the original manufacturing facility or facilities where the gas is or will be manufactured.

Proposed section 230.50 would also provide for the submission of additional information if FDA deems it appropriate to determine whether a medical gas meets the definition of a designated medical gas. This information would generally be in the form of a written request by FDA for the additional information.

Based on assumptions found in our PRIA, we estimate that five respondents will submit a total of five certification requests annually, including certification forms for original and resubmissions. We assume each certification request will require 3 hours to prepare and submit, totaling 15 hours annually.

Under proposed § 230.65, applicants would be allowed to withdraw a certification request that has not been deemed granted. An applicant could notify FDA that it withdraws its certification request at any time before the certification is deemed granted. Upon an applicant's withdrawal of a certification request, FDA would retain the certification request, and if the applicant requests a copy via FOIA request, FDA would provide it pursuant to the fee schedule in FDA's public information regulations. Since the passage of FDASIA, FDA has received several certification requests but has not received any withdrawal requests. FDA has no other data on which to provide a burden estimate. Therefore, the Agency does not expect to receive withdrawal requests except in exceedingly rare situations.

Proposed § 230.70, as discussed in section V.C.3 of the proposed rule would require applicants to submit a supplement if any information in the granted certification has changed. The proposed regulation would prescribe information to be included in a supplement submission.

Based on our experience with similar information collection, we estimate four applicants will submit supplements and assume, each submission will require 3 hours to prepare, totaling 12 hours annually.

Proposed § 230.72 would govern changes in ownership of a granted certification. An example of when a change in ownership could occur is during a merger or acquisition. Upon a change in ownership, the regulations would require that both the new and previous owner notify FDA.

Based on related submissions received by FDA over the last few years and averaged accordingly, we estimate two respondents will submit four letters or other supporting documents, and assume it will take 2 hours to complete this task, totaling 8 hours annually.

To assist respondents with the proposed submission requirements associated with proposed § 230.80 (annual reports), we are developing an annual report form.

Based on our records and informal requests received upon announcing this rulemaking, we estimate that 50 applicants will submit to FDA 108 annual reports (a total of 108 reports). We assume firms will expend 2 hours to perform this activity, totaling 216 hours annually.

Our estimate associated with proposed requirements in § 230.205 for field alert reporting for designated medical gases is based on our experience with similar reports that FDA received in 2019 and 2020.

We estimate that 1,380 applicants and nonapplicants will submit to FDA three FARs. We assume respondents will expend approximately 8 hours to perform this activity, totaling 24 hours annually.

Proposed § 230.210 would require that applicants and nonapplicants promptly review all safety information that the applicant or nonapplicant receives or otherwise obtains from any source (including both foreign and domestic sources). Applicants and nonapplicants would generate reports from their review and submit them under proposed §§ 230.220 and 230.230.

As described under proposed § 230.220(a) through (d) (see section V.D.4 of this document), firms would be required to submit ICSRs associated with the use of a designated medical gas in humans.

Proposed § 230.220 (see section V.D.4 of this document) would contain requirements for submission of ICSRs associated with the use of a designated medical gas in humans. Under proposed § 230.220(a)(1), applicants and nonapplicants would be required to submit each ICSR as soon as possible, but no later than 15 calendar days from the date the applicant or nonapplicant has met the reporting criteria under proposed § 230.220(b) and acquired a

minimum data set for an ICSR for that adverse event.

Under proposed § 230.220(a)(3), applicants and nonapplicants would submit new information they receive or otherwise obtain about a previously submitted ICSR to FDA. The proposed regulation would prescribe reporting schedules to ensure FDA becomes aware of any new information that arises about the adverse event.

Based on assumptions found in our PRIA and a review of safety report data, we estimate that 1,430 applicants and nonapplicants will submit to FDA 172 ICSRs annually. We assume it will take 6 hours for respondents to perform this activity, totaling 1,032 hours annually.

Proposed § 230.220(b) would describe the types of ICSRs that applicants and nonapplicants would need to report for human use. Under proposed § 230.220(b)(1), applicants and nonapplicants would be required to submit ICSRs for serious adverse events. Under proposed § 230.220(b)(2), FDA proposes to require an applicant to report to FDA, in a timeframe established by FDA, ICSRs for any adverse events that would not be required under proposed § 230.220(b)(1) upon notification by FDA.

Proposed § 230.220(e) would prescribe content and format requirements for records pertaining to human designated medical gas adverse events. For a period of 10 years from the initial receipt of information, each applicant or nonapplicant would be required to maintain records of information relating to adverse events, whether or not submitted to FDA. These records would need to include raw data, correspondence, and any other information relating to evaluating and reporting adverse event information that is received or otherwise obtained by the applicant or nonapplicant. Upon written notice by FDA, the applicant or nonapplicant would need to submit any and all of these records to FDA within 5 calendar days after receipt of the notice. The applicant or nonapplicant would need to permit any authorized FDA employee, at reasonable times, to access, copy, and verify the established and maintained records described in this section.

Based on available data, we estimate that 1,430 manufacturers will create 686 records pertaining to human designated medical gas requirements and that it would take approximately 16 hours to perform this activity, totaling 10,976 hours.

Proposed § 230.220(c) and (d) would include additional requirements for the content and format of ICSRs.

Based on available data, we assume all firms (1,696) will distribute designated medical gases for human and animal use and invite comment on our assumption.

Under proposed § 230.230(a)(1), an applicant or nonapplicant would need to submit serious adverse events related to the use of a designated medical gas in animals to FDA as soon as possible but no later than 15 calendar days from first receiving the information. The applicant or nonapplicant would need to submit the report to FDA in electronic format as described under proposed § 230.230(b)(1) of this section, unless the applicant or nonapplicant obtains a waiver under proposed § 230.230(b)(2) of this section or FDA requests the report in an alternate format.

Under proposed § 230.230(a)(2), upon notification by FDA, applicants and nonapplicants would need to submit reports of adverse events associated with the use of a designated medical gas in animals that do not qualify for reporting under proposed § 230.230(a)(1) of this section. The notice would specify the adverse events to be reported and the reason for requiring the reports.

We estimate approximately 7.5 records will be submitted per year and estimate that it will take approximately 5 hours to perform this activity, totaling 37.5 hours. We also estimate that approximately 7.5 reports will be maintained yearly and estimate it will take 5 hours to perform this activity, totaling 37.5 hours.

Under proposed § 230.230(b)(2), an applicant or nonapplicant could request, in writing, a temporary waiver of the electronic submission requirements under proposed § 230.230(b)(1). An applicant or nonapplicant would need to provide the initial request by telephone or email to CVM's Division of Veterinary Product Safety, with prompt written followup submitted as a letter to the granted certification or certifications. FDA would grant waivers on a limited basis for good cause shown. If FDA grants a waiver, the applicant or nonapplicant would need to comply with the conditions for reporting specified by FDA upon granting the waiver.

We estimate approximately 7.5 waiver requests will be submitted annually and estimate it will take 5 hours to perform this activity, totaling 37.5 hours annually.

To ensure that comments on information collection are received, OMB recommends that written comments be through *reginfo.gov* (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the PRA (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects 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. Accordingly, we conclude that the proposed rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the proposed rule does not contain policies that would 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. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. References

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

the date this document publishes in the **Federal Register**, but websites are subject to change over time.

*1. Food and Drug Administration (FDA) draft guidance for industry ''Certification Process for Designated Medical Gases,'' November 2015, available at *https://www.fda.gov/media/85013/download.*
*2. FDA, Medical Gas Regulation Public Workshops, available at *https://www.fda.gov/drugs/news-events-human-drugs/medical-gas-regulation-public-workshops.*
3. Lacasse, Y., M. Légaré, and F. Maltais, ''E-cigarette Use in Patients Receiving Home Oxygen Therapy,'' *Canadian Respiratory Journal,* vol. 22, no. 2, 83–85, March/April 2015. *https://downloads.hindawi.com/journals/crj/2015/215932.pdf.*
*4. Benowitz, N.M., ''E-cigarette Explosion in a Patient Room,'' *PSNet,* April 2019. *https://psnet.ahrq.gov/web-mm/e-cigarette-explosion-patient-room.*
5. Fire & Rescue NSW, ''Fire Research Report—E-Cigarette Fire Risks and Reported Incidents,'' January 30, 2015. *https://www.icao.int/safety/dangerousgoods/dgpwg15/dgpwg.15.ip.004.2.en.app.pdf.*
6. Rudy, S.F. and E.L. Durmowicz, ''Electronic Nicotine Delivery Systems: Overheating, Fires and Explosions,'' *Tobacco Control,* 26:10–18, 2017. *https://tobaccocontrol.bmj.com/content/tobaccocontrol/26/1/10.full.pdf.*
*7. FDA, Response to petition submitted by Compressed Gas Association, Docket No. 87P–0167/CP1, September 19, 1996.
*8. FDA, Public Health Advisory, ''Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities,'' March 2001, available at *https://www.fda.gov/media/70999/download.*
*9. Kreiter, P., T.G. Bizjak, and R.L. Friedman, ''Preventing Patients From Receiving Leaking or Empty Containers of Medical Gas: A Review of Inspectional Findings From 2003 to 2021,'' CDER Office of Manufacturing Quality, December 2021, U.S. Food and Drug Administration.
*10. CDER, Manual of Policies and Procedures 5310.7 Rev. 1, ''Acceptability of Standards from Alternative Compendia (BP/EP/JP),'' available at *https://www.fda.gov/media/72412/download.*
*11. FDA guidance for industry ''Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration,'' November 2014, available at *https://www.fda.gov/media/89926/download.*
*12. FDA draft guidance for industry ''Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines,'' March 2001, available at *https://www.fda.gov/media/73593/download.*
*13. FDA guidance for industry ''Field Alert Report Submission—Questions and Answers,'' July 2021, available at *https://www.fda.gov/media/114549/download.*
*14. FDA, Compliance Program Guidance Manual 7356.002E, ''Compressed Medical Gases,'' March 15, 2015, available at *https://www.fda.gov/media/75194/download.*
*15. FDA draft guidance for industry ''Providing Submissions in Electronic Format—Postmarketing Safety Reports,'' June 2014, available at *https://www.fda.gov/media/71176/download.*
16. International Council on Harmonization, MedDRA, available at *https://www.ich.org/page/meddra.*
*17. FDA, Veterinary Adverse Event Reporting for Manufacturers, available at *https://www.fda.gov/IndustryReport AnimalAE.*
*18. FDA, Preliminary Regulatory Impact Analysis: Current Good Manufacturing Practice, Certification, Postmarketing Safety Reporting, and Labeling Requirements for Certain Medical Gases, available at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

List of Subjects

21 CFR Part 4

Biologics, Drugs, Human cells and tissue-based products, Medical devices.

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 210

Drugs, Packaging and containers.

21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

21 CFR Part 213

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

21 CFR Part 230

Administrative practice and procedure, Animal drugs, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the Food and Drug Administration proposes to amend chapter I of title 21 of the Code of Federal Regulations as follows:

PART 4—REGULATION OF COMBINATION PRODUCTS

■ 1. The authority citation for part 4 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360b–360f, 360h–360j, 360l, 360hh–360ss, 360aaa–360bbb, 360ddd, 360ddd–1, 371(a), 372–374, 379e, 381, 383, 394; 42 U.S.C. 216, 262, 263a, 264, 271.

■ 2. Revise § 4.2 to read as follows:

§ 4.2 How does FDA define key terms and phrases in this subpart?

The terms listed in this section have the following meanings for purposes of this subpart:

Biological product has the meaning set forth in § 3.2(d) of this chapter. A biological product also meets the definitions of either a drug or device as these terms are defined under this section.

Combination product has the meaning set forth in § 3.2(e) of this chapter.

Constituent part is a drug, device, or biological product that is part of a combination product.

Co-packaged combination product has the meaning set forth in § 3.2(e)(2) of this chapter.

Current good manufacturing practice operating system means the operating system within an establishment that is designed and implemented to address and meet the current good manufacturing practice requirements for a combination product.

Current good manufacturing practice requirements means the requirements set forth under § 4.3(a) through (e).

Device has the meaning set forth in § 3.2(f) of this chapter. A device that is a constituent part of a combination product is considered a finished device within the meaning of the QS regulation.

