AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

FEDERAL REGISTER

Vol. 86 Wednesday

No. 90 May 12, 2021

Pages 25943–26148

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.federalregister.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.govinfo.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 1, 1 (March 14, 1936) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

The annual subscription price for the **Federal Register** paper edition is $860 plus postage, or $929, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $330, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 86 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:	
Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

The Federal Register Printing Savings Act of 2017 (Pub. L. 115-120) placed restrictions on distribution of official printed copies of the daily **Federal Register** to members of Congress and Federal offices. Under this Act, the Director of the Government Publishing Office may not provide printed copies of the daily **Federal Register** unless a Member or other Federal office requests a specific issue or a subscription to the print edition. For more information on how to subscribe use the following website link: *https://www.gpo.gov/frsubs.*

Printed on recycled paper.

Contents

Federal Register

Vol. 86, No. 90

Wednesday, May 12, 2021

Agency for Healthcare Research and Quality
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 26036–26039

Agricultural Marketing Service
PROPOSED RULES
Increased Assessment Rate:
Dried Prunes Produced in California, 25975–25977
National Organic Program:
Origin of Livestock, 25961–25974

Agriculture Department
See Agricultural Marketing Service
See Animal and Plant Health Inspection Service

Alcohol, Tobacco, Firearms, and Explosives Bureau
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Explosives Employee Possessor Questionnaire, 26069–26070

Animal and Plant Health Inspection Service
NOTICES
Pest Risk Analysis:
Importation of Fresh Mango Fruit from Colombia Into the United States, 25998–25999

Centers for Medicare & Medicaid Services
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Medicaid and Children's Health Insurance Program, 26042–26043
Request for Nominations:
Advisory Panel on Outreach and Education, 26039–26042

Coast Guard
RULES
Safety Zone:
Pierce County Ferry Steilacoom II, Puget Sound, WA, 25949–25951

Commerce Department
See Economic Analysis Bureau
See International Trade Administration
See National Oceanic and Atmospheric Administration
See Patent and Trademark Office

Drug Enforcement Administration
NOTICES
Bulk Manufacturer of Controlled Substances Application:
Patheon API Manufacturing, Inc., 26070–26071

Economic Analysis Bureau
NOTICES
Request for Nominations:
Federal Economic Statistics Advisory Committee, 25999–26000

Education Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Early Childhood Longitudinal Study, Kindergarten Class of 2023–24 Preschool Round Removal Change Request, 26018

Election Assistance Commission
NOTICES
Charter Renewal:
Federal Advisory Committee, 26018–26019

Energy Department
See Federal Energy Regulatory Commission

Environmental Protection Agency
RULES
Air Quality State Implementation Plans; Approvals and Promulgations:
Michigan; Part 18 and Part 19 Revisions, 25954–25956
Pennsylvania; Regulatory Updates to Nonattainment New Source Review Permitting Requirements for 2012 Fine Particulate Matter National Ambient Air Quality Standard, 25951–25953
Exemption from the Requirement of a Tolerance:
Sodium lauroyl sarcosinate, 25956–25960
PROPOSED RULES
Air Quality State Implementation Plans; Approvals and Promulgations:
Michigan; Part 18 and Part 19 Revisions, 25978
NOTICES
National Pollutant Discharge Elimination System:
2022 Issuance of General Permit for Stormwater Discharges from Construction Activities, 26023–26033
Privacy Act; Systems of Records, 26033–26035

Federal Aviation Administration
NOTICES
Intent to Rule on Request to Dispose 10.3 Acres of Land at Dillant-Hopkins Airport, Swanzey, NH, 26126–26127

Federal Communications Commission
PROPOSED RULES
Television Broadcasting Services:
Medford, Oregon, 25979–25980
Redding, CA, 25978–25979
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 26035–26036

Federal Energy Regulatory Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 26019–26020, 26022–26023
Combined Filings, 26020–26022
Complaint:
Spire Marketing Inc. v. Panhandle Eastern Pipe Line Company, LP, 26020

Federal Railroad Administration
NOTICES
Petition for Waiver of Compliance, 26127–26128

Federal Reserve System
NOTICES
Change in Bank Control:
Acquisitions of Shares of a Bank or Bank Holding Company, 26036

Fish and Wildlife Service
NOTICES
Endangered and Threatened Wildlife and Plants:
Draft Habitat Conservation Plan and Draft Categorical Exclusion for the Santa Barbara County Distinct Population Segment of the California Tiger Salamander; Orcutt Hill Resource and Solar Project, Pacific Coast Energy Company, Santa Barbara County, CA, 26063
Draft Recovery Plan for the Rufa Red Knot, 26062–26063

Food and Drug Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
State Enforcement Notifications, 26046–26047
Guidance:
COVID–19: Developing Drugs and Biological Products for Treatment or Prevention, 26050–26052
E9(R1) Statistical Principles for Clinical Trials: Addendum: Estimands and Sensitivity Analysis in Clinical Trials; International Council for Harmonisation, 26047–26048
M9 Biopharmaceutics Classification System-Based Biowaivers; International Council for Harmonisation, 26054–26056
Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management; International Council for Harmonisation, 26043–26045
Q3D(R2)—Guideline for Elemental Impurities; International Council for Harmonisation, 26052–26054
Qualified Infectious Disease Product Designation—Questions and Answers, 26045–26046
S11 Nonclinical Safety Testing in Support of Development of Pediatric Pharmaceuticals; International Council for Harmonisation, 26056–26058
S5(R3) Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals; International Council for Harmonisation, 26048–26050
Withdrawal of Approval of New Drug Applications:
Lederle Laboratories et al., 26058–26059

Health and Human Services Department
See Agency for Healthcare Research and Quality
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See National Institutes of Health
NOTICES
Meetings:
Presidential Advisory Council on Combating Antibiotic–Resistant Bacteria, 26059

Homeland Security Department
See Coast Guard

Interior Department
See Fish and Wildlife Service

International Trade Administration
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
Boltless Steel Shelving Units Prepackaged for Sale from the People's Republic of China, 26000–26001
Lightweight Thermal Paper from the People's Republic of China, 26009–26010
Determination of Sales at Less Than Fair Value:
Thermal Paper from Germany, 26001–26003
Thermal Paper from Japan, 26011–26013
Thermal Paper from Spain, 26003–26006
Thermal Paper from the Republic of Korea, 26007–26009
Quarterly Update:
Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty, 26010–26011
Request for Applications:
President's Advisory Council on Doing Business in Africa, 26006–26007

International Trade Commission
NOTICES
Complaint:
Certain Electrolyte Containing Beverages and Labeling and Packaging Thereof, 26066–26067
Investigations; Determinations, Modifications, and Rulings, etc.:
Certain Botulinum Toxin Products, Processes for Manufacturing or Relating to Same and Certain Products Containing Same; Return of Bond, 26068–26069
Certain Collapsible and Portable Furniture, 26069
Cut-to-Length Carbon Steel Plate from China, Russia, and Ukraine, 26067–26068
Foreign Censorship Part 1: Policies and Practices Affecting U.S. Businesses and Investigation No. 332–586: Foreign Censorship Part 2: Trade and Economic Effects on U.S. Businesses, 26064–26066

Justice Department
See Alcohol, Tobacco, Firearms, and Explosives Bureau
See Drug Enforcement Administration

Management and Budget Office
NOTICES
Designation of Databases for Treasury's Working System under the Do Not Pay Initiative, 26071

National Highway Traffic Safety Administration
PROPOSED RULES
Corporate Average Fuel Economy Preemption, 25980–25992
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Consolidated Vehicles' Owner's Manual Requirements for Motor Vehicles and Motor Vehicle Equipment, 26128–26133
Motorcycle Helmets (Labeling), 26136–26137
Petition for Exemption from the Federal Motor Vehicle Theft Prevention Standard:
Mazda Motor Corp., 26137–26140
Toyota Motor North America, Inc., 26133–26136
Petition for Exemption from the Federal Motor Vehicle Theft Prevention Standard:
North American Subaru, Inc., 26140–26143

National Institutes of Health
NOTICES
Meetings:
Center for Scientific Review, 26061–26062
National Cancer Institute, 26060–26061
National Center for Advancing Translational Sciences, 26060
National Institute of Mental Health, 26059–26060

National Oceanic and Atmospheric Administration
PROPOSED RULES
Atlantic Highly Migratory Species:
General Category Restricted-Fishing Days, 25992–25997
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Protocol for Access to Tissue Specimen Samples from the National Marine Mammal Tissue Bank, 26014
United States Pacific Highly Migratory Species Hook and Line Logbook, 26014–26015
Permits:
Marine Mammals and Endangered Species, 26013–26014

National Science Foundation
NOTICES
Meetings:
Committee on Equal Opportunities in Science and Engineering, 26071

Nuclear Regulatory Commission
PROPOSED RULES
American Society of Mechanical Engineers 2019–2020 Code Editions; Correction, 25977–25978
NOTICES
Meetings; Sunshine Act, 26071–26072

Patent and Trademark Office
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Trademark Post Registration, 26015–26018

Postal Regulatory Commission
NOTICES
New Postal Products, 26072–26073

Presidential Documents
PROCLAMATIONS
Special Observances:
Mother's Day (Proc. 10207), 26145–26148
National Hurricane Preparedness Week (Proc. 10205), 25943–25944
National Women's Health Week (Proc. 10206), 25945–25946
EXECUTIVE ORDERS
Committees; Establishment, Renewal, Termination, etc.:
Climate Change Support Office; Establishment (EO 14027), 25947–25948

Securities and Exchange Commission
NOTICES
Self-Regulatory Organizations; Proposed Rule Changes:
Cboe EDGA Exchange, Inc., 26113–26115
DTCC Data Repository (U.S.), LLC, 26115–26124
Financial Industry Regulatory Authority, Inc., 26084–26109
MIAX Emerald, LLC, 26111–26112
National Securities Clearing Corp., 26112–26113
New York Stock Exchange, LLC, 26110
New York Stock Exchange, LLC, NYSE American, LLC, NYSE Arca, Inc., et al., 26082–26084
NYSE Arca, Inc., 26073–26081, 26110

Susquehanna River Basin Commission
NOTICES
Grandfathering Registration, 26126
Meetings, 26126
Projects Approved:
Consumptive Uses of Water, 26124–26125

Transportation Department
See Federal Aviation Administration
See Federal Railroad Administration
See National Highway Traffic Safety Administration

Veterans Affairs Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Certification of School Attendance or Termination, 26143

Separate Parts In This Issue

Part II
Presidential Documents, 26145–26148

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

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

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.

3 CFR

Proclamations:
10205.....25943
10206.....25945
10207.....26147

Executive Orders:
14027.....25947

7 CFR

Proposed Rules:
205.....25961
993.....25975

10 CFR

Proposed Rules:
50.....25977

33 CFR
165.....25949

40 CFR
52 (2 documents) 25951, 25954
180.....25956

Proposed Rules:
52.....25978

47 CFR

Proposed Rules:
73 (2 documents) 25978, 25979

49 CFR

Proposed Rules:
531.....25980
533.....25980

50 CFR

Proposed Rules:
635.....25992

Federal Register
Vol. 86, No. 90
Wednesday, May 12, 2021

Presidential Documents

Title 3—

The President

Proclamation 10205 of May 7, 2021

National Hurricane Preparedness Week, 2021

By the President of the United States of America

A Proclamation

In 2020, the United States experienced a record year for extreme weather, with an unprecedented 30 named storms in the Atlantic Basin alone. Twelve of these storms, six of which were hurricanes, made landfall in the United States. These storms and hurricanes unleashed their devastating power on the individuals and communities in their paths. Their frequency and impact also highlight the existential threat posed to our Nation by climate change. During National Hurricane Preparedness Week, we encourage all Americans living in potentially affected areas to take precautions to ensure that they, their families, and their communities are best prepared for hurricanes, and commit to improving our resilience to climate-related catastrophes.