Drug has the meaning set forth in § 3.2(g) of this chapter and includes medical gas as defined in section 575(2) of the Federal Food, Drug, and Cosmetic Act. Medical gas includes designated medical gases as defined in section 575(1) of the Federal Food, Drug, and Cosmetic Act and medical gases approved under section 505 of the Federal Food, Drug, and Cosmetic Act. A drug other than a medical gas that is a constituent part of a combination product is considered a drug product within the meaning of the drug current good manufacturing practice regulations (CGMPs). A drug that is a medical gas

that is a constituent part of a combination product is considered a medical gas within the meaning of the medical gas CGMPs.

Drug CGMPs refers to the current good manufacturing practice regulations set forth in parts 210 and 211 of this chapter.

HCT/Ps refers to human cell, tissue, and cellular and tissue-based products, as defined in § 1271.3(d) of this chapter. An HCT/P that is not solely regulated under section 361 of the Public Health Service Act may be a constituent part of a combination product. Such an HCT/P is subject to part 1271 of this chapter and is also regulated as a drug, device, and/or biological product.

Manufacture includes, but is not limited to, designing, fabricating, assembling, filling, processing, testing, labeling, packaging, repackaging, holding, and storage.

Medical gas CGMPs refers to the current good manufacturing practice regulations set forth in part 213 of this chapter.

QS regulation refers to the quality system regulation in part 820 of this chapter.

Single-entity combination product has the meaning set forth in § 3.2(e)(1) of this chapter.

Type of constituent part refers to the category of the constituent part, which can be either a biological product, a device, or a drug, as these terms are defined under this section.

■ 3. Amend § 4.3 by revising paragraphs (a), (c), and (d), and adding paragraph (e) as follows:

§ 4.3 What current good manufacturing practice requirements apply to my combination product?

* * * * *

(a) The current good manufacturing practice requirements in parts 210 and 211 of this chapter apply to a combination product that includes a drug constituent part other than a medical gas;

* * * * *

(c) The current good manufacturing practice requirements among the requirements (including standards) for biological products in parts 600 through 680 of this chapter apply to a combination product that includes a biological product constituent part to which those requirements would apply if that constituent part were not part of a combination product;

(d) The current good tissue practice requirements including donor eligibility requirements for HCT/Ps in part 1271 of this chapter apply to a combination product that includes an HCT/P; and

(e) The current good manufacturing practice requirements in part 213 of this chapter apply to a combination product that includes a drug that is a medical gas.

■ 4. Amend § 4.4 by:

■ a. Revising paragraphs (b)(1) introductory text, (b)(2) introductory text, and (e);

■ b. Redesignating paragraphs (b)(3) and (b)(4) as (b)(4) and (b)(5), respectively; and

■ c. Adding new paragraph (b)(3).

The revisions and addition read as follows:

§ 4.4 How can I comply with these current good manufacturing practice requirements for a co-packaged or single-entity combination product?

* * * * *

(b) * * *

(1) If the combination product includes a device constituent part and a drug constituent part, and the current good manufacturing practice operating system has been shown to comply with the drug CGMPs or the medical gas CGMPs, as applicable, the following provisions of the QS regulation must also be shown to have been satisfied; upon demonstration that these requirements have been satisfied, no additional showing of compliance with respect to the QS regulation need be made:

* * * * *

(2) If the combination product includes a device constituent part and a drug constituent part other than a medical gas, and the current good manufacturing practice operating system has been shown to comply with the QS regulation, the following provisions of the drug CGMPs must also be shown to have been satisfied; upon demonstration that these requirements have been satisfied, no additional showing of compliance with respect to the drug CGMPs need be made:

* * * * *

(3) If the combination product includes a device constituent part and a drug constituent part that is a medical gas, and the current good manufacturing practice operating system has been shown to comply with the QS regulation, the following provisions of the medical gas CGMPs must also be shown to have been satisfied; upon demonstration that these requirements have been satisfied, no additional showing of compliance with respect to the medical gas CGMPs need be made:

(i) Section 213.84 of this chapter. Testing and approval or rejection of components, containers, and closures.

(ii) Section 213.94 of this chapter. Medical gas containers and closures.

(iii) Section 213.122 of this chapter. Materials examination and usage criteria.

(iv) Section 213.165 of this chapter. Testing and release for distribution.

(v) Section 213.166 of this chapter. Stability testing and expiration dating for medical gases marketed under applications submitted under section 505 or section 512 of the Federal Food, Drug, and Cosmetic Act.

(vi) Section 213.204 of this chapter. Returned medical gases.

(vii) Section 213.208 of this chapter. Salvaging of medical gases.

* * * * *

(e) The requirements set forth in this subpart and in parts 210, 211, 213, 820, 600 through 680, and 1271 of this chapter listed in § 4.3, supplement, and do not supersede, each other unless the regulations explicitly provide otherwise. In the event of a conflict between regulations applicable under this subpart to combination products, including their constituent parts, the regulations most specifically applicable to the constituent part in question shall supersede the more general.

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 5. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 6. In § 16.1, revise paragraph (b)(2) by numerically adding an entry for ''§ 230.150(b)'' to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 230.150(b), relating to revocation of the grant of a certification for a designated medical gas.

* * * * *

PART 201—LABELING

■ 7. The authority citation for part 201 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 343, 351, 352, 353, 355, 358, 360, 360b, 360ccc, 360ccc–1, 360ddd, 360ddd–1, 360ee, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

■ 8. In § 201.1, revise paragraph (b) to read as follows:

§ 201.1 Drugs; name and place of business of manufacturer, packer, or distributor.

* * * * *

(b) As used in this section, and for purposes of section 502(a) and (b)(1) of

the Federal Food, Drug, and Cosmetic Act, the manufacturer of a drug product is the person who performs all of the following operations that are required to produce the product:

(1) Mixing,
(2) Granulating,
(3) Milling,
(4) Molding,
(5) Lyophilizing,
(6) Tableting,
(7) Encapsulating,
(8) Coating,
(9) Sterilizing,
(10) Filling sterile or aerosol drugs into dispensing containers, and
(11) With respect to a medical gas, fabricating the gas by chemical reaction, physical separation, compression of atmospheric air, purification (*e.g.,* re-processing an industrial gas into a medical gas), by combining two or more distinct medical gases, or by other process.

* * * * *

■ 9. In § 201.10, revise paragraph (d)(2) to read as follows:

§ 201.10 Drugs; statement of ingredients.

* * * * *

(d) * * *

(2) A statement of the percentage of an ingredient in a drug shall, if the term *percent* is used without qualification, mean percent weight-in-weight, if the ingredient and the drug are both solids, or if the ingredient is a liquid and the drug is a solid; percent weight in volume at 68 °F. (20 °C.), if the ingredient is a solid and the drug is a liquid; percent volume in volume at 68 °F. (20 °C.), if both the ingredient and the drug are liquids, except that alcohol shall be stated in terms of percent volume of absolute alcohol at 60 °F. (15.56 °C.); and percent volume in volume if the ingredient is a designated medical gas (as defined in § 201.161(c)(1)).

* * * * *

■ 10. In § 201.51, revise paragraphs (a) and (b) to read as follows:

§ 201.51 Declaration of net quantity of contents.

(a) The label of a prescription or insulin-containing drug in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The statement of quantity of drugs in tablet, capsule, ampule, or other unit dosage form shall be expressed in terms of numerical count; the statement of quantity for drugs in other dosage forms shall be in terms of weight if the drug is solid, semi-solid, or viscous, in terms of fluid measure if the drug is liquid, or in terms of volume measure if the drug is a designated medical gas (as defined in § 201.161(c)(1)) or a medically appropriate combination of designated medical gases in a gaseous state. When the drug quantity statement is in terms of the numerical count of the drug units, it shall be augmented to give the weight or measure of the drug units or the quantity of each active ingredient in each drug unit or, when quantity does not accurately reflect drug potency, a statement of the drug potency.

(b) Statements of weight of the contents shall in the case of prescription drugs be expressed in terms of avoirdupois pound, ounce, and grain or of kilogram, gram, and subdivisions thereof. A statement of liquid measure of the contents shall in the case of prescription drugs other than designated medical gases and medically appropriate combinations thereof be expressed in terms of the U.S. gallon of 231 cubic inches and quart, pint, fluid-ounce, and fluid-dram subdivisions thereof, or of the liter and milliliter, or cubic centimeter, and shall express the volume at 68 °F. (20 °C.). A statement of the liquid measure of the contents in the case of insulin-containing drugs shall be expressed in terms of the liter and milliliter, or cubic centimeter, and shall express the volume at 68 °F. (20 °C.). A statement of the measure of the contents shall in the case of designated medical gases (as defined in § 201.161(c)(1)) and medically appropriate combinations thereof be expressed as follows:

(1) If in a gaseous state in a high pressure container, it shall be expressed in liters or cubic feet based on the filled pressure at 70 °F.;
(2) If in a liquefied compressed gas state in a high pressure container, it shall be expressed in gaseous liters or by an appropriate net weight statement;
(3) If in a liquefied state in a portable cryogenic container, it shall be expressed in gaseous liters, liquid liters (if identified as a liquid measure), gallons, or by an appropriate net weight statement at the time of fill;
(4) If in a bulk or transport container (as defined in § 201.161(c)(3)), labeling for net quantity of contents is not required;

* * * * *

■ 11. In § 201.105 revise the introductory text paragraph to read as follows:

§ 201.105 Veterinary drugs.

A drug subject to the requirements of section 503(f)(1) of the act shall be exempt from section 502(f)(1) of the act if it is a designated medical gas (as defined in § 201.161(c)(1)) or a medically appropriate combination of designated medical gases and is in compliance with § 201.161, or if all the following conditions are met:

* * * * *

■ 12. Revise § 201.161 to read as follows:

§ 201.161 Medical gases.

(a) The requirements of sections 503(b)(4) and 502(f) of the Federal Food, Drug, and Cosmetic Act are deemed to have been met for a designated medical gas or a medically appropriate combination of designated medical gases if the labeling on its final use container bears the following:

(1) In the case of oxygen:

(i) A warning statement providing that uninterrupted use of high concentrations of oxygen over a long duration, without monitoring its effect on oxygen content of arterial blood, may be harmful; that oxygen should not be used on patients who have stopped breathing unless used in conjunction with resuscitative equipment; and, in the case of oxygen that may be provided without a prescription for use in the event of depressurization or other environmental oxygen deficiency, or for oxygen deficiency or for use in emergency resuscitation when administered by properly trained personnel, a warning statement providing that oxygen may be used for emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation, and that for all other medical applications a prescription is required.

(ii) A clear and prominent warning containing the statements ''No Smoking'' and ''No Vaping'' and a graphic symbol conveying that smoking, vaping, and open flames near oxygen are dangerous.

(2) In the case of a designated medical gas other than oxygen, and in the case of medically appropriate combinations of any designated medical gases:

(i) A warning statement providing that the administration of the gas or gas combination (as applicable) may be hazardous or contraindicated; and that the gas or gas combination (as applicable) should be used only by or under the supervision of a licensed practitioner who is experienced in the use and administration of the gas or gas combination (as applicable) and is familiar with the indications, effects, dosages, methods, and frequency and duration of administration, and with the hazards, contraindications, and side effects and the precautions to be taken.

(ii) The symbol ''Rx only.''

(3) Appropriate directions and warnings concerning storage and handling.

(b) A designated medical gas or medically appropriate combination of designated medical gases in a bulk or transport container must be identified with the name of the product contained therein and accompanied by documentation identifying the product as meeting applicable compendial standards.

(c) For purposes of this section:

(1) A ''designated medical gas'' means a drug that:

(i) Is manufactured or stored in a liquefied, nonliquefied, or cryogenic state;

(ii) Is administered as a gas; and

(iii) Meets the definition in section 575(1) of the Federal Food, Drug, and Cosmetic Act.

(2) A ''final use container'' means a container that is for direct use or access by a patient or healthcare provider to administer a designated medical gas or medically appropriate combination of designated medical gases. The term ''final use container'' does not include bulk or transport containers and does not include containers that are described in § 868.5655 of this chapter.

(3) A ''bulk or transport container'' means a container used to transport or store designated medical gases or medically appropriate combinations of designated medical gases and that is not used directly to administer such gases to a patient.

■ 13. In § 201.328, revise paragraph (a)(1) introductory text and add paragraph (d) to read as follows.

§ 201.328 Labeling of medical gas containers.

(a) * * *

(1) Each portable cryogenic medical gas container must be conspicuously marked with a 360° wraparound label identifying its contents. Such label must meet the requirements of § 213.94(e)(3) of this chapter and the following additional requirements.

* * * * *

(d) Notwithstanding § 201.1, a container filled with a designated medical gas (as defined in § 201.161(c)(1)) or medically appropriate combination of designated medical gases may bear a statement identifying the name of the owner of the container or the address to which the container should be returned after use. Such statement may appear on a separate sticker or decal. If the owner of the medical gas container is not the manufacturer, packer, or distributor of the designated medical gas or medically appropriate combination of designated medical gases, that shall be clearly stated on the container. The addition of such statement shall not cause the owner of the cylinder to be a ''relabeler'' for purposes of registration and listing under part 207 of this chapter.

PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL

■ 14. The authority citation for part 210 is revised to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 360b, 360ddd, 360ddd–1, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

■ 15. In § 210.1, revise paragraphs (a) and (b) to read as follows:

§ 210.1 Status of current good manufacturing practice regulations.

(a) The regulations set forth in this part and in parts 211, 213, 225, and 226 of this chapter contain the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

(b) The failure to comply with any regulation set forth in this part and in parts 211, 213, 225, and 226 of this chapter in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under section 501(a)(2)(B) of the act and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action.

* * * * *

■ 16. In § 210.2, revise paragraphs (a) and (b) to read as follows:

§ 210.2 Applicability of current good manufacturing practice regulations.

(a) The regulations in this part and in parts 211, 213, 225, and 226 of this chapter as they may pertain to a drug; in parts 600 through 680 of this chapter as they may pertain to a biological product for human use; and in part 1271 of this chapter as they are applicable to a human cell, tissue, or cellular or tissue-based product (HCT/P) that is a drug (subject to review under an application submitted under section 505 of the act or under a biological product license application under section 351 of the Public Health Service Act); shall be considered to supplement, not supersede, each other, unless the regulations explicitly provide otherwise. In the event of a conflict between applicable regulations in this part and in other parts of this chapter, the regulation specifically applicable to the drug product in question shall supersede the more general.

(b) If a person engages in only some operations subject to the regulations in this part and in parts 211, 213, 225, 226, 600 through 680, and 1271 of this chapter, and not in others, that person need only comply with those regulations applicable to the operations in which the person is engaged.

* * * * *

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

■ 17. The authority citation for part 211 is revised to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 360b, 360ddd, 360ddd–1, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

■ 18. In § 211.1, revise paragraph (a) to read as follows:

§ 211.1 Scope.

(a) The regulations in this part contain the minimum current good manufacturing practice for preparation of drug products (excluding positron emission tomography drugs and medical gases as defined in § 213.3(b)(12) of this chapter) for administration to humans or animals.

* * * * *

§ 211.94 [Amended]

■ 19. In § 211.94, remove paragraph (e).

■ 20. In § 211.125 revise paragraph (c) to read as follows:

§ 211.125 Labeling issuance.

* * * * *

(c) Procedures shall be used to reconcile the quantities of labeling issued, used, and returned, and shall require evaluation of discrepancies found between the quantity of drug product finished and the quantity of labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. Such discrepancies shall be investigated in accordance with § 211.192. Labeling reconciliation is waived for cut or roll labeling if a 100-percent examination for correct labeling is performed in accordance with § 211.122(g)(2).

* * * * *

■ 21. In § 211.132, revise paragraph (c)(1) introductory text to read as follows:

§ 211.132 Tamper-evident packaging requirements for over-the-counter (OTC) human drug products.

* * * * *

(c) * * *

(1) In order to alert consumers to the specific tamper-evident feature(s) used, each retail package of an OTC drug product covered by this section (except ammonia inhalant in crushable glass ampules or aerosol products that depend upon the power of a liquefied or compressed gas to expel the contents from the container) is required to bear a statement that:

* * * * *

■ 22. In § 211.170, revise paragraph (b) introductory text to read as follows:

§ 211.170 Reserve samples.

* * * * *

(b) An appropriately identified reserve sample that is representative of each lot or batch of drug product shall be retained and stored under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics. The reserve sample consists of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens. Except for those for drug products described in paragraph (b)(2) of this section, reserve samples from representative sample lots or batches selected by acceptable statistical procedures shall be examined visually at least once a year for evidence of deterioration unless visual examination would affect the integrity of the reserve sample. Any evidence of reserve sample deterioration shall be investigated in accordance with § 211.192. The results of the examination shall be recorded and maintained with other stability data on the drug product. The retention time is as follows:

* * * * *

■ 23. Revise § 211.196 to read as follows:

§ 211.196 Distribution records.

Distribution records shall contain the name and strength of the product and description of the dosage form, name and address of the consignee, date and quantity shipped, and lot or control number of the drug product.

■ 24. Add part 213 to subchapter C to read as follows:

PART 213—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICAL GASES

Subpart A—General Provisions

Sec.
213.1 Scope.
213.3 Definitions.

Subpart B—Organization and Personnel

213.22 Responsibilities of quality unit.
213.25 Personnel qualifications and responsibilities.
213.34 Consultants.

Subpart C—Buildings and Facilities

213.42 Design and construction features.

Subpart D—Equipment

213.63 Equipment design, size, and location.
213.65 Equipment construction.
213.67 Equipment maintenance and cleaning.
213.68 Automatic, mechanical, and electronic equipment.

Subpart E—Control of Incoming Designated Medical Gas, Components, and Medical Gas Containers and Closures

213.80 General requirements.
213.82 Receipt and storage of incoming designated medical gases.
213.84 Testing and approval or rejection of components, containers, and closures.
213.89 Rejected components, incoming designated medical gases, and medical gas containers and closures.
213.94 Medical gas containers and closures.

Subpart F—Production and Process Controls

213.100 Written procedures; deviations.
213.101 Charge-in of components and incoming designated medical gases.
213.110 Sampling and testing of in-process materials.

Subpart G—Packaging and Labeling Control

213.122 Materials examination and usage criteria.
213.125 Labeling issuance.
213.130 Packaging and labeling operations.

Subpart H—Holding and Distribution

213.150 Warehousing and distribution procedures.

Subpart I—Laboratory Controls

213.160 General requirements.
213.165 Testing and release for distribution.
213.166 Stability testing and expiration dating for medical gases marketed under applications submitted under section 505 or section 512 of the Federal Food, Drug, and Cosmetic Act.

Subpart J—Records

213.180 General requirements.
213.182 Equipment cleaning and use log.
213.184 Records for components, medical gas containers and closures, and labeling.
213.186 Master production and control records.
213.189 Batch production and control records.
213.192 Production record review.
213.194 Laboratory records.
213.196 Distribution records.
213.198 Complaint files.

Subpart K—Returned and Salvaged Medical Gases

213.204 Returned medical gases.
213.208 Salvaging of medical gases.

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360b, 360ddd, 360ddd–1, 371, 374.

Subpart A—General Provisions

§ 213.1 Scope.

The regulations in this part contain the minimum current good manufacturing practice for preparation of medical gases for administration to humans or animals.

§ 213.3 Definitions.

(a) The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable to such terms when used in this part.

(b) The following definitions of terms apply to this part:

(1) *Acceptance criteria* means the product specifications and acceptance/rejection criteria, such as acceptable quality level and unacceptable quality level, with an associated sampling plan, that are necessary for making a decision to accept or reject a lot or batch (or any other convenient subgroups of manufactured units).

(2) *Batch* means a specific quantity of a medical gas or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

(3) *Commingling or commingled* refers to the act of combining one lot of designated medical gas or component with another lot or lots of the same designated medical gas or component.

(4) *Component* means any ingredient intended for use in the manufacture of a medical gas, including those that may not appear in such gas. It does not include an incoming designated medical gas.

(5) *Designated medical gas* means a drug that is manufactured or stored in a liquefied, nonliquefied, or cryogenic state; is administered as a gas; and is defined in section 575(1) of the Federal Food, Drug, and Cosmetic Act.

(6) *FDA* means the Food and Drug Administration.

(7) *In-process material* means any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and used in, the preparation of the medical gas.

(8) *Incoming designated medical gas* means a designated medical gas received from one source that is commingled with the same gas from another source, used in a medically appropriate combination of designated medical gases or in the production of another medical gas, or further distributed.

(9) *Lot* means a batch, or a specific identified portion of a batch, having uniform character and quality within specified limits; or, in the case of a medical gas produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits.

(10) *Lot number, control number, or batch number* means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of medical gas, or other material can be determined.

(11) *Manufacture, processing, packing, or holding of medical gases* includes packaging and labeling operations, testing, and quality control.

(12) *Medical gas* has the meaning given the term in section 575(2) of the Federal Food, Drug, and Cosmetic Act.

(13) *Original manufacturer* means the person or entity that initially produces a designated medical gas by chemical reaction, physical separation, compression of atmospheric air, purification (*e.g.,* re-processing an industrial gas into a medical gas), or other means.

(14) *Quality unit* means any person or persons designated with the authority and responsibility for overall quality management and other responsibilities as defined in § 213.22.

(15) *Strength* means:

(i) The concentration of the medical gas (for example, weight/weight, weight/volume, or unit dose/volume basis), and/or

(ii) The potency, that is, the therapeutic activity of the medical gas as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data (expressed, for example, in terms of units by reference to a standard).

Subpart B—Organization and Personnel

§ 213.22 Responsibilities of quality unit.

(a) There shall be a quality unit that shall have the responsibility and authority to approve or reject all components, medical gas containers and closures, in-process materials, packaging material, labeling, and medical gases, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality unit shall be responsible for approving or rejecting medical gases manufactured, processed, packed, or held under contract by another company.

(b) Adequate laboratory facilities for the testing and approval (or rejection) of components, medical gas containers and closures, packaging materials, in-process materials, and medical gases shall be available to the quality unit.

(c) The quality unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the medical gas.

(d) The responsibilities and procedures applicable to the quality unit shall be in writing; such written procedures shall be followed.

(e) Quality unit personnel may perform other functions provided appropriate written controls are in place to ensure any other functions are performed separately from quality unit responsibilities and such other functions do not interfere with the quality unit's responsibilities or subordinate the quality unit's responsibilities to any other unit.

§ 213.25 Personnel qualifications and responsibilities.

(a) Each person engaged in the manufacture, processing, packing, or holding of a medical gas shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with current good manufacturing practice requirements applicable to them. Written documentation shall be maintained demonstrating the completion of employee training, and shall include the date of the training, the type of the training, and the results of any completion criteria, such as test results.

(b) There shall be an adequate number of qualified personnel to perform the manufacture, processing, packing, or holding of each medical gas.

(c) Only authorized personnel shall enter those areas of the buildings and facilities designated as limited-access areas.

§ 213.34 Consultants.

Consultants advising on the manufacture, processing, packing, or holding of medical gases shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained stating the name, address, and qualifications of any consultants and the type of service they provide.

Subpart C—Buildings and Facilities

§ 213.42 Design and construction features.

(a)(1) Any buildings and facilities used in the manufacture, processing, packing, or holding of a medical gas shall be of adequate design, including having adequate space, for the orderly placement of equipment and materials to prevent mix-ups between:

(i) Components;

(ii) Incoming designated medical gases;

(iii) Medical gas containers and closures;

(iv) Labeling;

(v) In-process materials; or

(vi) Medical gases.

(2) Such buildings and facilities shall also allow for adequate cleaning, maintenance, and proper operations.

(b)(1) Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination or mix-ups during the course of the following procedures:

(i) Receipt, identification, storage, and withholding from use of components, incoming designated medical gases, medical gas containers and closures, and labeling, pending the appropriate sampling, testing, or examination by the quality unit before release for manufacturing or packaging;

(ii) Holding rejected components, incoming designated medical gases, medical gas containers and closures, and labeling before disposition;

(iii) Storage of released components, incoming designated medical gases, medical gas containers and closures, and labeling;

(iv) Storage of in-process materials;

(v) Manufacturing and processing operations;

(vi) Packaging and labeling operations;

(vii) Quarantine storage before release of medical gases;

(viii) Storage of medical gases after release; and

(ix) Control and laboratory operations.

(2) The flow of components, incoming designated medical gases, medical gas containers and closures, labeling, in-process materials, and medical gases through the buildings and facilities shall be designed to prevent contamination and mix-ups.