The costs exacted by these storms, in lives, livelihoods, and property damage, are staggering. Seven of last year's 30 named storms claimed 86 lives and caused $40 billion dollars in damage. Over the past two decades, tropical storms and hurricanes have taken over 6,000 lives in the United States and caused $853 billion in damage. These storms accounted for 60 percent of the costs of our most damaging weather events. In addition to the highly-visible damage, hurricanes also exact an unseen and long-lasting emotional toll; the trauma of a lost loved one, the sadness of losing treasured possessions, the stress of a financial setback. This is compounded for low-income communities and communities of color who are more likely to live in areas that make them vulnerable to flooding and other climate-related weather events, and less likely to have the funds to prepare for and recover from extreme weather events.

As changes in our climate lead to additional extreme weather events, we must pursue research and resilience policies that keep us safe and strengthen our resilience.

Since taking office, I have directed my Administration to put the climate crisis and the communities most vulnerable to it at the center of our domestic and foreign policy. This includes investing in weather forecasting and climate research to bolster our understanding of how our changing climate is altering the behavior of hurricanes, as well as ensuring every community has the resources to prepare for and respond to these changing storms. Although hurricanes cannot be prevented, we can predict and prepare for them.

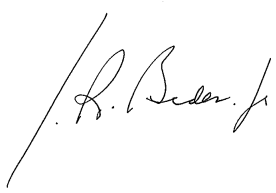
We are constantly improving our forecasts and communications with the public about the dangers posed by hurricanes. National Oceanic and Atmospheric Administration (NOAA) forecasters work around the clock and collaborate with State, local, Tribal, and territorial emergency managers and government officials to provide actionable information before, during, and after a hurricane. NOAA also collaborates with key decision makers in Federal agencies, including the Department of Homeland Security and the Federal Emergency Management Agency (FEMA). Such collaborative work ensures that communities standing in a storm's path have the information and resources they need to adequately prepare. After the storm, NOAA provides stakeholders with essential information for damage assessments and to re-open ports and coastal waterways critical to our Nation's commerce.

In addition to work being done by Federal, State, local, and Tribal governments, Americans should prepare themselves before a hurricane hits. Keep up with weather forecasts and have an evacuation kit prepared in case you ever need to relocate in advance of a hurricane. More information and preparedness plan templates are available from FEMA's ready.gov website.

Everyone has a role to play in hurricane preparedness and making us a Weather-Ready Nation. When hurricanes strike, that's how we will save lives, lessen the damage to our homes, communities, and infrastructure, and recover stronger and faster.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 9 through May 15, 2021, as National Hurricane Preparedness Week. I urge all Americans to help build our Weather-Ready Nation, so that individuals are empowered and organizations can fulfill leadership roles in their communities. I call on our Federal, State, Tribal, territorial and local government agencies to share information that will protect lives and property.

IN WITNESS WHEREOF, I have hereunto set my hand this seventh day of May, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-fifth.



[FR Doc. 2021–10128
Filed 5–11–21; 8:45 am]
Billing code 3295–F1–P

Presidential Documents

Proclamation 10206 of May 7, 2021

National Women's Health Week, 2021

By the President of the United States of America

A Proclamation

It's a simple proposition for me: women are entitled to the same rights and opportunities as men, including access to high-quality, affordable health care. National Women's Health Week is an opportunity to focus on the work we need to do as a Nation to ensure equal access to high-quality, affordable care for women, and to build a more prosperous, healthy future for all.

This starts by strengthening the Affordable Care Act, which ensures that women cannot be denied coverage for pre-existing conditions, such as pregnancy, or charged more for coverage simply because they are women. The Affordable Care Act also expanded coverage to millions of women who were previously uninsured, and made various preventive services available free of charge, including Pap smears and mammograms. In addition, it covers screening and counseling for domestic and intimate partner violence.

To cover more Americans, the Biden-Harris Administration began a special open enrollment period on healthcare.gov, so that women who are uninsured have the opportunity to sign up for coverage through August 15. And, we are committed to building on the successes of this law to make coverage more affordable. The American Rescue Plan, enacted earlier this year, will save women buying coverage on their own $50 per month on their health care premiums.

The theme of this year's National Women's Health Week is ''Ending the Pandemic and Elevating Women's Health.'' The quickest and most effective way to defeat this pandemic and restore public health is through vaccination.

My Administration is committed to advancing women's health and ensuring an equitable response to the COVID–19 pandemic. We have prioritized and increased access to the COVID–19 vaccine and expanded the criteria for eligibility to include all adults over the age of 16. We encourage women to talk to their doctors, nurses, nurse practitioners, or physician assistants about the COVID–19 vaccine.

And, it is important for women and girls to catch up on any missed vaccines or medical care from this past year. Delays in routine care—such as Pap smears, mammograms, bone density scans, stress tests, cholesterol screenings, blood pressure screenings, physical exams, general check-ups and other preventive health screenings—can cause many conditions to go undetected. As we mark National Women's Health Week, let us make sure that all women and girls, particularly those with underlying health conditions such as hypertension, diabetes, cardiovascular and respiratory conditions, and mental health needs, can prioritize their own health.

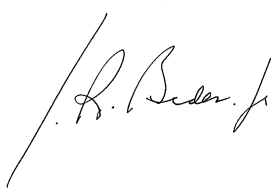
The COVID–19 pandemic has further revealed why the unique needs of women and girls must be centered in our health care system, and further brought to light the health disparities and systemic biases that women, particularly women of color, continue to face, including inequitable maternity care and access to reproductive health care.

My Administration aims to address persistent and unconscionable disparities in maternal health outcomes. Pregnancy-related mortality for Black and American Indian and Alaska Native women is two to three times higher than for white, Hispanic, and Asian American and Pacific Islander women. Ensuring that all women have equitable access to health care before, during, and after pregnancy is essential. I am committed to building a health care system that delivers equity and dignity to all women and girls. In addition, we must protect access to sexual and reproductive health care, including the broad range of family planning services.

As we strive to improve the health of our Nation, we must prioritize the health and well-being of our women and girls. During National Women's Health Week, we reaffirm our commitment to this important work.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 9 through May 15, 2021, as National Women's Health Week. During this week, I encourage all Americans to dedicate themselves to the work of improving the health of women and girls and promoting health equity for all.

IN WITNESS WHEREOF, I have hereunto set my hand this seventh day of May, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-fifth.



[FR Doc. 2021–10130
Filed 5–11–21; 8:45 am]
Billing code 3295–F1–P

Presidential Documents

Executive Order 14027 of May 7, 2021

Establishment of the Climate Change Support Office

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 202 of the Revised Statutes (22 U.S.C. 2656) and section 3161 of title 5, United States Code, it is hereby ordered as follows:

Section 1. *Establishment of the Climate Change Support Office.* (a) There is established within the Department of State, in accordance with section 3161 of title 5, United States Code, a temporary organization to be known as the Climate Change Support Office (CCSO).

(b) The CCSO shall be headed by a Director selected by the Secretary of State (Secretary). In addition to a Director, the CCSO may be staffed by persons in such numbers and with such skills as are necessary for the performance of CCSO functions.

(c) The purpose of the CCSO shall be to perform the specific project of supporting bilateral and multilateral engagement to advance the United States initiative to address the global climate crisis, led by the Department of State and in coordination with other executive departments and agencies, consistent with Executive Order 14008 of January 27, 2021 (Tackling the Climate Crisis at Home and Abroad). The CCSO shall support the Department of State, including the Special Presidential Envoy for Climate, in United States efforts to elevate and underscore the commitment my Administration will make towards addressing the global climate crisis.

(d) In carrying out its purpose as set forth in subsection 1(c) of this order, the CCSO shall:

(i) support the Department of State and other executive departments and agencies, as appropriate, in leading diplomatic engagement on climate change, exercising climate leadership in international fora, increasing international climate ambition, and ensuring that climate change is integrated into all elements of United States foreign policy-making decision processes;

(ii) support efforts that go beyond the climate work currently carried out by the Department of State across a wide range of international fora that address clean energy, aviation, shipping, the Artic, the ocean, sustainable development, and migration; and

(iii) perform such other functions related to the specific project set forth in subsection 1(c) of this order as the Secretary may assign.

(e) The CCSO shall terminate at the end of the maximum period permitted by section 3161(a)(1) of title 5, United States Code, unless sooner terminated by the Secretary.

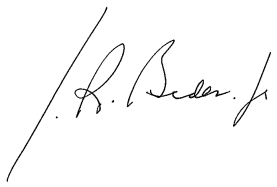
Sec. 2. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
May 7, 2021.

[FR Doc. 2021–10139
Filed 5–11–21; 8:45 am]
Billing code 3295–F1–P

Rules and Regulations

Federal Register
Vol. 86, No. 90
Wednesday, May 12, 2021

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

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

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0313]

RIN 1625–AA00

Safety Zone; Pierce County Ferry Steilacoom II, Puget Sound, WA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary moving safety zone for navigable waters within a 1,000-yard radius around the Pierce County ferry Steilacoom II. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by the on-the-water military exercise. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Puget Sound or a designated representative.

DATES: This rule is effective from 8:30 a.m. through 2:30 p.m. on May 13, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0313 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 Chief Warrant Officer William Martinez, Sector Puget Sound Waterways Management Division, U.S. Coast Guard; telephone 206–217–6051, email *SectorPugetSoundWWM@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
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. The Coast Guard was notified of the military exercise on April 7, 2021, and due to the evolving dynamic nature of the on-the-water exercise it was determined on May 4, 2021, that immediate action is needed to respond to the potential safety hazards associated with the exercise. The COTP determined this regulation is necessary to ensure the safety of the public. The Coast Guard lacks 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 this regulation is needed on May 13, 2021, less than 30 days after the Coast Guard received final details of the exercise, in order to ensure safety of the public, mariners, and exercise participants.

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 Puget Sector Sound (COTP) has determined that potential hazards associated with the on-the-water military exercise on May 13, 2021, will be a safety concern for anyone within a 1,000-yard radius of the Pierce County ferry Steilacoom II and the exercise participants. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the moving safety zone.

IV. Discussion of the Rule

This rule establishes a moving safety zone from 8:30 a.m. until 2:30 p.m. on May 13, 2021. The moving safety zone will cover all navigable waters within 1,000 yards of Pierce County ferry Steilacoom II. Part of this exercise includes the use of high speed Coast Guard and law enforcement vessel maneuvers and the use of blank fire ammunition. The duration of the zone is intended to protect mariners from the hazards associated with military training operations. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. As used in this section, a designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Puget Sound (COTP) in the enforcement of the safety zone.

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 size, location, and duration of the safety zone. Vessel traffic will be able to safely transit around this safety zone which would impact a small designated area of the Puget sound for a 6 hour period. The Coast Guard will

transmit a Safety Marine Information Broadcast to mariners via VHF–FM marine channel 16 regarding the safety zone enforcement and publish in the Local Notice to Mariners information about details of the safety zone. In addition, the rule allows mariners to seek permission to enter the zone. To seek permission to enter, contact the COTP or the COTP's representative by VHF Channel 16. 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.

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 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 moving safety zone lasting only 6 hours that will prohibit entry within 1,000 yards of Pierce County ferry Steilacoom II. It is categorically excluded from further review under paragraph L60 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

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.T13–0313 to read as follows:

§ 165.T13–0313 Safety Zone; Pierce County Ferry Steilacoom II, Puget Sound, WA.

(a) *Location.* The following area is a moving safety zone: All navigable waters within a 1,000-yard radius around the Pierce County ferry Steilacoom II.