(c) Any building or facility used in the manufacture, processing, packing, or holding of a medical gas shall be maintained in a clean condition so as to assure the safety, identity, strength, quality, and purity of the medical gas. Written procedures applicable to the maintenance and cleaning of buildings and facilities shall be established and followed.

Subpart D—Equipment

§ 213.63 Equipment design, size, and location.

Equipment used in the manufacture, processing, packing, or holding of a medical gas shall be of appropriate design and adequate size, and be suitably located to facilitate operations for its intended use and any necessary cleaning and maintenance.

§ 213.65 Equipment construction.

(a) Equipment shall be constructed so that surfaces that contact components, in-process materials, or medical gases shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the medical gas beyond the official or other established requirements.

(b) Any substances required for operation, such as lubricants or coolants, shall not come into contact with components, containers, closures, in-process materials, or medical gases so as to alter the safety, identity, strength, quality, or purity of the medical gas beyond the official or other established requirements.

§ 213.67 Equipment maintenance and cleaning.

(a) Written procedures shall be established, maintained, and followed for adequate cleaning and maintenance of equipment used in the manufacture, processing, packing, or holding of medical gases. These procedures shall include, but are not necessarily limited to, the following:

(1) Assignment of responsibility for cleaning and maintaining equipment;

(2) Maintenance and cleaning schedules, including, where appropriate, sanitizing schedules;

(3) A description in sufficient detail of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance;

(4) Removal or obliteration of previous batch identification;

(5) Protection of clean equipment from contamination prior to use; and

(6) Inspection of equipment for cleanliness immediately before use.

(b) The procedures described in paragraph (a) of this section shall not alter the safety, identity, strength, quality, or purity of the medical gas beyond the established requirements.

(c) Records shall be kept of cleaning, maintenance, and inspection as specified in § 213.180.

§ 213.68 Automatic, mechanical, and electronic equipment.

(a) Automatic, mechanical, and electronic equipment used in the manufacture of medical gases shall be routinely calibrated, inspected, and checked according to a written program designed to ensure proper performance. Written procedures and records of calibration, inspections, and checks shall be maintained.

(b) Computerized systems that record, store, or use data shall be appropriately validated.

(c) A backup file of data entered into the computer system shall be maintained except where certain data, such as calculations performed in connection with laboratory analysis, are eliminated by computerization or other automated processes.

(d) Appropriate change control shall be used whenever modifications are made to computer systems to assure that any changes do not adversely affect data integrity or product quality. Records of such modifications shall be maintained.

Subpart E—Control of Incoming Designated Medical Gas, Components, and Medical Gas Containers and Closures

§ 213.80 General requirements.

(a) There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components, incoming designated medical gases, and medical gas containers and closures; such written procedures shall be followed.

(b) Components, incoming designated medical gases, and medical gas containers and closures shall at all times be handled and stored in a manner to prevent contamination and mix-ups.

(c) Lots of incoming designated medical gases or components, whether used directly as supply or commingled with an existing supply, shall be assigned a unique identification number.

§ 213.82 Receipt and storage of incoming designated medical gases.

(a)(1) Upon receipt of an incoming designated medical gas, the firm shall verify and record that a signed certificate of analysis from the supplier accompanies each different designated medical gas in a shipment. The certificate of analysis shall include the following:

(i) Supplier's name;

(ii) Name of the incoming designated medical gas;

(iii) Lot number or other unique identification number;

(iv) Actual analytical result obtained for strength, as well as the results of other tests performed;

(v) Identification of the test method(s) used for analysis;

(vi) New drug application and/or new animal drug application number of the incoming designated medical gas; and

(vii) Supplier representative's signature and the date of signature.

(2) If the incoming designated medical gas is obtained from a supplier other than the original manufacturer, the shipment shall also include complete information from the original manufacturer's certificate of analysis. The firm shall establish and maintain a program to ensure the reliability of the supplier's capabilities through appropriate assessment and testing procedures.

(b) An identity test shall be performed upon receipt of the incoming designated medical gas.

§ 213.84 Testing and approval or rejection of components, containers, and closures.

(a) Components, containers, and closures (including valves) shall be examined for conformance with appropriate written procedures and specifications, and approved or rejected, prior to the manufacturing or filling process. In lieu of such examination by the firm, a statement of verification that the component, container, or closure meets specifications may be accepted from the supplier, provided that the firm establishes and maintains a program to ensure the reliability of the supplier's capabilities through appropriate assessment and testing provisions. Any rejected items shall be handled in accordance with § 213.89.

(b) Firms shall take appropriate actions to protect against container and closure leaks, which shall include performing leak tests on containers and closures at the time of fill and after fill but prior to release.

(c) Each component shall be sampled, tested, and approved or rejected as appropriate prior to use. This requirement can be met by performing testing for conformance with written specifications or by an identity test on the component accompanied by an acceptable certificate of analysis from the supplier, provided that the firm establishes and maintains a program to ensure the reliability of the supplier's capabilities through appropriate assessment and testing procedures.

§ 213.89 Rejected components, incoming designated medical gases, and medical gas containers and closures.

Rejected components, incoming designated medical gases, and medical gas containers and closures shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable and shall be documented and assessed.

§ 213.94 Medical gas containers and closures.

(a) Medical gas containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the gas beyond the official or established requirements.

(b) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the medical gas.

(c) Medical gas containers and closures shall be clean to assure that they are suitable for their intended use.

(d) Standards or specifications, methods of testing, and, where indicated, methods of cleaning shall be written and followed for medical gas containers and closures.

(e) Medical gas containers and closures must meet the following requirements—

(1) *Gas-specific use outlet connections.* Portable cryogenic medical gas containers that are not manufactured with permanent gas use outlet connections (*e.g.,* those that have been silver-brazed) must have gas-specific use outlet connections that are attached to the valve body so that they cannot be readily removed or replaced (without making the valve inoperable and preventing the containers' use) except by the manufacturer. For the purposes of this paragraph, the term ''manufacturer'' includes any individual or firm that fills high-pressure medical gas cylinders or cryogenic medical gas containers. For the purposes of this section, a ''portable cryogenic medical gas container'' is one that is capable of being transported and is intended to be attached to a medical gas supply system within a hospital, healthcare entity, nursing home, other facility, or home healthcare setting, or is a base unit used to fill small cryogenic gas containers for use by individual patients. The term does not include cryogenic containers that are not designed to be connected to a medical gas supply system, *e.g.,* tank trucks, trailers, rail cars, or small cryogenic gas containers for use by individual patients (including portable liquid oxygen units as defined at § 868.5655 of this chapter).

(2) *Gauges for certain medical gas containers.* Portable cryogenic medical gas containers as described in paragraph (e)(1) of this section and small cryogenic gas containers for use by individual patients (including portable liquid oxygen units as defined at § 868.5655 of this chapter) must have a working gauge sufficient to indicate whether the container contains an adequate supply of medical gas for continued use.

(3) *Label and coloring requirements.* The labeling specified at § 201.328(a) of this chapter must be affixed to the container in a manner that does not interfere with other labeling. Each such label as well as materials used for coloring medical gas containers must be reasonably resistant to fading, durable when exposed to atmospheric conditions, and not readily soluble in water.

Subpart F—Production and Process Controls

§ 213.100 Written procedures; deviations.

(a) There shall be written procedures for production and process controls designed to assure that medical gases have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality unit.

(b) Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified.

§ 213.101 Charge-in of components and incoming designated medical gases.

Written production and control procedures shall include the following, which are designed to assure that the medical gases produced have the identity, strength, quality, and purity they purport or are represented to possess:

(a) Except when a monograph or formulary specifies a range, the batch shall be formulated with the intent to provide 100 percent of the labeled or established amount of each medical gas. When a monograph or formulary specifies a range for the contents of a medical gas, the batch shall be formulated with the intent to provide an amount of the medical gas within such specified range.

(b) Components and incoming designated medical gases added to in-process supply or final product containers shall be weighed or measured as appropriate. In-process and final product containers shall identify the name of the component or designated medical gas or the name and percentage of each component or designated medical gas if they contain multiple components or designated medical gases, and the unique lot number assigned.

§ 213.110 Sampling and testing of in-process materials.

(a) In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality unit during the production process.

(b) To assure batch uniformity and integrity of drug products, written procedures shall be established and followed that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch. Such control procedures shall be established to monitor the output and to validate the performance of those manufacturing processes.

(c) Rejected in-process materials shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable.

Subpart G—Packaging and Labeling Control

§ 213.122 Materials examination and usage criteria.

(a) There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials; such

written procedures shall be followed. Labeling and packaging materials shall be representatively sampled, and examined or tested upon receipt and before use in packaging or labeling of a medical gas.

(b) Any labeling or packaging materials meeting appropriate written specifications may be approved and released for use. Any labeling or packaging materials that do not meet such specifications shall be rejected to prevent their use in operations for which they are unsuitable.

(c) Records shall be maintained for each shipment received of each different labeling and packaging material indicating receipt, examination, and whether accepted or rejected.

(d) Labels and other labeling materials for each different medical gas, strength, or quantity of contents, shall be stored with suitable identification to avoid mix-ups. Access to the label storage area shall be limited to authorized personnel.

(e) Labels, labeling, and other packaging materials that are obsolete, outdated, or that do not meet applicable requirements shall be destroyed.

(f) Packaging and labeling operations shall include one of the following special control procedures:

(1) Dedication of labeling and packaging lines to each different strength of each different medical gas;

(2) Use of appropriate electronic or electromechanical equipment to conduct a 100-percent examination for correct labeling during or after completion of finishing operations; or

(3) Use of visual inspection to conduct a 100-percent examination for correct labeling during or after completion of labeling operations for hand-applied labeling. Such examination shall be performed by one person and independently verified by a second person.

(g) Printing devices on, or associated with, manufacturing lines used to imprint labeling upon the unit label or case shall be monitored to assure that all imprinting conforms to the print specified in the batch production record.

(h) Labels may be reused if they are legible, properly affixed to the container, and otherwise meet all applicable requirements.

§ 213.125 Labeling issuance.

(a) Labeling and packaging operations must be controlled to prevent labeling and product mix-ups. Procedures shall be written and followed describing in sufficient detail the control procedures employed for the issuance of labeling.

(b) Procedures shall be used to reconcile the quantities of labeling issued, used, and returned, and shall require evaluation of discrepancies found between the quantity of medical gas and the quantity of labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. Such discrepancies shall be investigated in accordance with § 213.192. Labeling reconciliation is waived for cut or roll labeling if a 100-percent examination for correct labeling is performed in accordance with § 213.122(f)(2). Labeling reconciliation is also waived for 360° wraparound labels on portable cryogenic medical gas containers.

(c) All excess lot number stickers or decals bearing lot or control numbers shall be discarded.

(d) Bulk or transport containers (as defined in § 201.161(c)(3) of this chapter) are exempt from this section.

§ 213.130 Packaging and labeling operations.

There shall be written procedures designed to assure that correct labels, labeling, and packaging materials are used for medical gases; such written procedures shall be followed. These procedures shall incorporate the following features:

(a) Prevention of mix-ups by physical or spatial separation from operations on other products.

(b) Identification and handling of filled containers of medical gas that are set aside and held in unlabeled condition for future labeling operations to preclude mislabeling of individual containers, lots, or portions of lots. Identification need not be applied to each individual container but shall be sufficient to determine name, strength, quantity of contents, and lot or control number of each container.

(c) Identification of the medical gas with a lot or control number that permits determination of the history of the manufacture and control of the batch. The lot or control number of the medical gas may be identified by use of a separate identification sticker or decal.

(d) Examination of packaging and labeling materials for suitability and correctness before packaging operations, and documentation of such examination in the batch production record. Product labels, including 360° wraparound labels, can be reused provided they meet all applicable labeling requirements, all information on the label is legible, and the label is in good condition.

(e) Inspection of the packaging and labeling facilities immediately before use to assure that all medical gases have been removed from previous operations. Inspection shall also be made to assure that packaging and labeling materials not suitable for subsequent operations have been removed. Results of inspection shall be documented in the batch production records.

(f) Bulk or transport containers (as defined in § 201.161(c)(3) of this chapter) are exempt from this section provided they are identified with the name of the product contained therein and accompanied by documentation identifying the product as meeting applicable compendial standards.

Subpart H—Holding and Distribution

§ 213.150 Warehousing and distribution procedures.

(a) Written procedures shall be established, and followed, describing the distribution of medical gases and including a system by which the distribution of each lot can be readily determined to facilitate its recall if necessary.

(b) Written procedures shall be established, and followed, describing the warehousing of medical gases, including quarantine of such gases before release by the quality unit.

Subpart I—Laboratory Controls

§ 213.160 General requirements.

(a) The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality unit. The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified.

(b) Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, medical gas containers and closures, in-process materials, labeling, and medical gases conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:

(1) Determination of conformity to applicable written specifications for the acceptance of each lot within each shipment of components, medical gas containers and closures, and labeling used in the manufacture, processing,

packing, or holding of a medical gas. The specifications shall include a description of the sampling and testing procedures used. Samples shall be representative and adequately identified. Such procedures shall also require appropriate retesting of any component, container, or closure that is subject to deterioration.

(2) Determination of conformance to written specifications and a description of sampling and testing procedures for in-process materials. Such samples shall be representative and properly identified.

(3) Determination of conformance to written descriptions of sampling procedures and appropriate specifications for medical gases. Such samples shall be representative and properly identified.

(4) The calibration or verification of calibration for instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. Instruments, apparatus, gauges, and recording devices not meeting established specifications shall not be used.

§ 213.165 Testing and release for distribution.

(a) For each batch of medical gas, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the medical gas, including the identity and strength, prior to release.

(b) Any sampling and testing plans shall be described in written procedures that shall include the method of sampling, the number of units per batch to be tested, and acceptance criteria. Such written procedures shall be followed.

(c) The accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented. Such validation and documentation may be accomplished in accordance with § 213.194(a)(2). The suitability of all testing methods shall be verified under actual conditions of use.

(d) Medical gases failing to meet established standards or specifications and any other relevant quality criteria shall be rejected.

(e) This section does not apply to the filling of a designated medical gas or medically appropriate combination of designated medical gases via liquid to liquid into a container at a delivery site.

§ 213.166 Stability testing and expiration dating for medical gases marketed under applications submitted under section 505 or section 512 of the Federal Food, Drug, and Cosmetic Act.

(a) For medical gases marketed under applications submitted under section 505 or section 512 of the Federal Food, Drug, and Cosmetic Act, any stability testing performed and any expiration date established shall be in accordance with paragraph (b) of this section, subject to the conditions established in their approved applications, if any.

(b) To assure that the medical gas described in paragraph (a) of this section meets applicable standards of identity, strength, quality, and purity at the time of use:

(1) The stability testing program shall be designed to assess the stability characteristics of the medical gas and its container closure system. The results of stability testing shall be used in determining appropriate storage conditions and any expiration date included on the label. The stability program shall include the appropriate sample size, test intervals, container closure systems, and storage conditions for samples retained for testing.

(2) Any expiration dates included on the label shall appear in accordance with the requirements of § 201.17 of this chapter.

(3) Stability shall be evaluated periodically to ensure that the medical gas continues to meet the standards for identity, strength, quality, and purity stated on the labeling to support the expiration date.

Subpart J—Records

§ 213.180 General requirements.

(a) *Record availability.* All records required under this part, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred and are subject to copying as part of such inspection. Records that can be immediately retrieved from another location by computer or other electronic means shall be considered as meeting the requirements of this paragraph.

(b) *Record requirements.* All records must be legible, stored to prevent deterioration or loss, and original or accurate reproductions of the original records.

(c) *Record retention period.* Except where otherwise provided, all records required to be maintained in compliance with this part must be maintained for a period of at least 3 years after the distribution of the batch of medical gas.

(d) *Maintenance of written records.* Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each medical gas to determine the need for changes in specifications or manufacturing or control procedures. Written procedures shall be established and followed for such evaluations and shall include provisions for:

(1) A review of a representative number of batches, whether approved or rejected, and, where applicable, records associated with the batch; and

(2) A review of complaints, recalls, returned or salvaged medical gases, and investigations conducted under § 213.192 for each gas.

(e) *Written procedure requirements.* A firm shall establish and follow written procedures to assure that responsible officials of the firm are notified in writing of any recalls, reports of inspectional observations by FDA, regulatory actions related to good manufacturing practices brought by FDA, or investigations resulting from adverse event complaints.

§ 213.182 Equipment cleaning and use log.

A written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use shall be included in individual equipment logs that show the date, time, product, and lot number of each batch processed. If equipment is dedicated to manufacture of one product, then individual equipment logs are not required, provided that lots or batches of such product follow in numerical order and are manufactured in numerical sequence. In cases where dedicated equipment is employed, the records of cleaning, maintenance, and use shall be part of the batch record. The persons performing and double-checking the cleaning and maintenance (or, if the cleaning and maintenance is performed using automated equipment under § 213.68, just the person verifying the cleaning and maintenance done by the automated equipment) shall date and sign or initial the log indicating that the work was performed. Entries in the log shall be in chronological order.

§ 213.184 Records for components, medical gas containers and closures, and labeling.

These records shall include the following:

(a) The results of any test or examination performed (including those performed as required by § 213.84 or § 213.122) and the conclusions derived therefrom.

(b) Documentation of the examination and review of labels and labeling for conformity with established specifications in accordance with §§ 213.122 and 213.130.

(c) The disposition of rejected components, medical gas containers and closures, and labeling.

§ 213.186 Master production and control records.

(a) To assure uniformity from batch to batch, master production and control records for each medical gas shall be prepared, dated, and signed. The preparation of master production and control records shall be described in a written procedure and such written procedure shall be followed.

(b) Master production and control records shall include:

(1) The name and strength of the product;

(2) A complete list of components and any incoming designated medical gases used in manufacturing designated by names or codes sufficiently specific to indicate any special quality characteristic;

(3) A description of the medical gas containers and closures, and packaging materials and labels; and

(4) Complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed.

§ 213.189 Batch production and control records.

(a) Batch production and control records shall be prepared for each batch of medical gas produced.

(b) These records shall include documentation that each significant step in the manufacture, processing, packing, or holding of the medical gas produced was accomplished, including:

(1) Dates and times of each significant step, including in-process and laboratory tests as applicable;

(2) A description of the container for the medical gas, including the number and size of the containers filled as applicable;

(3) Specific identification of each component and its source or in-process material used as applicable;

(4) Measures of components used in the course of processing as applicable;

(5) Testing results, including any in-process test results and finished product test results;

(6) Dated signature or initials of the persons performing and directly supervising or checking each significant event in the operation;

(7) Inspection of the packaging and labeling area before and after use;

(8) Complete labeling control records, including specimens or copies of all labeling used and label application and reconciliation records as appropriate;

(9) Any investigation made according to § 213.192.

§ 213.192 Production record review.

(a) Manufacturing production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality unit to determine compliance with all established, approved written procedures before a batch is released or distributed. The quality unit must review production records to determine whether errors or unexplained discrepancies have occurred prior to batch release. If errors or unexplained discrepancies have occurred, or a batch or any component of the batch fails to meet any of its specifications, the firm must thoroughly investigate and take appropriate corrective actions. A written record of the investigation shall be made and shall include the conclusions and followup.

(b) For production and control records of filling at a delivery site, quality unit review as described in paragraph (a) of this section shall be within one business day after fill.

§ 213.194 Laboratory records.

(a) Laboratory records related to the manufacture of a medical gas must include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays, as follows:

(1) A description of the sample, the batch or lot number to be tested, the date the sample was taken, and the date the sample was tested.

(2) The method used in the testing of the sample, the result of the test, how the results compare with established standards of identity, strength, quality, and purity for the component, container, closure, in-process materials (as applicable), and medical gas tested, a record of any calculations performed in connection with each test and any calculated results, and the unit of measurement of the result for each test. It is not necessary to provide the actual calculation where the result is evident through use of simple addition and subtraction.

(3) Where applicable, any graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific component, in-process material, or medical gas for each lot tested.

(4) The initials or signature of the person performing the test and the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards.

(b) Complete records shall be maintained of any modification of an established method employed in testing. Such records shall include the reason for the modification and data to verify that the modification produced results that are at least as accurate and reliable for the material being tested as the established method.

(c) Complete records shall be maintained of any testing and standardization of laboratory reference standards, reagents, and standard solutions.

(d) Complete records shall be maintained of the periodic calibration or verification of calibration of laboratory instruments, apparatus, gauges, and recording devices required by § 213.160(b)(4).

(e) Complete records shall be maintained of all stability testing performed in accordance with § 213.166.

§ 213.196 Distribution records.

Distribution records shall contain the name of the product, lot or batch number, name and address of the consignee, and date and quantity shipped. For medical air and medically appropriate combinations of designated medical gases, the distribution record shall include the percentage of each gas.

§ 213.198 Complaint files.

(a) Written procedures shall be established and followed for the receipt and handling of all written or oral complaints concerning a medical gas. These procedures must include quality unit review of any complaint involving the possible failure of a medical gas to meet any of its specifications and an investigation to determine the cause of the failure. Such procedures shall include provisions for determining the need for an investigation in accordance with § 213.192 as well as determining whether the complaint represents an event that is required to be reported to FDA under part 230 of this chapter.

(b) A written record of each complaint regarding a medical gas must be maintained. The record must include the name of the gas, the lot or batch number, the name of the complainant, the date the complaint was received, the nature of the complaint, and the response to the complaint. It must also include the findings of any investigation and followup. Where an investigation is not conducted, the written record shall include the reason that an investigation

was found not to be necessary and the name of the responsible person making such a determination.

(c) Complaint files shall be maintained in a manner such that they are readily available for inspection by the firm or by FDA during an inspection. Complaint files shall be maintained for at least 1 year after the date the complaint was received or for at least 3 years after distribution of the medical gas, whichever is longer.

Subpart K—Returned and Salvaged Medical Gases

§ 213.204 Returned medical gases.

Returned medical gases shall be identified as such and held. If the conditions under which such returned gases have been held, stored, or shipped before or during their return, or if the condition of the gas, its container, carton, or labeling, as a result of storage or shipping, casts doubt on the safety, identity, strength, quality, or purity of the gas, the returned gas shall be destroyed unless examination, testing, or other investigations prove the gas meets appropriate standards of safety, identity, strength, quality, or purity. Records of returned medical gases shall be maintained and shall include the name, lot number (or control number or batch number), reason for the return, quantity returned, date of disposition, and ultimate disposition of the returned gas. If the reason for a medical gas being returned implicates associated batches, an appropriate investigation shall be conducted in accordance with the requirements of § 213.192. Procedures for the holding, testing, and use of returned medical gases shall be in writing and shall be followed. This section is not applicable to the routine refilling of cryogenic medical gas containers in the normal course of business, unless the cryogenic medical gas container was returned due to a quality issue.

§ 213.208 Salvaging of medical gases.

Medical gases in containers that have been subjected to improper storage conditions may be salvaged unless their containers have been subjected to adverse conditions that impact the identity, strength, quality, and purity of the product or integrity of the container closure. Whenever there is a question whether medical gases have been subjected to such conditions, salvaging operations may be conducted only if there is evidence from laboratory tests that such gases meet all applicable standards of identity, strength, quality, and purity, and the integrity of the container closure system is not compromised. Procedures for the holding, testing, and use of salvaged medical gases shall be in writing and shall be followed.

■ 25. Add part 230 to subchapter C to read as follows:

PART 230—CERTIFICATION AND POSTMARKETING REPORTING FOR DESIGNATED MEDICAL GASES

Sec.

Subpart A—General Provisions

230.1 Scope of this part.
230.2 Purpose.
230.3 Definitions.

Subpart B—Certification of Designated Medical Gases

230.50 General requirements for all submission types.
230.65 Withdrawal by the applicant of a certification request before it is deemed granted.
230.70 Supplements and other changes to a granted certification.
230.72 Change in ownership of a granted certification.
230.80 Annual report.
230.100 FDA review of submissions.
230.105 When a submission is deemed granted.
230.150 Withdrawal or revocation of approval of an application.

Subpart C—Postmarketing Quality and Safety Reporting

230.205 Field alert reports.
230.210 General reporting requirements for designated medical gas adverse events.
230.220 Human designated medical gas ICSR requirements.
230.230 Animal designated medical gas adverse event reporting requirements.

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 355f, 356, 356a, 356b, 356c, 356e, 360b, 360cc, 360ddd, 360ddd–1, 371, 374, 379e, 379k–1, 381.