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

(c) *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 COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF Channel 16. 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.

(d) *Enforcement period.* This section will be enforced from 8:30 a.m. to 2:30 p.m. on May 13, 2021.

Dated: May 5, 2021.

P.M. Hilbert,

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

[FR Doc. 2021–10085 Filed 5–11–21; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2020–0416; FRL–10023–38–Region 3]

Air Plan Approval; Pennsylvania; Regulatory Updates to Nonattainment New Source Review (NNSR) Permitting Requirements for 2012 Fine Particulate Matter ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) revision submitted by the Commonwealth of Pennsylvania, on March 10, 2020. This revision pertains to the Pennsylvania Department of Environmental Protection's (PADEP) amendments to 25 Pa. Code Chapters 121 (General Provisions) and 127 (Construction, Modification, Reactivation and Operation of Sources) to implement Federal nonattainment new source review (NNSR) provisions for the 2012 annual fine particulate matter ($PM_{2.5}$) national ambient air quality standard (NAAQS). EPA is approving these revisions to the Pennsylvania SIP in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on June 11, 2021.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2020–0416. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Amy Johansen, Permits Branch (3AD10), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2156. Ms. Johansen can also be reached via electronic mail at *johansen.amy@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 9, 2021 (86 FR 13511), EPA published a notice of proposed rulemaking (NPRM) for the Commonwealth of Pennsylvania. In the NPRM, EPA proposed approval of amendments to 25 Pa. Code Chapters 121 (General Provisions) and 127 (Construction, Modification, Reactivation and Operation of Sources) to implement Federal NNSR provisions for the 2012 $PM_{2.5}$ NAAQS. Specifically, the SIP revision establishes that emissions of volatile organic compounds (VOC) and ammonia are precursors to $PM_{2.5}$ for new and modified major sources emitting $PM_{2.5}$ in nonattainment areas for $PM_{2.5}$ in Pennsylvania; [1] establishes a significant impact level for $PM_{2.5}$; proposes emission offset ratios for emissions of VOC and ammonia as $PM_{2.5}$ precursors; and amends relevant definitions. The formal SIP revision was submitted by PADEP on March 10, 2020.

EPA has revised the NAAQS for $PM_{2.5}$ on multiple occasions, most recently in 2012. On December 14, 2012, the annual primary standard for $PM_{2.5}$ was lowered from 15 micrograms per meter cubed ($\mu g/m^3$) to 12 $\mu g/m^3$. See 78 FR 3087 (January 15, 2013). The existing 24-hour standards (primary and secondary) were retained at 35 $\mu g/m^3$, as was the annual secondary standard of 15 $\mu g/m^3$. Upon promulgation of the 2012 $PM_{2.5}$ NAAQS, EPA formally classified all of Delaware County and Lebanon County, Pennsylvania as moderate nonattainment for the 2012 annual $PM_{2.5}$ standard. See 80 FR 2206 (January 15, 2015).[2] For areas designated as nonattainment for one or more NAAQS, the SIP must include preconstruction permit requirements for new or modified major stationary sources of such nonattainment pollutant(s), commonly referred to as ''Nonattainment New Source Review.'' See CAA section 172(c)(5).

PADEP's SIP revision revises NNSR permit requirements for major sources of $PM_{2.5}$. Specifically, PADEP's 25 Pa. Code Chapters 121 and 127 have been amended to implement additional provisions pertaining to $PM_{2.5}$ precursors, as promulgated in EPA's rule entitled Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements (2016 Implementation Rule). 81 FR 58010 (August 24, 2016).

As required by EPA's 2016 Implementation Rule, which implements the D.C. Circuit court's January 2013 decision in *NRDC* v. *EPA,*[3] areas classified as nonattainment for any $PM_{2.5}$ NAAQS are required to comply with the parts of CAA subpart 4 section 189(e) that require the control of major sources of PM_{10} precursors (and hence under the court decision, $PM_{2.5}$ precursors) ''except where the Administrator determines that such sources do not contribute significantly to PM_{10} levels which exceed the standard in the area.'' [4] The 2016 Implementation Rule amended the definitions of (1) ''regulated NSR pollutant'' with regard to $PM_{2.5}$ precursors; (2) ''major stationary source'' with regard to major sources of direct $PM_{2.5}$ emissions and $PM_{2.5}$ precursors locating in $PM_{2.5}$ nonattainment areas classified as moderate and serious; and (3) ''significant'' with regard to emissions of direct $PM_{2.5}$ and its precursors.

II. Summary of SIP Revision and EPA Analysis

A. Summary of SIP Revision

25 Pa. Code Chapters 121 and 127 address NNSR permit requirements for major sources of $PM_{2.5}$. PADEP's SIP revision has been amended to implement additional provisions pertaining to precursors, as promulgated in EPA's final 2016 Implementation Rule.

B. EPA's Proposed Action

At proposal, EPA evaluated the revised portions 25 Pa. Code Chapters 121 and 127 to determine if the revisions meet current applicable requirements for a $PM_{2.5}$ NNSR permit program, as revised by EPA's 2016 Implementation Rule. 25 Pa. Code 121.1—(1) contains revisions to clarify that 25 Pa. Code applies to major polluting facilities that will emit $PM_{2.5}$ or its precursors in areas designated as

[1] Allegheny County, Pennsylvania sources are regulated under the Allegheny County Health Department's Article XXI, not PADEP 25 Pa. Code.

[2] EPA subsequently issued Additional Air Quality Designations and Technical Amendment to Correct Inadvertent Error in Air Quality Designations for the 2012 Primary Annual Fine Particulate Matter ($PM_{2.5}$), which impacted Delaware and Lebanon counties. 80 FR 18535, 18549 (April 7, 2015).

[3] 706 F.3d 428 (D.C. Cir. 2013).

[4] This requirement was codified in 40 CFR 51.165(a)(13). See 81 FR 58010 (August 24, 2016).

nonattainment for $PM_{2.5}$; (2) the definition of ''major facility'' has been updated to include a 70 tons per year (tpy) emissions threshold for $PM_{2.5}$ and all precursors to $PM_{2.5}$ in a serious nonattainment area; (3) the definition of ''regulated NSR pollutant'' has been updated to include sulfur dioxide (SO_2), VOC, and ammonia in all $PM_{2.5}$ nonattainment areas; (4) revisions were made to the definition of ''significant'' to include emission rates for $PM_{2.5}$ at 10 tpy and emission rates for $PM_{2.5}$ precursors as follows: 40 tpy of SO_2, 40 tpy of VOC, 40 tpy of ammonia, and 40 tpy of nitrogen oxides (NO_X). Section 127.202(a)—Effective date, was amended to establish that emission of VOC and ammonia will be regulated as $PM_{2.5}$ precursors after the effective date of the adoption of the proposed rulemaking. EPA proposed to find these revisions approvable and consistent with applicable requirements for a $PM_{2.5}$ NNSR permit program, as revised by the 2016 Implementation Rule.

Section 127.203(a)—Facilities subject to special permit requirements, was amended to add ''significant air quality impact'' levels for $PM_{2.5}$ at 0.2μg/m^3 for the annual averaging time and 1.2 μg/m^3 for the 24-hour averaging time. PADEP's annual averaging time is more stringent than what EPA requires in 40 CFR 51.165(b)(2), therefore, EPA finds this more stringent requirement approvable. Section 127.210(a)—Offset ratios, establishes offset ratios for VOC and ammonia at a ratio of 1:1 for flue emissions and fugitive emissions. EPA finds the addition of offset ratios to be approvable.

Other specific provisions of this SIP revision and the rationale for EPA's proposed action are explained in the NPRM, and its associated technical support document (TSD), and will not be restated here. No public comments were received on the NPRM.

III. Final Action

EPA is approving amendments to 25 Pa. Code Chapters 121 (General Provisions) and 127 (Construction, Modification, Reactivation and Operation of Sources), as a revision to the Pennsylvania SIP.

IV. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of certain subsections of 25 Pa. Code Chapters 121 (General Provisions) and 127, (Construction, Modification, Reactivation and Operation of Sources), as described in the amendments to 40 CFR part 52 sets forth below.

EPA has made, and will continue to make, these materials generally available through *https://www.regulations.gov* and at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rule of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[5]

V. Statutory and Executive Order Reviews

A. General Requirements

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 12, 2021. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action approving NNSR requirements under the 2012 $PM_{2.5}$ NAAQS may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

[5] 62 FR 27968 (May 22, 1997).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: May 6, 2021.

Diana Esher,

Acting Regional Administrator, Region III.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart NN—Pennsylvania

■ 2. In § 52.2020, the table in paragraph (c)(1) is amended by:

■ a. Under ''Chapter 121—General Provisions'' by adding a fourth entry for ''Section 121.1'' after a third existing entry for ''Section 121.1'';

■ b. Under ''Chapter 127—Construction, Modification, Reactivation, and Operation of Sources, Subchapter E'' by revising the entries for ''Section 127.202'', ''Section 127.203a'', and ''Section 127.210''.

The addition and revisions read as follows:

§ 52.2020 Identification of plan.

* * * * *

(c) * * *

(1) * * *

State citation	Title/subject	State effective date	EPA approval date	Additional explanation/§ 52.2063 citation
Title 25—Environmental Protection Article III—Air Resources				
*	*	*	*	* * *
Chapter 121—General Provisions				
*	*	*	*	* * *
Section 121.1	Definitions	12/21/19	5/12/21, [insert **Federal Register** citation].	Revised definitions for ''major facility,'' ''regulated NSR pollutant,'' and ''significant'' to address 2016 $PM_{2.5}$ Implementation Rule requirements.
*	*	*	*	* * *
Chapter 127—Construction, Modification, Reactivation, and Operation of Sources				
*	*	*	*	* * *
Subchapter E—New Source Review				
*	*	*	*	* * *
Section 127.202	Effective date	12/21/19	5/12/21, [insert **Federal Register** citation].	Revised to include VOC and ammonia as $PM_{2.5}$ precursors. Previous approval was July 13, 2012. Docket No. EPA–R03–OAR–2011–0924.
*	*	*	*	* * *
Section 127.203a ...	Applicability determination.	12/21/19	5/12/21, [insert **Federal Register** citation].	Revised to include annual and 24-hour levels for ''significant air quality impacts for $PM_{2.5}$.'' Previous approval was July 13, 2012. Docket No. EPA–R03–OAR–2011–0924.
*	*	*	*	* * *
Section 127.210	Offset ratios	12/21/19	5/12/21, [insert **Federal Register** citation].	Revised to include $PM_{2.5}$ offset ratios for both VOC and ammonia. Previous approval was July 13, 2012. Docket No. EPA–R03–OAR–2011–0924.
*	*	*	*	* * *

* * * * *

[FR Doc. 2021–10041 Filed 5–11–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2020–0412; FRL–10023–86–Region 5]

Air Plan Approval; Michigan; Part 18 and Part 19 Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving Michigan Department of Environment, Great Lakes, and Energy (EGLE) promulgated revisions to its Part 18 Prevention of Significant Deterioration of Air Quality rule and the Part 19 New Source Review for Major Sources Impacting Nonattainment Areas rule. The revisions made to Part 18 and Part 19 were adopted to ensure consistency with Federal rule language and other parts of the Michigan air quality rules. The rule changes are administrative and are intended to provide clarity to the already approved rule language.

DATES: This direct final rule is effective July 12, 2021, unless EPA receives adverse comments by June 11, 2021. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2020–0412 at *http://www.regulations.gov* or via email to *damico.genevieve@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically 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, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: YeChan Lim, Environmental Engineer, Air Permits Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–7259, *lim.yechan@epa.gov.* The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

I. What action is EPA taking?

On August 5, 2020, EGLE submitted a revision to its Michigan State Implementation Plan (SIP). The changes are administrative and involve wording changes to ensure consistency across the Michigan Part 18 and 19 rules, updates to make the Michigan rules consistent with Federal requirements, transfer of adoptions by reference, and corrections to grammar and typographical errors.