Subpart A—General Provisions

§ 230.1 Scope of this part.

(a) This part sets forth procedures and requirements for the submission to, and the review by, the Food and Drug Administration of certifications to market designated medical gases under sections 575 and 576 of the Federal Food, Drug, and Cosmetic Act, as well as amendments and supplements to those certifications. This part also sets forth the postmarketing safety reporting requirements for designated medical gases.

(b) References in this part to regulations in the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§ 230.2 Purpose.

The purpose of this part is to establish an efficient process for the certification of designated medical gases and to establish an effective system for surveillance of such gases.

§ 230.3 Definitions.

(a) The definitions and interpretations contained in sections 201 and 575 of the Federal Food, Drug, and Cosmetic Act apply to those terms when used in this part of this chapter.

(b) The following definitions of terms apply to this part:

(1) *Adverse event* means any untoward medical occurrence associated with the use of a designated medical gas in humans or animals, whether or not it is considered related to the designated medical gas. An adverse event can occur in the course of the use of a designated medical gas; from overdose of a designated medical gas, whether accidental or intentional; from abuse of a designated medical gas; from discontinuation of the designated medical gas (*e.g.,* physiological withdrawal); and it includes any failure of expected pharmacological action.

(2) *Applicant* means any person or entity who submits a certification request for a designated medical gas under this part, including a supplement, and any person or entity who owns a granted certification for a designated medical gas under this part.

(3) *Certification request* means a submission under section 576 of the Federal Food, Drug, and Cosmetic Act requesting certification of a medical gas as a designated medical gas.

(4) *FDA or Agency* means the Food and Drug Administration.

(5) *Individual case safety report* (ICSR) means a description of an adverse event related to an individual patient or subject.

(6) *ICSR attachments* means documents related to the adverse event described in an ICSR, such as medical records, hospital discharge summaries, or other documentation.

(7) *Life-threatening adverse event* means any adverse event that places the patient, in the view of the initial reporter, at *immediate* risk of death from the adverse event as it occurred, *i.e.,* it does not include an adverse event that, had it occurred in a more severe form, might have caused death.

(8) *Minimum data set for an ICSR for an adverse event* means the minimum four elements required for reporting an ICSR of an adverse event: An identifiable patient, an identifiable reporter, a suspect designated medical gas, and an adverse event.

(9) *Nonapplicant* means any person other than the applicant whose name appears on the label of a designated

medical gas container as a manufacturer, packer, or distributor.

(10) *Serious adverse event* means:

(i) An adverse event is considered ''serious'' if it results in any of the following outcomes:

(A) Death;

(B) A life-threatening adverse event;

(C) Inpatient hospitalization or prolongation of existing hospitalization;

(D) A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; and/or

(E) A congenital anomaly/birth defect.

(ii) Other events that may be considered serious adverse events: Important medical events that may not result in one of the listed outcomes in this definition may be considered serious adverse events when, based upon appropriate medical judgment, they may jeopardize the patient or study subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples include: Allergic bronchospasm requiring intensive treatment in an emergency department or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of product dependency or product abuse. Additional examples in animals include: Severe hypersensitivity reactions or respiratory distress.

Subpart B—Certification of Designated Medical Gases

§ 230.50 General requirements for all submission types.

(a) *Who must submit a request for certification.*

(1) The certification process described in this subpart applies to designated medical gases for the indications described in section 576(a)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act. Any person who seeks to initially introduce or deliver for introduction a designated medical gas into interstate commerce shall file a request for certification. The certification process is the same for all designated medical gases, regardless of whether it is intended for human use, animal use, or both. The applicant must identify its intention to market its designated medical gas for human use, animal use, or both.

(2) Any person that proposes to market a medical gas that is a new drug for human use must obtain approval under part 314 of this chapter, and any person that proposes to market a medical gas that is a new animal drug for animal use must obtain approval under part 514 of this chapter, unless—

(i) The medical gas meets the definition of a designated medical gas; and

(ii) The medical gas is proposed to be marketed:

(A) Alone, or

(B) In combination (as medically appropriate) with another designated medical gas or other designated medical gases; and

(C) For which a certification or certifications have been granted, for a use described under section 576(a)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act.

(b) *The applicant must include the following information in its certification request:*

(1) *Applicant information.* The applicant must identify the name, address, telephone number, and email address of the person or entity requesting certification. If the address of the entity requesting certification is not in the United States, the certification request is required to contain the name and address of, and be countersigned by, an attorney, agent, or other authorized official who resides or maintains a place of business within the United States.

(2) *Type of submission.* The applicant must indicate the type of submission as one of the following:

(i) Original Certification Request—An initial request submitted by an applicant for certification of a medical gas as a designated medical gas.

(ii) Amendment to a Pending Certification Request—Any submission related to a pending submission that revises existing information or provides additional information, including responses to Information Request Letters.

(iii) Resubmission—Any submission that has been revised and submitted again following a previous denial. If an applicant chooses to resubmit its submission, it must provide a written response to the deficiencies identified in FDA's denial letter, along with other information required for certification requests.

(iv) Supplement to a granted certification—Any submission that contains a change to a granted certification.

(v) Other—Any submission that does not fit in one of the other categories.

(3) *Description of medical gas.* A separate certification request is required to be submitted for each designated medical gas for which certification is sought. Each designated medical gas certification request must include the name of the medical gas and a certification statement from the applicant that the designated medical gas meets the appropriate compendial standard.

(4) *Facility information.* Each certification request must include the name and address of the facility or facilities where the designated medical gas will be initially produced. For each facility, include a brief description of the manufacturing or processing activities performed, the FDA Establishment Identifier (FEI), if one exists, and the Unique Facility Identifier in accordance with the requirements of part 207 of this chapter and section 510 of the Federal Food, Drug, and Cosmetic Act. For amendments and supplements, only changes to the list of facilities are required to be included.

(5) *Certification of adequate manufacture, processing, packaging, and holding of designated medical gas.* The applicant must certify that the applicant's methods, facilities, and controls used for the manufacture, processing, packing, and holding of the designated medical gas, as applicable, are adequate to ensure its safety, identity, strength, quality, and purity.

(6) *Additional information.* The applicant must provide any other information which FDA deems appropriate to determine whether the medical gas is a designated medical gas. The applicant may also provide other information that the applicant believes will assist FDA in evaluating the request.

(c) *Where and how to submit a request for certification.* The applicant must submit a signed, completed request for certification form either in an electronic format that FDA can process, review, and archive, or in hard copy by submitting two paper copies to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Road, Beltsville, MD 20705.

§ 230.65 Withdrawal by the applicant of a certification request before it is deemed granted.

An applicant may at any time withdraw a certification request that is not yet deemed granted by notifying FDA in writing. A decision to withdraw the certification request is without prejudice to refiling. The Agency will retain the certification request and will provide a copy to the applicant on request under the fee schedule in § 20.45 of this chapter (FDA's public information regulations).

§ 230.70 Supplements and other changes to a granted certification.

(a) The applicant must submit a supplement if any information in the certification request changes after the

request has been deemed granted, including, but not limited to, the addition of a new facility manufacturing the designated medical gas, a change in contact information, or a change in the corporate name.

(b) Each supplement must include a signed, completed request for certification form with the updated information in accordance with § 230.50. The updated information must be submitted no later than 30 calendar days after the date the change occurred.

§ 230.72 Change in ownership of a granted certification.

An applicant may transfer ownership of its certification. At the time of transfer the new and former owners are required to submit information to FDA as follows:

(a) The former owner must submit a letter or other document that states that all rights to the certification have been transferred to the new owner.

(b) The new owner must submit a supplement under § 230.70 signed by the new owner describing any changes in the conditions in the granted certification and a letter or other document containing the date that the change in ownership is effective.

§ 230.80 Annual report.

(a) The applicant must submit each year within 60 calendar days of the anniversary of the date the certification was deemed granted, an annual report containing the information described in paragraph (b) of this section. The applicant must submit a signed, completed annual report form either in an electronic format that FDA can process, review, and archive, or in hard copy by submitting two paper copies to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Road, Beltsville, MD 20705.

(b) The report must contain, for the prior 12 months, the following information in the order listed:

(1) *Summary.* A brief summary of significant new information that might affect the safety, effectiveness, or labeling of the designated medical gas, including any actions the applicant has taken or intends to take as a result of this new information.

(2) *Distribution data.* Information about the quantity of the designated medical gas distributed by the applicant. The information must include the National Drug Code (NDC) numbers and the quantities distributed for domestic use and the quantities distributed for foreign use. Disclosure of financial or pricing data is not required.

(3) *Administrative changes.* Any changes to the applicant's name or contact information.

(4) *Current facilities.* A list of current facilities, and a list of facilities that are no longer in use.

§ 230.100 FDA review of submissions.

(a) In reviewing a submission pursuant to § 230.50, FDA will consider information provided with the submission along with any other available, relevant information of which FDA becomes aware, including information obtained from State or Federal officials, FDA inspection reports, or any other source.

(b) FDA will deny a submission if FDA finds that:

(1) The medical gas that is the subject of the submission is not a designated medical gas;

(2) The submission does not contain the required information or otherwise appears to lack sufficient information to determine that the medical gas is a designated medical gas;

(3) The applicant's methods, facilities, and controls used for the manufacture, processing, and handling of the designated medical gas, as applicable, are not adequate to ensure its safety, identity, strength, quality, and purity; or

(4) Denying the request is otherwise necessary to protect the public health.

(c) Within 60 calendar days of filing of a submission, FDA may contact the applicant to request additional information regarding the submission if it determines that required information is not included in the submission, that FDA needs such information to determine whether the medical gas is a designated medical gas, or that FDA determines such information is necessary to protect the public health. Upon receipt of an amendment to a pending certification request, this 60-day review period will restart. If FDA is not able to contact the applicant to obtain and evaluate the information within the 60-day review period, FDA may find that the submission lacks sufficient information to permit a determination that the medical gas is a designated medical gas and deny the submission. If FDA is able to contact the applicant but is not provided with the additional information requested within the 60-day review period, FDA may find that the request lacks sufficient information to permit a determination that the medical gas is a designated medical gas and deny the submission.

(d) Within 60 calendar days of filing of a submission, if FDA makes one of the findings described in § 230.100(b), FDA will notify the applicant in writing that the submission is denied and provide the basis for FDA's determination.

§ 230.105 When a submission is deemed granted.

Unless FDA makes one of the findings described in § 230.100(b) and notifies the applicant within 60 calendar days of filing that the submission is denied, the certification is deemed to be granted and the designated medical gas will be deemed to have in effect an approved application under section 505 or section 512 of the Federal Food, Drug, and Cosmetic Act, or both, as applicable, for the indications described in section 576(a)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act. FDA will notify the applicant in writing.

§ 230.150 Withdrawal or revocation of approval of an application.

(a) *Withdrawal.*

(1) FDA will notify the applicant, and afford an opportunity for a hearing on a proposal to withdraw approval of the application under the procedure in §§ 314.200, 514.200, or both, as applicable, if any of the following apply:

(i) The Secretary of Health and Human Services has suspended the approval of the application for a designated medical gas on a finding that there is an imminent hazard to the public health. FDA will promptly afford the applicant an expedited hearing following summary suspension on a finding of imminent hazard to health.

(ii) FDA finds:

(A) That clinical or other experience, tests, or other scientific data show that the designated medical gas is unsafe for use under the conditions of use upon the basis of which the application was approved; or

(B) That new evidence of clinical experience not available to FDA until after the application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when the application was approved, evaluated together with the evidence available when the application was approved, reveal that the designated medical gas is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or

(C) Upon the basis of new information before FDA with respect to the designated medical gas, evaluated together with the evidence available when the application was approved, that there is a lack of substantial evidence from adequate and well-controlled investigations as defined in § 314.126 of this chapter, that the designated medical gas will have the effect it is purported or represented to

have under the conditions of use prescribed, recommended, or suggested in its labeling; or

(D) That the application contains any untrue statement of a material fact.

(2) FDA may notify the applicant, and afford an opportunity for a hearing on a proposal to withdraw approval of the application under the procedure in §§ 314.200, 514.200, or both, as applicable, if the Agency finds:

(i) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain required records or to make required reports applicable to designated medical gases, including under sections 505(k) and 512(l) of the Federal Food, Drug, and Cosmetic Act and this part and part 213 of this chapter, or that the applicant has refused to permit access to, or copying or verification of, its records.