EPA is approving into the Michigan SIP revisions to Michigan air pollution control rules Part 18, Prevention of Significant Deterioration of Air Quality. Specifically, we are approving revisions to R 336.2801 ''Definitions'', R 336.2802 ''Applicability'', R 336.2809 ''Exemptions'', R 336.2810 ''Control technology review'', R 336.2813 ''Air quality analysis'', R 336.2816 ''Sources impacting federal class I areas; additional requirements'', and R 336.2823 ''Actuals plantwide applicability limits (PALs)''. These revisions were made to ensure consistency with Federal rule language and other parts of the Michigan air quality rules.

EPA is also approving into the Michigan SIP revisions to Part 19, New Source Review for Major Sources Impacting Nonattainment Areas. Specifically, we are approving revisions to R 336.2901 ''Definitions'', R 336.2902 ''Applicability'', R 336.2903 ''Additional permit requirements for sources impacting nonattainment areas'', R 336.2907 ''Actuals plant wide applicability limits or PALs'', and R 336.2908 ''Conditions for approval of a major new source review permit in a nonattainment area''. Part 19 was missing definitions that were in the corresponding Federal regulations. The R 336.2901 revisions provided definitions for the phrases ''Functionally equivalent component'' and ''Process Unit'', along with revisions to the definition ''Net emissions increase''. Additionally, portions of R 336.2802 and R 336.2902 were based on identical Federal language, and revisions were made to ensure consistency in rule interpretation across both of these rule parts and with Federal regulations. These revisions were made to ensure consistency with Federal rule language and other parts of the Michigan air quality rules. Finally, EPA is approving into the Michigan SIP, the removal of R 336.2901a from Part 19. R 336.2901a, the adoption by reference, was transferred to Part 9 of Michigan's administrative rules. EGLE also requested the removal of R 336.2801a from Part 18 of the SIP however, R 336.2801a was never approved into the SIP. Therefore, EPA will not be acting on that request.

We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the state plan if relevant adverse written comments are filed. This rule will be effective July 12, 2021 without further notice unless we receive relevant adverse written comments by June 11, 2021. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. If we do not receive any comments, this action will be effective July 12, 2021.

II. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR

51.5, EPA is finalizing the incorporation by reference of the Michigan Regulations described in the amendments to 40 CFR part 52 set forth below. EPA has made, and will continue to make, these documents generally available through *www.regulations.gov* and at the EPA Region 5 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the Clean Air Act as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[1]

Also in this document, as described in the amendments to 40 CFR part 52 set forth below, EPA is removing provisions of the EPA-Approved Michigan Regulations and Statutes from the Michigan SIP, which is incorporated by reference in accordance with the requirements of 1 CFR part 51.

III. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Clean Air Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 12, 2021. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2) of the Clean Air Act.)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: May 7, 2021.

Cheryl Newton,

Acting Regional Administrator, Region 5.

For the reasons stated in the preamble, EPA amends title 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. In § 52.1170, the table in paragraph (c) is amended:

■ a. Under ''Part 18. Prevention of Significant Deterioration of Air Quality'' by revising the entries for R 336.2801, R 336.2802, R 336.2809, R 336.2810, R 336.2813, R 336.2816, and R 336.2823; and

■ b. Under ''Part 19. New Source Review for Major Sources Impacting Nonattainment Areas'':

■ i. By revising the entries for R 336.2901, R 336.2902, R 336.2903, R 336.2907, and R 336.2908; and

■ ii. By removing without replacement the entry for R 336.2901a.

The revisions read as follows:

§ 52.1170 Identification of plan.

* * * * *

(c) * * *

[1] 62 FR 27968 (May 22, 1997).

EPA-APPROVED MICHIGAN REGULATIONS

Michigan citation	Title	State effective date	EPA approval date	Comments
*	*	*	*	*
Part 18. Prevention of Significant Deterioration of Air Quality				
R 336.2801	Definitions	01/02/2019	May 12, 2021, [INSERT **Federal Register** CITATION].	
R 336.2802	Applicability	01/02/2019	[May 12, 2021, [INSERT **Federal Register** CITATION].	
*	*	*	*	*
R 336.2809	Exemptions	01/02/2019	May 12, 2021, [INSERT **Federal Register** CITATION].	
R 336.2810	Control technology review	01/02/2019	May 12, 2021, [INSERT **Federal Register** CITATION].	
*	*	*	*	*
R 336.2813	Air quality analysis	01/02/2019	May 12, 2021, [INSERT **Federal Register** CITATION].	
*	*	*	*	*
R 336.2816	Sources impacting federal class I areas; additional requirements.	01/02/2019	May 12, 2021, [INSERT **Federal Register** CITATION].	
*	*	*	*	*
R 336.2823	Actuals plantwide applicability limits (PALs).	01/02/2019	May 12, 2021, [INSERT **Federal Register** CITATION].	
Part 19. New Source Review for Major Sources Impacting Nonattainment Areas				
R 336.2901	Definitions	01/02/2019	May 12, 2021, [INSERT **Federal Register** CITATION].	
R 336.2902	Applicability	01/02/2019	May 12, 2021, [INSERT **Federal Register** CITATION].	
R 336.2903	Additional permit requirements for sources impacting nonattainment areas.	01/02/2019	May 12, 2021, [INSERT **Federal Register** CITATION].	
R 336.2907	Actuals plant wide applicability limits or PALs.	01/02/2019	May 12, 2021, [INSERT **Federal Register** CITATION].	
R 336.2908	Conditions for approval of a major new source review permit in a nonattainment area.	01/02/2019	May 12, 2021, [INSERT **Federal Register** CITATION].	
*	*	*	*	*

* * * * *

[FR Doc. 2021–10044 Filed 5–11–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0451; FRL–10022–72]

Sodium lauroyl sarcosinate; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of sodium lauroyl sarcosinate when used as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at an end-use concentration not to exceed 10,000 parts per million (ppm). Clorox Services Company representing Clorox Professional Products Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of sodium lauroyl sarcosinate when used in accordance with this exemption.

DATES: This regulation is effective May 12, 2021. Objections and requests for hearings must be received on or before July 12, 2021, 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–2020–0451, is available at *http://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 is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; 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 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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–2020–0451 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 12, 2021. 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–2020–0451, by one of the following methods:

- *Federal eRulemaking Portal: http://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 *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of September 30, 2020 (85 FR 61681) (FRL–10014–74), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11391) by Clorox Services Company representing Clorox Professional Products Company, P.O. Box 493, Pleasanton, CA 94566–0803. The petition requested that 40 CFR 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of sodium lauroyl sarcosinate (CAS Reg. No. 137–16–6) when used as an inert ingredient at an end-use concentration not to exceed 10,000 ppm in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. That document referenced a summary of the petition prepared by Clorox Services Company, the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that EPA has determined 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 an exemption 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.''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the

inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), 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 to sodium lauroyl sarcosinate, including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with sodium lauroyl sarcosinate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by sodium lauroyl sarcosinate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Sodium lauroyl sarcosinate is metabolized to the fatty acid lauric acid and the amino acid sarcosine, both of which are found naturally in food. Sodium lauroyl sarcosinate has low acute oral toxicity, and results on a surrogate chemical showed low dermal toxicity. Two acute inhalation studies in rats showed varying LC_{50} values (lethal concentration for 50% of the animals), with one study reporting the LC_{50} to be between 0.05–0.5 mg/L and the other indicating a LC_{50} of 1 to 5 mg/L. These studies indicate that sodium lauroyl sarcosinate is potentially toxic if inhaled. However, inhalation exposure to sodium lauroyl sarcosinate is not likely because it is unlikely that sodium lauroyl sarcosinate will volatilize based on its physical/chemical properties (*e.g.* vapor pressure and Henry's Law Constant). Sodium lauroyl sarcosinate caused minimal eye irritation, did not cause skin irritation, and was not a skin sensitizer.

Repeat dose oral toxicity testing in rats include a 90-day, 6-month, and 2-year study. In addition, a developmental toxicity test was conducted. High repeated exposures to sodium lauroyl sarcosinate in the diet resulted in minor irritation to the stomach in studies up to 2 years. This effect was not seen as an adverse effect of treatment and therefore, the NOAEL for the 6-month and 2-year studies were 1,000 mg/kg/day, the highest dose tested. When the test substance was administered by gavage, the effects were more severe and include, in addition to increasing thickness in the stomach wall, a yellow discoloration of non-glandular gastric mucosa, more severe squamous cell hyperplasia, hyperkeratosis/parakeratosis, inflammation and edema of the non-glandular gastric mucosa. Systemic effects of sodium lauroyl sarcosinate have not been observed in animal studies.

Sodium lauroyl sarcosine tested negative for genotoxic effects in various studies. Similarly, there was no evidence of carcinogenicity or neuropathological changes or effects reported in any of the studies. The agency does not believe sodium lauroyl sarcosine is carcinogenic or neurotoxic.

B. Toxicological Points of Departure/Levels of Concern

The local effects seen in the stomach in the 90-day and developmental studies are the result of gavage dosing and are not relevant for end point selection for the purposes of assessing this chemical as an inert ingredient in pesticide formulations. Therefore, no toxicological significant endpoint of concern for sodium lauroyl sarcosinate has been identified in the database.

C. Exposure Assessment

1. *Dietary exposure from food, feed uses, and drinking water.* In evaluating dietary exposure to sodium lauroyl sarcosinate, EPA considered exposure under the proposed exemption from the requirement of a tolerance. Sodium lauroyl sarcosinate is currently exempt from the requirement of a tolerance under 40 CFR 180.1207 for use as an inert ingredient (surfactant) at levels not to exceed 10% in pesticide formulations containing glyphosate. Dietary exposure to sodium lauroyl sarcosinate may occur from eating foods treated with pesticide formulations containing this inert ingredient, from eating foods that come in contact with surfaces treated with pesticide formulations containing the inert ingredient, and drinking water containing runoff from soils containing the treated crops. In addition, sodium lauroyl sarcosinate is used as an additive in food packaging. However, no toxicological endpoint of concern was identified for sodium lauroyl sarcosinate and therefore, a quantitative assessment of dietary exposure is not necessary.

2. *Non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Residential exposure to sodium lauroyl sarcosinate may occur based on its use as an inert ingredient in pesticide formulations registered for residential uses. Additional non-dietary exposure may occur from use of sodium lauroyl sarcosinate in household products and cosmetics. However, no toxicological endpoint of concern was identified for sodium lauroyl sarcosinate and therefore a quantitative residential exposure assessment for sodium lauroyl sarcosinate was not conducted.

3. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found sodium lauroyl sarcosinate to share a common mechanism of toxicity with any other substances, and sodium lauroyl sarcosinate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has assumed that sodium lauroyl sarcosinate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

Section 408(b)(2)(C) of the FFDCA requires EPA to retain an additional tenfold margin of safety in the case of threshold effects 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. As noted in Unit IV.B., there is no indication of threshold

effects being caused by sodium lauroyl sarcosinate. Therefore, this requirement does not apply to the present analysis. Moreover, due to the lack of any toxicological endpoints of concern, EPA conducted a qualitative assessment of magnesium sulfate, which does not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on sodium lauroyl sarcosinate, EPA has determined that there is a reasonable certainty that no harm to the general population or any population subgroup, including infants and children, will result from aggregate exposure to sodium lauroyl sarcosinate. Therefore, the establishment of an exemption from the requirement of a tolerance under 40 CFR 180.940(a) for residues of sodium lauroyl sarcosinate when used as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at a maximum end-use concentration of 10,000 ppm is safe under FFDCA section 408.

V. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for sodium lauroyl sarcosinate (CAS Reg. No. 137–16–6) when used as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at an end-use concentration not to exceed 10,000 ppm.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance 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 exemption 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).

VIII. 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 4, 2021.

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 § 180.940, in paragraph (a), add alphabetically the inert ingredient ''Sodium lauroyl sarcosinate'' to table 180.940(a) to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

TABLE 180.940(a)

Pesticide chemical	CAS reg. No.	Limits
* *	*	* * * *
Sodium lauroyl sarcosinate	137–16–6	When ready for use, the end-use concentration is not to exceed 10,000 ppm.
* *	*	* * * *

* * * * *

[FR Doc. 2021–10000 Filed 5–11–21; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 86, No. 90
Wednesday, May 12, 2021

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 AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS–NOP–11–0009; NOP–21–04PR]

RIN 0581–AD89

National Organic Program; Origin of Livestock; Reopening of Comment Period

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) is reopening the comment period on our April 28, 2015, proposed rule to amend the origin of livestock requirements for dairy animals under the USDA organic regulations. We are reopening the proposed rule's comment period for 60 days to give all interested parties an opportunity to comment on whether AMS should prohibit the movement of transitioned cows in organic dairy production as part of the final rule. Comments previously submitted need not be resubmitted, as they are already incorporated into the public record and will be fully considered in any future final rule.

DATES: For the proposed rule published on April 28, 2015 (80 FR 23455), send comments on or before July 12, 2021.

ADDRESSES: You may send comments on the proposed rule to the Federal eRulemaking Portal at *https://www.regulations.gov/*. You can access the proposed rule and instructions for submitting public comments by searching for document number, AMS–NOP–11–0009. Comments may also be sent to Jennifer Tucker, Deputy Administrator, National Organic Program, USDA–AMS–NOP, 1400 Independence Ave. SW, Room 2642–S, Ag Stop 0268, Washington, DC 20250–0268.

Instructions: All comments received must include the docket number AMS–NOP–11–0009; NOP–21–04PR, and/or Regulatory Information Number (RIN) 0581–AD89 for this rulemaking. You should clearly indicate the topic and section number of this proposed rule to which your comment refers, state your position(s), offer any recommended language change(s), and include relevant information and data to support your position(s) (*e.g.,* scientific, environmental, manufacturing, industry, or industry impact information, etc.). All comments and relevant background documents posted to *https://www.regulations.gov* will include any personal information provided.

FOR FURTHER INFORMATION CONTACT: Jennifer Tucker, Deputy Administrator, National Organic Program, USDA–AMS–NOP, 1400 Independence Ave. SW, Room 2642–S, Stop 0268, Washington, DC 20250–0268. (202) 260–8077

SUPPLEMENTARY INFORMATION: On April 28, 2015, AMS (''we'') published in the **Federal Register** (80 FR 23455) a proposed rule to clarify requirements for organic dairy farms under the USDA organic regulations. The proposed rule would add requirements about transitioning dairy animals to organic production. Please refer to the proposed rule for information about AMS' proposed changes, rationale, and analysis.

AMS received over 1,500 public comments on the proposed rule. On October 1, 2019, we reopened the comment period and received approximately 750 comments. These comments may be viewed at *https://www.regulations.gov* under docket number AMS–NOP–11–0009. We are again reopening the comment period to solicit views on two additional issues on the movement of the transitioned animals and on the updated economic analysis of the proposed rule.

I. Movement of Transitioned Animals and Regulatory Framework

Origin of livestock in organic regulations refers to the requirements for continuous organic management of animals that produce organic meat or dairy products. In the 2015 proposed rule, AMS sought comment on a proposal to amend those requirements for dairy animals. The purpose of the proposed rule is to ensure that the origin of livestock provisions for organic dairy animals are consistently applied by all certifying agents. The proposed rule would require that organic milk and milk products must be from animals that have been under continuous organic management from the last third of gestation onward, with a limited exception for newly certified organic dairy producers. Those producers have the opportunity to transition non-organic livestock that has been under continuous organic management for twelve months into organic production. Once transitioned, the proposed rule would not distinguish between transitioned livestock and those that were under continuous organic management from the last third of gestation onward. AMS received numerous comments that advocated for different approaches that were not part of the proposed rule. AMS is issuing this notice to request public input on those different approaches and to provide an updated economic analysis.

First, in the 2015 proposed rule, we declined to limit the movement of transitioned cows because we ''believe that some movement or inter-farm sales of transitioned animals is reasonable and expected.'' 80 FR 23463. Several commenters disagreed with this approach, and recommended that we limit the movement of transitioned animals to prevent organic producers or operations from continually transitioning animals and/or continually sourcing off-farm transitioned animals. Based on these comments, we are reopening the comment period to solicit views on whether the final rule should prohibit organic dairy operations from acquiring transitioned animals to expand or replace animals to produce organic milk.

Second, we are also seeking comment on whether the final rule should use the term ''operation'' to describe the regulated entity. While the proposed rule used ''producer,'' several commenters noted that the term ''producer'' can be interpreted in different ways, and inconsistent interpretations may lead to inconsistent application of the organic regulations. Some certifier commenters stated that it would be simpler to verify an operation's eligibility (as opposed to a producer's eligibility) to transition animals. Additionally, the use of

''operations'' would align the proposal with the rest of the USDA organic regulations and the existing framework for certification and oversight.

If these provisions are implemented, existing certified dairy operations that purchase animals, individually or as an entire herd, would not be allowed to purchase any transitioned animals for organic milk production beginning on the compliance date. They would be able to purchase and sell only livestock that had been under continuous organic management from the last third of gestation. New operations would have only one opportunity to transition in non-organic animals into the operations. Those transitioned animals could then be sold to other operations, but only as non-organic. Once sold, those animals would not be eligible to produce organic milk.

In addition to comments on the provisions above, AMS is interested in comments on the following topics and options:

1. Implementation timeframe. AMS had proposed that all requirements be implemented upon the effective date of a final rule, with an exception for any transition that was already approved by a certifying agent. AMS requests comments about whether an implementation timeframe is necessary for organic dairies to comply. If one is needed, AMS requests comments on how long this implementation period should be and why.

2. Accuracy of the estimates in the Regulatory Impact Analysis (RIA)/ Regulatory Flexibility Analysis. The cost estimates presented in this notice are based on USDA and industry data. AMS requests feedback on the assumptions related to costs and benefits, with supporting information (data and sources) where available.

3. Exceptions to the one-time allowance requirement. AMS has not proposed exceptions to the one-time transition requirement, but the current regulations permit temporary variances in some scenarios (§ 205.290) and allow for re-transition following Federal or State emergency treatments (§ 205.672). AMS seeks comments on whether the rule should include any additional exceptions to the one-time transition requirement for scenarios where the current regulations would not apply, and if so, what scenario(s) would warrant an exception.

II. Regulatory Impact Analysis/ Regulatory Flexibility Analysis

Because the Regulatory Impact Analysis and the Regulatory Flexibility Analysis for the proposed rule were completed in 2015, we decided to update those analyses with more current information. We have updated the analyses to reflect more current information about the dairy market, including the number of certified organic operations and the number of organic dairy animals. This updated information revises the estimated costs of the proposed rule ($488,000–$1,462,500) compared to the estimated costs ($288,000–$935,000) in our analysis published in 2015. The analysis below also includes updated information on the distribution of dairy farms, dairy farm practices, and the market for dairy products. We also discuss public comments on those prior regulatory analyses.

Need for the Rule

AMS determined that the USDA organic regulations for sourcing dairy animals and managing breeder stock require additional specificity to ensure organic dairy operations meet a consistent standard. Interpretations of these regulations have differed between certifying agents, and the different interpretations have led to widely divergent practices by organic dairy operations for sourcing replacement dairy animals. AMS proposes revising the regulations to ensure the USDA organic regulations are administered and enforced in a clear, uniform, and equitable manner, and to address inconsistencies determined in the 2013 USDA Office of Inspector General (OIG) Audit.[1] Furthermore, AMS expects that increased clarity will support trust in the USDA organic seal by assuring consumers that organic dairy products meet a consistent standard, a stated purpose of the Organic Foods Production Act (OFPA) of 1990 (7 U.S.C. 6501).

In a 2006 final rule related to this issue (June 7, 2006; 71 FR 32803), AMS recognized that the regulations allowed different methods for replacing organic dairy animals depending on how the producer transitioned to organic production. AMS further stated that, given the almost 13,000 comments on the 2006 proposed rule (71 FR 32804), the issue was a significant concern of the organic community, including organic dairy producers, certifying agents, trade organizations, and consumers.

The July 2013 OIG audit also identified a need for this rulemaking, and AMS concurred with this finding. The OIG audit of organic milk operations found that the interpretation and implementation of the origin of livestock requirements differed across producers and certifying agents. As a result, organic milk producers may have faced materially different organic production requirements based on their particular certifier's interpretation of the National Organic Program's (NOP) origin of livestock requirements. AMS agrees with OIG's recommendation that the regulations should be revised to clarify the origin of livestock requirements and ensure consistent application of the requirements by certifying agents.

As described at the beginning of this **SUPPLEMENTARY INFORMATION** section, AMS published in 2015 a proposed rule to revise the origin of livestock regulations. The public comments received on the proposed rule in 2015 and during the reopened comment period in 2019 indicate there remains a need for rulemaking in this area.

Of the comments received by AMS on the 2015 proposed rule, a large number were submitted by producers and consumers of organic dairy products and groups representing producers and consumers. These commenters generally expressed a desire for AMS to establish and enforce clearer rules for organic dairy production. They expressed that organic dairies should raise animals organically from birth and not be allowed to cycle animals in and out of organic production (*i.e.,* by continually transitioning animals).

NOP's experience is that because organic products cannot be readily distinguished from nonorganic products based on sight inspection, buyers rely on process verification methods to ensure that organic claims are true. Within the economics literature, organic food products are ''credence goods,'' or goods with characteristics that are valuable but are difficult to verify, both before and after purchase.[2] [3] [4] Foods certified under USDA's NOP, including milk, have a common standard that specifies production practices, such as dairy herd pasture requirements, permitted feeds, and permitted use of antibiotics and hormones, that cannot

[1] The July 2013 OIG audit report on organic milk operations may be accessed at the following website: *http://www.usda.gov/oig/webdocs/01601-0002-32.pdf.*

[2] Caswell, Julie A. and Eliza M. Mojduszka. 1996. ''Using Informational Labeling to Influence the Market for Quality in Food Products.'' American Journal of Agricultural Economics. Vol. 78, No. 5: 1248–1253.

[3] Zorn, Alexander, Christian Lippert, and Stephan Dabbert. 2009. ''Economic Concepts of Organic Certification.'' Deliverable 5 of the EU FP7 CERTCOST Project: Economic Analysis of Certification Systems in Organic Food and Farming.

[4] Michael Darby and Edi Karni, ''Free Competition and the Optimal Amount of Fraud'' *Journal of Law and Economics* 16(1973)1:67–88.

be independently verified by consumers.

When producing goods with credence characteristics, producers face a moral hazard problem stemming from their incentive to forego taking costly actions or investments associated with the label claim if handlers or consumers have no way of verifying the production process (*i.e.,* asymmetric information). In providing guidance to Federal agencies undertaking rulemaking, OMB Circular A–4 cites asymmetric information as a source of market failure and as a potential justification for regulation. Lassoued and Hobbs (2015) further emphasize the role of trust in the institutions and brands that verify credence good attributes as being essential for developing the consumer confidence that drives brand loyalty.[5]

AMS developed the 2015 proposed rule in the context of maintaining trust in the NOP label, as it pertains specifically to organic dairy farms and to organic farms and organic handlers/processors generally. AMS anticipates that rulemaking on this topic will support both producer and consumer confidence in the organic label by reducing major inconsistencies in production practices across organic dairies.

Baseline

A final rule would specify the conditions under which operations can transition non-organic animals to organic for the purpose of milk production. Current dairy production and husbandry practices provide important context for the baseline and cost analysis. For a general description of replacement animal production, see ''Overview of Organic Dairy Production'' in the 2015 proposed rule (80 FR 23468).

The baseline presented below focuses on production practices of bovine dairy farms maintaining cows and heifers and does not include quantitative estimates for non-bovine dairy farms that maintain sheep and goats. AMS does not expect the rule would have a substantial economic impact on those specific sub-sectors for the following reasons: Goat does and sheep ewes are able to produce milk earlier than cows, so the potential cost-savings for non-bovine dairy farms to continually source transitioned animals (vs. animals under organic management from the last third of gestation) is small compared to that for bovine dairy farms. For this reason, the practice of continually adding transitioned animals to organic non-bovine herds is likely less prevalent than with organic bovine herds. These operations also make up a relatively small portion of the organic dairy industry. The Organic Integrity Database [6] of certified organic operations includes 56 dairy goat operations and 5 dairy sheep operations.

AMS used multiple data sources to describe the baseline and build quantitative estimates. The first source is the Agricultural Resource Management Survey (ARMS), which is maintained by USDA's Economic Research Service (ERS) and includes questions about dairy farm cattle purchases, restocking rates, and organic status.[7] In 2016, ERS conducted a supplemental ARMS that focused on organic dairy operations. AMS worked with ERS to analyze recent ARMS data and develop an estimation of organic dairy production practices and costs for this rule.

Other sources of data are the National Agricultural Statistics Service's (NASS) 2016 Certified Organic Production Survey and 2017 Census of Agriculture,[8] which include State-level data on production, herd sizes, output, and sales for organic and non-organic crops and livestock. Additionally, we used the Organic Trade Association's (OTA) 2019 Organic Industry Survey, conducted by the Nutrition Business Journal, to summarize market information and trends within the organic industry.[9] Also, AMS requested an organic dairy farm special tabulation from the National Animal Health Monitoring System (NAHMS) Dairy 2014 report collected by USDA's Animal and Plant Health Inspection Service.[10]

A final source of data is the NOP list of all certified operations included in the Organic Integrity Database. In January of each calendar year, every USDA-accredited certifying agent is required to submit an annual list of the operations it certifies to NOP (7 CFR 205.501(a)(15)(ii)). NOP consolidates this information into a public, searchable online database.[11] AMS used information from this database to cross-check NASS data on the number of organic dairy operations.

The Organic Dairy Market—Sales and Number of Operations

According to the OTA Industry Survey, U.S. organic food, fiber, and agricultural product sales were over $55.0 billion in 2019, up 5 percent from 2019.[12] Organic dairy and eggs is the third largest sector in organic retail food sales (13 percent), after fruits and vegetables (36 percent) and beverages (14 percent). Sales of organic dairy products, including milk, cream, yogurt, cheese, butter, cottage cheese, sour cream, and ice cream, reached almost $5.8 billion in 2019. Table 1 shows the organic dairy market characteristics by subcategory. In 2019, organic dairy saw total sales growth of 2 percent, with the fluid milk growing 3 percent, yogurt growing 1 percent and cheese falling 1 percent.

TABLE 1—ORGANIC DAIRY MARKET—RETAIL SALES BY SUBCATEGORY

Subcategory	2019 Sales ($ M)	2019 Growth	Percent of organic dairy sales [a]	Avg. markup [b] (%)	Organic markup [c] ($ M)
Milk/Cream	$3,394	2.9	58.8	51	$1,146
Yogurt [d]	1,260	0.5	21.8	10	115
Cheese [e]	572	−1.4	9.9	75	245
Butter/Cottage Cheese/Sour Cream [d]	425	0.3	7.4	76	184

[5] Lassoued, R. and J.E. Hobbs (2015) ''Consumer Confidence in Credence Attributes: The Role of Brand Trust'' *Food Policy* 52:99–107.

[6] Certifying agents are required to send information on certified operations to AMS annually. Current and historical data may be accessed through the Organic Integrity Database at the following link: *https://organic.ams.usda.gov/Integrity/*. Accessed 11/21/2019.

[7] The ERS ARMS survey information may be found at the following link: *http://www.ers.usda.gov/data-products/arms-farm-financial-and-crop-production-practices.aspx*.

[8] The USDA NASS surveys may be found at the following link: *https://www.nass.usda.gov/Surveys/Guide_to_NASS_Surveys/Organic_Production/*.

[9] OTA/Nutrition Business Journal, 2019 Organic Industry Survey. Nutrition Business Journal conducted a survey between January 1 and April 25, 2019, to obtain information for their estimates. Over 200 organic firms responded to the survey. Available online at *https://ota.com/resources*.

[10] The 2014 Dairy NAAHMS report may be found at the following link: *http://go.usa.gov/xKfEh*.

[11] Certifying agents are required to send information on certified operations yearly. Current and historical data may be accessed through the Organic Integrity Database at the following link: *https://organic.ams.usda.gov/Integrity/*.

[12] Organic Trade Association (OTA)/Nutrition Business Journal, 2020 Organic Industry Survey (pp. 4, 80).

TABLE 1—ORGANIC DAIRY MARKET—RETAIL SALES BY SUBCATEGORY—Continued

Subcategory	2019 Sales ($ M)	2019 Growth	Percent of organic dairy sales [a]	Avg. markup [b] (%)	Organic markup [c] ($ M)
Ice Cream	118	1.3	2.0	100	118
Total	5,769	1.7	100.0	47	1,808

[a] The Organic Trade Association's 2019 Organic Industry Survey (p. 80) included eggs as a subcategory for its summary on organic dairy sales, but we have excluded the data on eggs from this table.

[b] USDA's AMS weekly reported prices in the 2020 weekly dairy retail report based on the first weekly report in January, April, July, and October. These reports are available at: *https://www.ams.usda.gov/market-news/dairy.* Average prices of product categories are averages across the four periods weighted by store counts. Markups are calculated as the: ((Organic Price − Conventional Price)/Conventional Price).

[c] The dollar value of the organic markup for each category is: (Organic Sales × Markup)/(1+Markup).

[d] The yogurt and butter, sour cream and cottage cheese markups are respectively the average of the markups of four yogurt products and butter, sour cream and cottage cheese products, weighted by counts of stores advertising organic products. Cheese markups are for natural varieties in 8 oz. blocks.

Table 1 also includes markups in the prices of dairy products marketed as organic versus conventional (or ''nonorganic'') products. For dairy products, the average organic markup was 47 percent and totaled $1.8 billion in value.[13] In market equilibrium, this markup reflects both the higher costs of organic production and the value consumers place on organically labeled products and their various underlying attributes. While AMS does not have estimates of the specific values of each attribute, the agency assumes that adjustments to the organic production standards that would reduce production costs must be simultaneously weighed against those adjustments' potential to affect markups.

The 2016 NASS Organic Production Survey estimated that U.S. had approximately 2,559 certified and exempt organic dairy farms that milked a peak of 279,021 cows in 2016.[14] These organic dairy farms had milk sales of nearly $1.4 billion in 2016. Despite the more recent sales declines, total organic milk production in the United States increased to 4.0 billion pounds in 2016, representing an 18.5 percent increase in production from 2015 and 44.5 percent increase since 2011. In that same time frame, the number of certified organic farms grew 1 percent over 2015 (2,531 farms in 2015) and grew 41 percent compared to 2011 (1,812 farms in 2011).

In comparison, the Organic Integrity Database [15] identified approximately 3,516 organic livestock operations certified for production in January of 2020 that included ''dairy, milk, cow, cattle'' in their description of operations.[16] Of these operations, 49 operations were identified as operations milking ''goats'' or ''sheep'' (and not bovine animals). An additional 286 were breeders, replacement heifer operations, or cull cattle handlers, all of which did not indicate that they produced milk. In all, the 3,181 farms in this database are likely to produce organic milk and be affected by the rule through their organic replacement heifer purchases.

AMS decided to use the 2016 NASS data for our analysis for the following reasons. Primarily, the Organic Integrity Database does not track the number of organic dairy cattle maintained by certified operations. Absent information indicating a higher population of dairy cattle (compared to NASS data), an upward adjustment of farm numbers alone, without an adjustment of animal numbers, has little effect on our analysis. Secondly, the NASS survey of organic production records the number of organic dairy cows even if it does not necessarily classify the farm owning them as a dairy farm. This could undercount the number of operations, but not the number of organic dairy animals. Lastly, the Organic Integrity Database may overcount the number of operations that are actively engaged in dairy farming because mixed use farms may obtain additional certifications if they intend to handle organic dairy cattle but are not actively engaged in it.[17]

Organic Dairy Farms—Characteristics and Distribution

Organic dairy farms are, on average, smaller than conventional dairy farms. NASS' Certified Organic Surveys Agriculture show that the number of milk cows owned by organic dairy farms averaged 116 head in 2011, 106 head in 2015, and 109 head in 2016. In contrast, NASS' Census of Agriculture showed the number of milk cows for conventional dairy farms averaged 144 head in 2012 and 175 head in 2017.

Organic dairy farms also have lower yields, on average, than conventional dairy farms. The 2016 Survey of Organic Agriculture showed that each organic cow produces about 14,461 pounds of milk annually, or 48 pounds per day over a 300-day lactation period. NASS production data for 2018 shows that across all operations (conventional and organic) average production is 23,149 pounds of milk per animal annually, or 77 pounds per day over the same 300-day period. Despite higher production costs and lower yields, organic dairy farms can be economically viable through the price markups they receive over conventional milk and milk products. Table 1 shows that the average markup for organic milk products averaged 47 percent at the retail level.

Based on the 2016 NASS Survey of Organic Production Data, Table 2 shows that the highest concentration of organic dairy farms is in the Northeast and Upper Midwest regions,[18] but that large organic dairy farms in California and Texas represent a large share of output. The five States with the largest number of certified organic dairy farms (Wisconsin, Pennsylvania, New York, Ohio, and Indiana) accounted for 65.7 percent of the total farms. However, those States represented less than 30 percent of national organic milk production.

By contrast, the West and South Central regions accounted for the highest milk production per farm. The two highest organic milk producing States (California and Texas)

[13] National Retail Report—Conventional vs Organic—*https://usda.library.cornell.edu/concern/publications/000000043?locale=en.*

[14] USDA NASS. 2017. Census of Agriculture—2016 Certified Organic Survey. Available online at: *https://www.nass.usda.gov/Surveys/Guide_to_NASS_Surveys/Organic_Production/.*

[15] The Organic Integrity Database is available online at: *https://organic.ams.usda.gov/Integrity/.*

[16] Data was filtered for operations certified for livestock scope with certified livestock or handling products that include terms ''milk'' or ''dairy.''

[17] For instance, these operations may become certified for dairy so that they can manage organic dairy animals under favorable market conditions.

[18] USDA's Certified Organic Production Survey available online at: *https://www.nass.usda.gov/Surveys/Guide_to_NASS_Surveys/Organic_Production/.*

represented only 4.3 percent of total certified organic dairy farms, while producing 31.6 percent of the total organic milk nationally. The survey also showed significant regional differences in the number of milk cows on dairy farms. The Northeast and North Central regions average 58 head per farm; the Southeast 112 head; the West 405 head, and the South Central 1,667 head per farm. ARMS and NAHMS data showed similar patterns of size difference across regions.