(ii) That on the basis of new information before FDA, evaluated together with the evidence available when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the designated medical gas are inadequate to ensure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Agency.

(iii) That on the basis of new information before FDA, evaluated together with the evidence available when the application was approved, the labeling of the designated medical gas, based on a fair evaluation of all material facts, is false or misleading in any particular, and the labeling was not corrected by the applicant within a reasonable time after receipt of written notice from the Agency.

(iv) That the applicant has failed to comply with the notice requirements of section 510(j)(2) of the Federal Food, Drug, and Cosmetic Act.

(3) FDA will withdraw approval of an application if the applicant requests its withdrawal because the designated medical gas subject to the application is no longer being marketed, provided none of the conditions listed in paragraphs (a)(1) and (2) of this section applies to the designated medical gas. FDA will consider a written request for a withdrawal under this clause to be a waiver of an opportunity for hearing otherwise provided for in this section. Withdrawal of approval of an application under this clause is without prejudice to refiling.

(4) FDA may notify an applicant that it believes a potential problem associated with a designated medical gas is sufficiently serious that the designated medical gas should be removed from the market and may ask the applicant to waive the opportunity for hearing otherwise provided for under this section, to permit FDA to withdraw approval of the application for the product, and to remove voluntarily the product from the market. If the applicant agrees, the Agency will not make a finding under paragraph (a) of this section, but will withdraw approval of the application in a notice published in the **Federal Register** that contains a brief summary of the Agency's and the applicant's views of the reasons for withdrawal.

(5) If FDA withdraws an approval, FDA will publish a notice in the **Federal Register** announcing the withdrawal of approval.

(b) *Revocation.* FDA may revoke the grant of a certification if FDA determines, after providing the applicant with notice and opportunity for an informal hearing in accordance with part 16 of this chapter, that the request for certification contains any material omission or falsification.

Subpart C—Postmarketing Quality and Safety Reporting

§ 230.205 Field alert reports.

The applicant shall submit all information described in paragraphs (a) and (b) of this section about distributed designated medical gases and articles to the FDA district office that is responsible for the facility involved within 3 working days of receipt by the applicant. The information may be provided by telephone or other rapid communication means, with prompt written followup. The report and its mailing cover should be plainly marked: ''Designated Medical Gas—Field Alert Report.''

(a) Information concerning any incident that causes the designated medical gas or its labeling to be mistaken for, or applied to, another article.

(b) Information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed designated medical gas, or any failure of one or more distributed batches of the designated medical gas to meet established specifications.

§ 230.210 General reporting requirements for designated medical gas adverse events.

(a) *Review of safety information.* Each applicant and nonapplicant must promptly review all safety information that the applicant or nonapplicant receives or otherwise obtains from any source, foreign or domestic, such as information derived from commercial marketing experience, reports in the published scientific and medical literature, unpublished scientific papers, and reports from regulatory authorities.

(b) *Safety reporting disclaimer.* (1) A report or information submitted by an applicant or nonapplicant (and any release by FDA of that report or information) under § 230.220 or 230.230 does not necessarily reflect a conclusion by the applicant or nonapplicant or by FDA that the report or information constitutes an admission that the designated medical gas caused or contributed to an adverse effect.

(2) An applicant or nonapplicant need not admit, and may deny, that the report or information submitted under § 230.220 or 230.230 constitutes an admission that the designated medical gas caused or contributed to an adverse effect.

§ 230.220 Human designated medical gas ICSR requirements.

(a) *ICSR Reporting.* (1) *General.* Except as provided in paragraph (c) of this section, applicants and nonapplicants must submit each ICSR associated with the use of a designated medical gas in humans described in paragraph (b) of this section to FDA as soon as possible but no later than 15 calendar days from the date when the applicant or nonapplicant has both met the reporting criteria described in paragraph (b) of this section and acquired a minimum data set for an ICSR for that adverse event.

(2) *Copies of ICSRs obtained from FDA.* An applicant or nonapplicant should not resubmit under this section any ICSRs obtained from FDA's adverse event reporting database or forwarded to the applicant or nonapplicant by FDA.

(3) *Followup information.* Applicants and nonapplicants must submit any new information that is related to a previously submitted ICSR or an ICSR that was sent to the applicant by FDA no later than 15 calendar days after the information is received or otherwise obtained.

(b) *Reporting requirements.* (1) *Serious adverse events.*

(i) *Reported spontaneously.* Applicants and nonapplicants must submit ICSRs for serious adverse events reported to the applicant or nonapplicant spontaneously (such as a report initiated by a patient, consumer, or healthcare professional).

(ii) *Reported from the scientific literature.* Applicants and nonapplicants must submit ICSRs for serious adverse events obtained from published

scientific and medical journals either as case reports or as the result of a formal clinical trial.

(iii) *Exception to reporting requirements for serious adverse events.* Notwithstanding paragraph (b)(1)(i) and (ii) of this section, ICSRs are not required for reports of the death of a patient who was administered oxygen, unless the applicant or nonapplicant is aware of evidence to suggest that the death was caused by the administration of oxygen.

(2) *Other adverse event reports to be submitted upon notification by FDA.* Upon notification by FDA, applicants and nonapplicants must submit, in a timeframe established by FDA, ICSRs for any adverse event that are not required under paragraph (b)(1) of this section. The notification will specify the adverse events to be reported and the reason for requiring the reports.

(c) *Completing and submitting ICSRs.* This paragraph describes how to complete and submit ICSRs required under this section.

(1) *Electronic format for submissions.*

(i) ICSRs and ICSR attachments must be in an electronic format that FDA can process, review, and archive, as described in § 314.80(g)(1) of this chapter.

(ii) An applicant or nonapplicant may request, in writing, a temporary waiver of the requirements in paragraph (c)(1)(i) of this section, as described in § 314.80(g)(2). These waivers will be granted on a limited basis for good cause shown.

(2) *Submitting ICSRs.*

(i) *Single submission of each ICSR.* Submit each ICSR only once.

(ii) *Separate ICSR for each patient.* The applicant or nonapplicant must submit a separate ICSR for each patient who experiences an adverse event reportable under paragraph (b) of this section.

(iii) *Coding terms.* The adverse event terms described in the ICSR must be coded using standardized medical terminology.

(iv) *Minimum data set.* All ICSRs submitted under this section must contain at least the minimum data set for an ICSR for an adverse event. The applicant or nonapplicant must actively seek the minimum data set in a manner consistent with the written procedures under paragraph (f) of this section. Applicants and nonapplicants must document and maintain records of their efforts to obtain the minimum data set.

(v) *ICSR elements.* The applicant or nonapplicant must complete all known, available elements of an ICSR as specified in paragraph (d) of this section.

(A) For adverse events, applicants and nonapplicants must actively seek any information needed to complete all applicable elements, consistent with their written procedures under paragraph (f) of this section.

(B) Applicants and nonapplicants must document and maintain records of their efforts to obtain the missing information.

(vi) *Supporting documentation.* An applicant or nonapplicant must submit the following types of supporting documentation in an ICSR, if available:

(A) A copy of the autopsy report if the patient died, or a copy of the hospital discharge summary if the patient was hospitalized. The applicant or nonapplicant must submit each document as an ICSR attachment. The ICSR attachment must be submitted either with the initial ICSR or no later than 15 calendar days after obtaining the document. English translations of foreign language documents must be provided.

(B) A copy of the published article as an ICSR attachment for each ICSR of an adverse event obtained from the published scientific and medical literature. Foreign language articles must be accompanied by an English translation of the abstract. When submitting more than one ICSR from the same published article, the applicant or nonapplicant must submit only one copy of the article with one of the ICSRs. For the remaining ICSRs not accompanied by a copy of the published article, the applicant or nonapplicant must include the cross-reference to the specific ICSR to which the article is attached.

(d) *Information reported on ICSRs.* ICSRs must include the following information, subject to paragraph (c)(2)(v) of this section:

(1) Patient information, which includes:

(i) Patient identification code;

(ii) Patient age at the time of adverse event, or date of birth;

(iii) Patient gender; and

(iv) Patient weight.

(2) Adverse event, which includes:

(i) Outcome attributed to adverse event;

(ii) Date of adverse event;

(iii) Date of ICSR submission;

(iv) Description of adverse event;

(v) Adverse event term(s);

(vi) Description of relevant tests conducted, including dates and laboratory data; and

(vii) Other relevant patient history, including preexisting medical conditions.

(3) Suspect designated medical gas(es), which includes:

(i) Name;

(ii) Dose, frequency, and route of administration used;

(iii) Therapy dates;

(iv) Diagnosis for use (indication);

(v) Whether the adverse event abated after the use of the designated medical gas(es) stopped or the dose was reduced;

(vi) Whether the adverse event reappeared after reintroduction of the designated medical gas(es);

(vii) Lot number;

(viii) National Drug Code (NDC) number; and

(ix) Concomitant medical products and therapy dates.

(4) Initial reporter information, which includes:

(i) Name, address, email address, and telephone number;

(ii) Whether the initial reporter is a healthcare professional; and

(iii) Occupation, if a healthcare professional.

(5) Applicant or nonapplicant information, which includes:

(i) Applicant or nonapplicant name, address, email address, and telephone number;

(ii) Report source, such as spontaneous, literature, or study;

(iii) Date the report was received by applicant or nonapplicant;

(iv) New drug application and/or new animal drug application number;

(v) Whether the ICSR is an expedited report;

(vi) Whether the ICSR is an initial report or followup report; and

(vii) Unique case identification number, which must be the same in the initial report and any subsequent followup report(s).

(e) *Recordkeeping.*

(1) For a period of 10 years from the initial receipt of information, each applicant or nonapplicant must maintain records of information relating to adverse events under this section, whether or not submitted to FDA.

(2) These records must include raw data, correspondence, and any other information relating to the evaluation and reporting of adverse event information that is received or otherwise obtained by the applicant or nonapplicant.

(3) Upon written notice by FDA, the applicant or nonapplicant must submit any or all of these records to FDA within 5 calendar days after receipt of the notice. The applicant or nonapplicant must permit any authorized FDA employee, at reasonable times, to access, copy, and verify these established and maintained records described in this section.

(f) *Written procedures.* The applicant or nonapplicant must develop written

procedures needed to fulfill the requirements in this section for the surveillance, receipt, evaluation, and reporting to FDA of adverse event information, including procedures for employee training and for obtaining and processing adverse event information from other applicants and nonapplicants.

(g) *Patient privacy.* An applicant or nonapplicant should not include in reports under this section the names and addresses of individual patients; instead, the applicant or nonapplicant should assign a unique code for identification of the patient. The applicant or nonapplicant should include the name of the reporter from whom the information was received as part of the initial reporter information, even when the reporter is the patient. As set forth in FDA's public information regulations in part 20 of this chapter, FDA generally may not disclose the names of patients, individual reporters, healthcare professionals, hospitals, and geographical identifiers submitted to FDA in adverse event reports.

§ 230.230 Animal designated medical gas adverse event reporting requirements.

(a) *Report for adverse events.* This report provides information on each adverse event associated with the use of a designated medical gas in animals, regardless of the source of the information.

(1) *Serious adverse events.* The applicant or nonapplicant must submit serious adverse events to FDA as soon as possible but no later than within 15 calendar days of first receiving the information. The report must be submitted to the Agency in electronic format as described in paragraph (b)(1) of this section, unless the applicant or nonapplicant obtains a waiver under paragraph (b)(2) of this section or FDA requests the report in an alternate format.

(i) *Reported spontaneously.* Applicants and nonapplicants must submit reports for *each serious adverse event* reported to the applicant or nonapplicant spontaneously (such as reports initiated by a patient, consumer, veterinarian, or other healthcare professional), regardless of whether the applicant or nonapplicant believes the events are related to the designated medical gas.

(ii) *Reported from the scientific and medical literature.* Applicants and nonapplicants must submit reports for each serious adverse event obtained from the published scientific and medical literature regardless of whether the applicant or nonapplicant believes the events are related to the designated medical gas.

(iii) *Exception to reporting requirements for serious adverse events.* Notwithstanding paragraphs (a)(1)(i) and (ii) of this section, reports are not required to be submitted for the death of an animal that was administered oxygen, unless the applicant or nonapplicant becomes aware of evidence to suggest that the death was caused by the administration of oxygen.