TABLE 2—TOP STATES WITH ORGANIC DAIRY FARMS COMPARED TO PRODUCTION

[2016]

	Number of organic dairy farms	Percent of U.S. organic dairy farms	Milk production (pounds)	Percent of U.S. milk production
United States	2,559	100	4,034,989,854	100
California	104	4.1	795,750,804	19.7
Texas	6	0.2	481,392,352	11.9
Wisconsin	453	17.9	370,627,696	9.2
Oregon	46	1.8	342,534,830	8.5
New York	471	18.6	327,387,420	8.1
Pennsylvania	300	11.9	196,641,598	4.9
Vermont	172	6.8	171,463,088	4.2
Washington	41	1.6	128,685,429	3.2
Minnesota	108	4.3	127,828,496	3.2
Ohio	212	8.4	119,264,078	3.0
Idaho	20	0.8	118,291,465	2.9
Indiana	225	8.9	113,879,386	2.8
Michigan	70	2.8	65,950,978	1.6
Iowa	74	2.9	46,847,454	1.2
Maine	63	2.5	44,456,548	1.1

The Organic Dairy Market—Replacement Animals

Cull and Mortality Rates

Operations source replacement animals from on- and off-farm sources to replace animals that are sold, die, or are intentionally removed (''culled''). The APHIS NAHMS surveys [19] in 2007 and 2014 provide data on how many animals are culled (removed) from U.S. dairies annually and the reasons for their removal. Most dairy cows were removed for udder problems or reproductive problems, followed by lameness and poor production.[20] In the 2007 APHIS NAHMS survey of dairies, the national rate of permanently removing a dairy animal from a farm (excluding cows that died) was 23.6 percent [21] while the 2014 survey found a rate of 28.4 percent.[22] The 2014 NAHMS survey found that 21 percent of adult organic cows were removed from the organic herd. These figures include animals that are sold as replacement females to other dairies. The 2014 survey found a lower percentage of cows were permanently removed on small and medium operations (26.0 and 26.3 percent, respectively) than on large operations (29.7 percent).

The same surveys provide information about the deaths of animals on dairies. Overall, annual mortality rates were 7.8 percent for un-weaned heifers, 1.8 percent for weaned heifers, and 5.7 percent for cows (2007 survey). In 2014, NAHMS identified that about 5 percent of adult organic dairy cows die on the farm (compared to 21 percent of adult organic cows that were removed for other reasons). These numbers were roughly consistent with the 2007 report.

Between culling and mortality, a dairy farm would need to raise or purchase females that represent about 30 percent (23.6 percent culled plus 5.7 percent deaths) of the farm's herd size to maintain its size. As a lactating dairy herd (cattle) typically calves about 50 percent female offspring each year, the overall dairy herd should have enough replacement females to replace culled animals and animals that die. This conclusion considers downward adjustments for mortality (using 2007 NAHMS rates noted above of 7.8 percent and 1.8 percent) and additional reduction for culling.[23] The additional (excess) replacement female animals should allow organic dairy operations to expand the number of animals in their herds should they wish to expand. This scenario has not considered that producers may choose to breed with sexed semen which will increase the number of female offspring available to the dairy farm.

Sourcing Organic Replacement Animals

Most organic dairy farms replace culls and deaths with replacement heifers that are born and raised on the farm. The 2014 NAHMS data reports that 96.5 percent of organic replacement heifers are born and raised on the organic operation. An additional 2.6 percent of the replacement heifers are born on the operation and are subsequently raised off the operation before returning to the operation. The remaining 0.9 percent of replacement females are born off the operation and are presumably purchased from other operations.

The 2016 ARMS data also provides information about how dairies source replacement animals. Overall, ARMS data indicates that in 2016, the average organic dairy farm milked 102.7 cows and added 43.0 replacement animals of all types. Of those replacements, 93.8 percent (40.35 head) were born on the farm (and owned continuously by it)

[19] USDA APHIS. NAHMS Dairy, 2007, Part I: Reference of Dairy Cattle Health and Management Practices in the United States, 2007. This survey included both nonorganic and organic dairy animals. Available online at: *http://go.usa.gov/xKfEh.*

[20] USDA APHIS. NAHMS Dairy 2007, 84.

[21] USDA APHIS. NAHMS Dairy 2007, 87.

[22] USDA APHIS. NAHMS Dairy 2014, Report I: Dairy Cattle Management Practices in the United States, 2014. Available online at: *http://go.usa.gov/xKfEh,* 218.

[23] As an example, a 100-cow lactating dairy herd would produce about 50 heifers annually (*i.e.,* 50 percent of births). Considering this heifer group as a single group, a 7.8 percent mortality rate would reduce the herd to about 46.1 animals by the end of year one (assuming a 7.8 percent mortality rate over the entire year). Additionally, we assume a 10 percent cull rate could further reduce this to 41.5 animals at the end of year one. By the end of the second year, this number could be reduced another 1.8 percent (mortality rate for weaned heifers) to 40.7 animals. Assuming a further 10 percent reduction due to culls, the original 50-animal group may be reduced to 36.6 animals by the end of year two.

and 85.1 percent (36.62 head) were both born and raised on the farm. Based on 2,559 total dairy farms with a mid-point herd size of 267,523 reported in the Census of Agriculture, ARMS data indicates that 110,037 total heifers and milk cows (41.1 percent of the herd) were added to operations in 2016.[24] Purchased animals from off-farm sources included 4,325 milk cows (3.9 percent), 1,953 large heifers weighing more than 500 pounds (0.73 percent), and 559 small heifers weighing less than 500 pounds (0.2 percent).

Of the organic farms responding to the 2016 ARMS, 8.7 percent reported purchasing dairy cows and 10.9 percent reported buying replacement heifers. Farms that purchased milk cows purchased an average of 19 cows per farm and those that purchased heifers bought an average of 7 head. Most organic dairies also reported selling cull cows (animals that are no longer productive for milk production and are sold for beef), milk cows, and replacement heifers. Organic dairy farms sold an average of 1.6 milk cows and 1.3 replacement heifers with sales of replacement heifers exceeding purchases. Alternatively, the 2014 NAHMS data similarly show that the average organic dairy farm added 39 replacements that were born on the operation and added to the milking herd and purchased 7 replacements that were added to the milking herd.

Exact data on how many replacement heifers bought were transitioned heifers and how many were managed organically from the last third of gestation are not available. For this reason, this RIA calculates costs for two conjectured values for the share of purchased replacements that are transitioned heifers. Furthermore, AMS does not have aggregated data on what approach producers currently use when purchasing replacement heifers. Therefore, we do not have data on how many producers are bringing heifers into organic production as nonorganic animals and transitioning them into organic (or purchasing animals transitioned on other organic operations) versus sourcing and managing animals as organic from the last third of gestation. Excluding small heifers, the percentage of replacement heifers that are transitioned to organic production is, at most, 1.7 percent.[25] AMS also notes that the OIG report provided survey data indicating the proportion of sampled producers that may be practicing continuous transitioning. OIG found that out of a sample of six of the top ten certifying agents that certify the most organic dairy operations in the U.S., three allowed continuous transitioning.

Regulatory Impact Analysis

Comments Received on Costs and Benefits

AMS specifically sought input from the public about the estimated costs and benefits presented in the 2015 proposed rule. We received 29 comments in 2015 and 82 comments in 2019 that addressed our estimated costs and benefits. We summarize and respond to these comments below.

Availability of Replacement Animals

In 2015, some comments noted that organic heifer supplies were tight and that the heifers for sale were not of consistently high quality. This led commenters to believe the proposed rule could curtail growth of existing or new operations, restrict milk supply, and raise consumer prices. Some comments urged AMS to seek a consistent standard for all operations while considering that operations may need to grow to meet consumer demand.

A comment in 2015 calculated that a dairy could be expected to raise only enough of its own heifers to grow at an annual rate of 5 percent, after accounting for morbidity and culling. This commenter questioned AMS' conclusion there would be an ''ample supply'' of organic heifers under the rule. The commenter estimated that the industry would take time to catch up with the demand for organic (from last third of gestation) heifers.

Other comments in 2015 argued that there was an adequate supply of organic (last third of gestation) heifers available or that operations would raise and sell them if the price was higher and reflected the cost of raising them. In 2019, commenters claimed there is a surplus of organic (last third of gestation) heifers available to meet market needs and that there is an ample supply of animals even if morbidity/mortality rates are high or heifer selection is aggressive. No comments in 2019 claimed that organic heifer supplies were constrained.

AMS response: Based on our analysis of the comments received, AMS continues to believe that sufficient numbers of organic heifers (organically managed from last third of gestation) would be available after rule implementation to maintain and/or grow existing organic dairies. To mitigate potential and unforeseen impacts, AMS proposes establishing a compliance date for this rule to allow animals in the middle of an approved transition to complete the transition and produce organic milk. AMS received many comments that supported this approach during the 2019 comment period.

Price of Replacement Animals

A commenter in 2019 disagreed with AMS' estimate of a $1,300 cost difference between transitioned animals and last-third-of-gestation organic animals. The commenter believed AMS' estimate was too high. The commenter further explained that its ''discussions with dairy auction sales barns that previously sold organic cattle do not align with that value'' and the most common response it received from extension agents in the Northeast was that ''demand and verified sales have all but dried up for organic springing heifers.''

AMS received many comments in 2019 related to the cost difference for raising heifers organically vs. nonorganically during the first 12 months of life. One commenter found a $469 average cost difference (organic being more costly) per animal. Most comments noted a cost difference from $600 to $1,000 per calf, and some comments noted a difference as high as $1,300 per calf. Commenters tended to use the difference in production costs to describe the financial disadvantage and the harm to operations that source only last-third-of-gestation organic animals in comparison to operations that continually transition heifers to organic production.

Commenters in 2015 and 2019 generally agreed that implementation of the proposed rule would result in greater demand for organic heifers and would likely increase the price of organic replacement animals. Many commenters viewed this scenario favorably, as it would benefit organic producers who sell last-third-of-gestation organic animals (as opposed to heifer-raising operations selling transitioned animals).

AMS response: AMS continues to present the costs of the rule as a range based on different potential scenarios (see Table 4). We agree with comments that the price of organic heifers may increase, and we have estimated costs under two scenarios where the price of heifers increases by $500 and where the price does not increase. We estimate that the price of an organic (last third of gestation) heifer is $2,000 and up to $2,500 if increased demand drives

[24] The 2017 ARMS survey indicates that the average organic herd size is 102.7 head while the 2016 Census of Organic Production indicates it is 104.5 (= 267,523 head/2,559 farms).

[25] This percentage represents 0.75 purchased (large) heifers divided by 43.0 replacements (2016 AMRS data).

prices upward. This represents at least a $1,000 premium for organic (last third of gestation) animals over transitioned animals. The estimated difference seems to agree with comments that production costs for these animals are $600 to $1,300 higher. We recognize that this price estimate may be high and thus the result might be considered an upper bound of the estimated costs.

Effect on Consumer Milk Price

A commenter in 2015 estimated the rule would increase the cost of producing organic milk by 3.7 to 6.0 cents per half gallon (0.87 percent to 1.42 percent, respectively) and that the increase would be passed to consumers and negatively affect consumer demand. However, AMS also received comments in 2015 from organic milk consumers that supported the proposed rule even recognizing the price of milk could increase. Another comment in 2015 noted that if supply of organic milk were to become very restricted under the new requirements, retail prices could increase to a point where consumer demand would flatten or even decrease.

In 2019, stakeholders were more concerned with how consumer milk prices negatively affect organic dairy producers than how they affect consumers. Comments frequently discussed the idea that there is an oversupply of organic milk currently ''flooding the market'' that are driving consumer prices down.