(2) *Other adverse event reports to be submitted upon notification by FDA.* Upon notification by FDA, applicants and nonapplicants must submit reports of adverse events associated with the use of a designated medical gas in animals that do not qualify for reporting under paragraph (a)(1) of this section. The notice will specify the adverse events to be reported and the reason for requiring the reports.

(3) *Copies of adverse event reports obtained from FDA.* An applicant or nonapplicant should not resubmit under this section any adverse event reports obtained from FDA's adverse event reporting database or forwarded to the applicant or nonapplicant by FDA.

(b) *Format for submissions.*

(1) *Electronic submissions.* Reports submitted to FDA under this section must be submitted in an electronic format that FDA can process, review, and archive. Data provided in electronic submissions must be in conformance with the data elements in Form FDA 1932 and FDA technical documents describing transmission. As necessary, FDA will issue updated technical documents on how to provide the electronic submission (*e.g.,* method of transmission and processing, media, file formats, preparation and organization of files). Unless requested by FDA, paper copies of reports submitted electronically should not be submitted to FDA.

(2) *Waivers.* An applicant or nonapplicant may request, in writing, a temporary waiver of the electronic submission requirements in paragraph (b)(1) of this section. The initial request may be provided by telephone or email to CVM's Division of Veterinary Product Safety, with prompt written followup submitted as a letter to the granted certification(s). FDA will grant waivers on a limited basis for good cause shown. If FDA grants a waiver, the applicant or nonapplicant must comply with the conditions for reporting specified by FDA upon granting the waiver.

(c) *Records to be maintained.*

(1) For a period of 5 years from the initial receipt of information, each applicant or nonapplicant must maintain records of information relating to adverse event reports under this section, whether or not submitted to FDA.

(2) These records must include raw data, correspondence, and any other information relating to the evaluation and reporting of adverse event information that is received or otherwise obtained by the applicant or nonapplicant.

(3) Upon written notice by FDA, the applicant or nonapplicant must submit any or all of these records to FDA within 5 calendar days after receipt of the notice. The applicant or nonapplicant must permit any authorized FDA employee, at reasonable times, to access, copy, and verify these established and maintained records described in this section.

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 26. The authority citation for part 314 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 355f, 356, 356a, 356b, 356c, 356e, 360cc, 360ddd, 360ddd–1, 371, 374, 379e, 379k–1.

■ 27. In § 314.1, redesignate paragraph (c) as paragraph (d) and add new paragraph (c) to read as follows:

§ 314.1 Scope of this part.

* * * * *

(c) The following provisions do not apply to designated medical gases, which are subject to the certification and postmarketing reporting requirements under part 230 of this chapter:

(1) §§ 314.50 through 314.72;
(2) § 314.80 except paragraph (g);
(3) § 314.81(a), (b)(1), and (b)(2);
(4) § 314.90;
(5) Subpart C;
(6) §§ 314.100 through 314.162;
(7) Subpart H; and
(8) Subpart I.

* * * * *

PART 514—NEW ANIMAL DRUG APPLICATIONS

■ 28. The authority citation for part 514 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 354, 356a, 360b, 360ccc, 360ddd, 360ddd–1, 371, 379e, 381.

■ 29. In § 514.1, add an eighth sentence to the end of paragraph (a) to read as follows:

§ 514.1 Applications.

(a) * * * The following provisions do not apply to designated medical gases, which are subject to the certification requirements under part 230 of this

chapter: §§ 514.1(b) through 514.8, 514.12, and 514.15; and Subpart B.

* * * * *

■ 30. Amend § 514.80 by:

■ a. In the intro text table adding a new entry after the sixth row.

■ b. Adding a new paragraph (a)(6).

The additions read as follows.

§ 514.80 Records and reports concerning experience with approved new animal drugs.

The following table outlines the purpose for each paragraph of this section:

Purpose	21 CFR paragraph and title
* * * * * * *	
Does this section apply to designated medical gases subject to the certification requirements under part 230?.	514.80(a)(6).
* * * * * *	

(a) * * *

(6) This section does not apply to designated medical gases, which are subject to the certification requirements under part 230 of this chapter. Part 230 of this chapter contains requirements related to records and reports concerning experience with the use of a designated medical gas in animals.

* * * * *

Dated: May 9, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022–10458 Filed 5–20–22; 8:45 am]

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FEDERAL REGISTER PAGES AND DATE, MAY

25569–26120 2
26121–26266 3
26267–26652 4
26653–26960 5
26961–27438 6
27439–27916 9
29717–28750 10
28751–29024 11
29025–29216 12
29217–29646 13
29647–29818 16
29819–30096 17
30097–30384 18
30385–30766 19
30767–31092 20
31093–31356 23

CFR PARTS AFFECTED DURING MAY

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.

1 CFR

12 26267

2 CFR

200 29025
1500 30393

3 CFR

Proclamations:
10375 25569
10376 26121
10377 26653
10378 26655
10379 26657
10380 26659
10381 26661
10382 26663
10383 26665
10384 26667
10385 26669
10386 26671
10387 26673
10388 26959
10389 27905
10390 27907
10391 27915
10392 28751
10393 28753
10394 30095
10395 30385
10396 30387
10397 30387
10398 30391
Executive Orders:
14073 27909
Administrative Orders:
Memorandums:
Memorandum of May 6, 2022 29647
Notices:
Notice of May 9, 2022 ....28749, 29019, 29021, 29023
Notice of May 12, 2022 29645
Presidential Determinations:
No. 2022–12 of May 12, 2022 30383

5 CFR

1601 27917

6 CFR

Ch. I 31093

7 CFR

1 25571
927 30767
1728 26961
1755 26961

8 CFR

214 .....30334, 31095
217 30769
274a 26614, 30334, 31095

9 CFR

355 30773
Proposed Rules:
201 26695
203 26695

10 CFR

430 .....27439, 27461, 28755, 30775
Proposed Rules:
20 .....27025, 29840
26 .....27025, 29840
50 .....27025, 29840
51 .....27025, 29840
52 .....27025, 29840
72 .....27025, 29840
73 .....27025, 29840
140 .....27025, 29840
430 .....26303, 26304, 29576, 30433
431 .....27025, 28782, 30610

12 CFR

14 27482
201 29649
204 29650
329 27483
611 27483
615 27483
620 27483
621 27483
628 27483
630 27483
1002 30097

13 CFR

107 28756
120 28756
142 28756
146 28756

14 CFR

27 26123
39 .....26964, 26967, 26969, 26972, 27494, 27923, 29025, 29027, 29030, 29033, 29037, 29217, 29651, 29654, 29819, 29821, 30402, 30405, 30408, 30411, 30794, 30797, 31095, 31097, 31116, 31119, 31123, 31125, 31129
71 .....26974, 26975, 26977, 26978, 26980, 26981, 26983, 26984, 26985, 27506, 27507, 27508, 27509, 27925, 27927, 29039, 29220, 29222, 29823, 29825, 30414, 31132

73 ....26987, 27510
91 27928
97 ....29657, 29659
Proposed Rules:
29 26143
39 ....26699, 26702, 27029, 27032, 27035, 27037, 27533, 27954, 29841, 30434, 30840
71 ....26705, 27537, 27539, 27956, 29238, 29239, 29243, 31192, 31193

15 CFR
746 28758
922 29606
Proposed Rules:
740 31195
742 31195
774 31195

16 CFR
Proposed Rules:
Ch. II 30436

17 CFR
Proposed Rules:
201 28872
210 ....29059, 29458
229 ....29059, 29458
230 29458
232 ....28872, 29059, 29458
239 ....29059, 29458
240 ....28872, 29059, 29458
242 ....28872, 29059
249 ....28872, 29059, 29458
270 29458
275 29059

18 CFR
Proposed Rules:
35 26504

19 CFR
122 30415

20 CFR
220 27512
404 26268
641 26988
655 ....30334, 31095
Proposed Rules:
641 27041

21 CFR
73 27931
175 31080
176 31080
177 31080
178 31080
866 29661
870 26989
876 26991
878 26993
Proposed Rules:
4 31301
16 31301
172 26707
175 31065
176 31065
177 31065
178 31065
190 30843
201 31301
210 31301
211 31301
213 31301
230 31301
314 31301
514 31301
1162 ....26311, 26454
1166 ....26311, 26396

23 CFR
650 27396

24 CFR
887 30020
984 30020

26 CFR
301 31133
Proposed Rules:
1 ....26806, 30845
20 26806
25 26806
54 30845

27 CFR
9 31164

28 CFR
50 27936
85 27513

29 CFR
2520 31133
4065 31133

30 CFR
917 27938
Proposed Rules:
250 29790

31 CFR
589 26094

32 CFR
310 ....28774, 30416

33 CFR
100 ....25571, 25572, 26270, 26273, 26996, 27943, 30800
110 29668
117 ....30418, 31182
165 ....26273, 26675, 26996, 26998, 27943, 27944, 27945, 27947, 28776, 29041, 29043, 29226, 29228, 29828, 30802, 30804, 31183
Proposed Rules:
100 ....26313, 26315, 27041, 30846
117 26145
140 30849
143 30849
146 30849
165 ....27959, 29244, 29246, 30846, 31203
334 25595

36 CFR
Proposed Rules:
242 29061

37 CFR
1 30806
201 30060
220 30060
222 30060
224 30060
225 30060
226 30060
227 30060
228 30060
229 30060
230 30060
231 30060
232 30060
233 30060
Proposed Rules:
1 27043

38 CFR
3 26124
13 29671

39 CFR
20 29830
111 30101
241.3 ....29673, 30821
Proposed Rules:
3055 25595

40 CFR
33 30393
35 30393
45 30393
46 30393
47 30393
50 29045
51 29045
52 ....26677, 26999, 27519, 27521, 27524, 27526, 27528, 27949, 29046, 29048, 29228, 29232, 29830, 29837, 30420, 30423, 30821, 30828
60 30105
61 30105
62 ....26680, 30105
63 ....27002, 31185
70 30105
81 ....30821, 30828
82 26276
170 29673
180 ....26684, 26687, 26691, 29050, 29053, 29056, 30425, 30832, 31186
194 26126
271 26136
312 25572
Proposed Rules:
2 ....26146, 29078
52 ....26707, 26710, 27048, 27050, 27540, 28783, 29103, 29105, 29108, 29707, 30129, 30437
55 30849
59 26146
60 ....26146, 29710, 30141, 30160
61 30160
62 30160
70 30160
75 29108
78 29108
80 26146
81 ....26146, 26710, 27540, 30129
82 30852
85 26147
86 26146
87 26146
97 29108
118 29728
152 27059
174 30855
180 ....29843, 30855
271 26151
300 29728
600 26146
702 29078
703 29078
704 ....27060, 29078
707 29078
716 29078
717 29078
720 29078
723 29078
725 29078
790 29078
1027 26146
1030 26146
1033 26146
1036 26146
1037 26146
1039 26146
1042 26146
1043 26146
1045 26146
1048 26146
1051 26146
1054 26146
1060 26146
1065 26146
1066 26146
1068 26146
1090 26146

42 CFR
417 27704
422 27704
423 27704
447 29675
Proposed Rules:
88 27961
412 28108
413 28108
482 28108
485 28108
495 28108

45 CFR
144 27208
147 27208
153 27208
155 27208
156 27208
158 27208
Proposed Rules:
2507 25598

46 CFR
Proposed Rules:
61 30849
62 30849
520 27971

47 CFR
20 26139
27 30836
54 30108
73 30429
Proposed Rules:
10 30857
14 30442
15 29248
20 29248
22 29248
24 29248
25 29248
27 29248
30 29248

54 30161
73 29248
74 29248
76 29248
78 29248
80 29248
87 29248
90 29248
95 29248
96 29248
101 29248

48 CFR

4 25572

49 CFR

107 28779
190 28779
191 26296
192 26296
214 27530
531 25710
533 25710
536 25710
537 25710
Ch. XII 31093

Proposed Rules:

350 27981
393 26317
1146 25609
1249 27549

50 CFR

17 26141
622 ....25573, 29236, 31190
635 ....26299, 30838
648 27952
660 ....27530, 29690, 30430
665 25590

Proposed Rules:

17 ....26152, 26319, 29272
100 29061
600 30730
622 ....26178, 30730
660 27557

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List May 18, 2022

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