AMS response: Table 1 figures indicate that the retail markup of organic milk products over conventional milk products is 47 percent. The AMS organic dairy report for February 8th to 12th, 2021, indicated that the 2020 average (farm-level) organic milk pay price was $31.55 per hundredweight while the USDA World Agricultural Demand and Supply Estimates for April 2021 indicate that the 2020 (farm-level) all milk price was $18.32 per hundredweight. Together these values indicate that the farm-level organic markup is 72 percent. The ERS farm share of the retail price for the milk and dairy basket in 2018 was 28 percent. Collectively, this implies that the farm share of the retail price for organic milk is 32 percent.

Table 4 shows that the total costs of this proposal to the organic milk producers net of transfers would be $1,462,500 under our 50 percent transitioning scenario and $731,000 under our 25 percent transitioning scenario discussed further below. The Census of Organic Agriculture indicates that farm-level organic milk revenue was $57.8 million in 2016.[26] Based on these figures, AMS estimates that a final rule would increase producer costs by 1.3 to 2.5 percent and retail costs by 0.4 to 0.8 percent. Price effects will depend on the specific products being considered. AMS first-of-the-quarter price reports indicate that a half gallon of organic milk has an average retail price of $3.98. Based on our calculations, a final rule might raise this price by 2 to 3 cents. AMS does not believe that price effects of this magnitude are likely to limit industry growth or noticeably affect demand.

Number of Transitioning Animals

One commenter in 2015 estimated there were 60,000 conventional animals transitioning to organic production on new dairy farms and established dairy farms. The commenter predicted this could lead to an oversupply of milk and decrease in milk price (income for the dairy farm). Another commenter in 2019 believed that ''tens of thousands'' of animals had transitioned since 2015.

AMS response: AMS recognizes that we do not have precise data on how many animals are transitioned on an annual basis by certified organic operations. Our experience indicates that most organic dairy farms do not continually transition animals. However, because of the lack of precise numbers available, we estimate that transitioned animals comprise 25 percent (low end) to 50 percent (high end) of all purchased replacement animals. AMS did not receive concrete data from comments to support alternative figures.

Changes in Dairy Market Since 2015

In 2019, many comments noted that the organic dairy industry had changed considerably since AMS published the proposed rule in 2015. Primarily, commenters noted a decline in consumer demand for organic milk and increased availability of organic milk and organic dairy cows. Some comments noted that fewer operations are transitioning to organic production due to limited opportunities to secure a contract with a milk handler or because the price premium for organic production is no longer an incentive to transition. Some 2019 comments noted that the cost of the rule would be less than AMS estimated in 2015 due to increased availability of organic (from last third of gestation) replacement animals and a corresponding drop in prices for these animals.

AMS response: AMS recognizes that the organic dairy market in 2015 differed from the current organic dairy market. Our calculation of costs for this proposal is higher than those calculated in 2015 because the cost calculation is based, in part, on the number of organic dairy operations and total organic herd size. These numbers have both increased since 2015, so the estimated cost is higher.

Costs and Benefits (General)

A commenter in 2019 disagreed with AMS' cost analysis in the proposed rule. It stated that the cost analysis ''fails to capture the cost inequities of not implementing the proposed rule,'' and specifically points to its ''failure to distinguish production costs between organic and transitioned heifers.'' Without this information, the commenter argues ''neither the agency nor stakeholders can understand the true cost, and true harm, of implementing or not implementing the proposed rule.'' Furthermore, the commenter calculated the harm to operations that source only last-third-of-gestation organic animals using the difference in production costs for transitioned animals and last-third-of-gestation organic animals. The commenter estimated that 25 percent or 50 percent of all culled organic dairy animals are replaced with transitioned animals and calculated competitive harm of $9.29 million to $18.58 million annually ($469 multiplied by 25 percent to 50 percent of all culled animals using a cull rate of 28.4 percent).

AMS response: The commenter estimates that the competitive harm from the current enforcement practice of allowing transitioned animals is $9.29 million (under the 25 percent scenario) and $18.58 million (under the 50 percent scenario). These estimates are based on the commenter's finding that a conventional heifer costs $462 less to raise and that organic farms require 79,242 replacement heifers annually based on a 28.4 percent cull rate on the 279,021 (head) total U.S. organic herd.

AMS agrees with the commenter's general concern that organic dairy farms need to replace a substantial share of cows each year and that the uneven application of rules regarding transition of heifers creates artificial cost disparities. AMS uses the price difference for purchased replacement heifers (transitioned vs. organic from last third of gestation) as its estimate of the per animal increase in costs for dairy farms that have used transitioned animals. AMS recognizes that this does

[26] Given the recency of the data and the relatively low inflation rate throughout, we do not adjust for inflation in our estimates. We note that ARMS data and the Census of Agriculture Data both reflect 2016 data indicating no need to adjust for inflation in calculating markups.

not account for increased costs to operations that might maintain ownership of offspring that are born on-farm, subsequently removed from organic production, and then transitioned back into organic production. We understand that most certifiers do not interpret the current regulations to allow this practice. For this reason, AMS believes that applying the cost differential to replacement heifers that are both purchased and unpurchased (*i.e.,* owned) would likely overstate the cost of the rule. However, AMS seeks data from industry regarding the extent to which unpurchased heifers are transitioned to inform our cost calculations.

As described in our consideration of regulatory alternatives, AMS expects that purchases of replacement heifers that are transitioned animals would increase if AMS allowed this practice (Alternative A). Additionally, dairy operations utilizing heifer-raising operations while retaining ownership may switch to operations that use conventional practices and then transition the animals. Table 3 shows that only 11 percent of operations purchase replacement heifers. The uneven application of the current rule suggests that a smaller share of producers is benefiting from the cost advantage of transitioned heifers, at a level higher than that suggested by the average number of head purchased.

Costs of Proposed Rule

The proposed rule would likely increase production costs on organic livestock and dairy operations that currently continually transition nonorganic animals and/or operations that source transitioned dairy animals as replacements. Additionally, any dairy that purchases organic heifers may pay higher prices for organic animals due to increased demand, but organic operations selling replacement heifers would benefit from any higher prices.

We assume that farms that exclusively raise their own organic replacement heifers and manage those animals organically from birth would not incur additional costs under the proposed rule. Similarly, dairy farms that send organic heifer calves to other certified organic operations to have the animals continuously managed as organic (for some period of time before returning to the farm) would not incur additional costs. Finally, nonorganic dairy operations converting to organic production for the first time would not incur new costs during the 12-month transition period; they may transition animals on a one-time basis under the proposed rule.

Estimated Costs for Dairies

The proposed rule creates two costs for organic dairy farms. First, dairy farms that regularly transition heifers or regularly purchase transitioned replacement heifers after their initial transition to organic would be required either to purchase higher-cost organic (from last third of gestation) replacement heifers or to raise their own replacement by raising organic calves to maturity. This analysis assumes that transitioned animals are currently sold at a discount compared to organic (from the last third of gestation) replacement animals.

Second, by raising the demand for organic replacement heifers, the proposed rule may raise the price of organic replacement heifers if operations currently selling organic (transitioned) replacement heifers cannot comply with the proposed requirements and operations that sell organic (last third of gestation) replacement heifers cannot easily increase offerings. While this price increase is likely to be small, it would raise costs to any organic dairy farm that is a net buyer of organic replacement heifers, regardless of whether it continually transitions animals or purchases transitioned replacement heifers. This same price effect, however, would create an offsetting benefit to any dairy farm that is a net seller of organic replacement heifers.

AMS estimates the costs of the proposed rule below by estimating the total number of replacement animals purchased by U.S. organic dairy cattle operations annually. We then estimate the percentage of all purchased animals that does not meet the requirements of the proposed rule (*i.e.,* the percentage of animals bought by organic operations that are not organic from the last third of gestation). Due to the unavailability of precise data, we estimated a range of possibilities (25 percent to 50 percent of all purchased animals). To calculate costs, we then multiply the number of animals by the price difference between organic (from the last third of gestation) and nonorganic heifers (we use nonorganic heifer prices as a substitute for transitioned animals in the absence of that data). Finally, we considered a possible increase for the price of organic animals to calculate the maximum expected costs. Below we discuss the data and calculations in detail.

The ARMS survey includes farm-level data on purchases and sales of heifers weighing more than 500 pounds, a category that explicitly includes sales of springers.[27] While the ARMS survey does not identify whether purchased heifers have been organic from birth or have transitioned to organic status, it does identify whether the farms themselves are certified or transitioning to organic status. Since all cattle sold by organic dairies are themselves organic and all cattle sold by non-organic dairies are conventional, this analysis assumes that the difference in the large heifer sales prices for organic or transitioning farms and other farms reflects the difference in costs for those animals. This analysis estimates costs under the alternative assumptions that either 25 or 50 percent of all purchased heifers are transitioned heifers.

We used 2016 ARMS data to estimate the number of replacement animals purchased by organic operations. Table 3 provides the average numbers and prices of large heifers bought and sold by organic or transitioning farms, divided into four different size categories, along with figures for all organic or transitioning farms and all other non-organic farms. Compared with their non-organic counterparts, organic and transitioning dairy farms are smaller in herd size, less likely to purchase large heifers as replacements, and more likely to sell large heifers. On average, organic dairies purchase replacement large heifers at a rate of 0.73 percent of their total herd size (or 0.75 head) and sold large replacement heifers at a rate of 1.2 percent of their total herd size (or 1.27 head).

However, only 10.9 percent of dairy farms purchased large heifers so that the average farm purchasing heifers bought 6.9 head. Based on an average mid-point herd size of 267,523 milk cows,[28] all organic dairies purchase 1,953 large heifers annually. Rounding the large heifer purchase figure to 1,950, these

[27] A springer is a heifer (*i.e.,* a female cow that has not previously calved) that is 7 to 9 months pregnant and will begin producing milk within 0 to 2 months.

[28] The mid-point herd size is the average of the Jan 1 and Dec 31 herd size for 2016. NASS Organic Production Survey. It is slightly less than peak heard size of 279,021.

figures imply that 488 purchased heifers are transitioned (rather than managed organically from the last third of gestation) under our 25 percent assumption, and 975 are transitioned heifers under our 50 percent assumption.

TABLE 3—HEIFER PURCHASE AND SALES PRICE AND RELATED STATISTICS BY DAIRY FARM SIZE AND ORGANIC STATUS

[ARMS]

	1–49	49–99	100–199	200+	All
Organic and Organic Transitioning Farms					
Number of Farms in ARMS Survey	144	114	42	32	.....
Largest Number of Cows Milked	33	68	132	499	103
L. Heifers Sold (Head)	0.31	0.84	0.60	8.02	1.27
Sold L Heifers ($/Head)	$1,350	$1,993	$2,111	$1,918	$1,887
% of Farms Purchasing L. Heifers	8%	16%	10%	7%	11%
Purch. L. Heifers as a % of Herd	1.5%	1.0%	1.3%	0.2%	0.7%
Other Farms					
L. Heifers Sold (Head)	1.14	1.37	1.73	9.68	5.5
Sold L Heifers ($/Head)	$600	$1,161	$1,304	$989	$1,012
% of Farms Purchasing L. Heifers	3.3%	7.2%	4.8%	12.1%	3.3%
Purch. L. Heifers as a % of Herd	0.2%	1.0%	0.8%	3.2%	2.9%

We also used the 2016 ARMS data to estimate the price difference between organic replacement animals and nonorganic replacement animals. Table 3 shows the price at which organic and transitioning dairies sold large replacement heifers. Because the price of transitioned heifers compared to last-third-of-gestation organic heifers is not available, our analysis uses the cost of non-organic large heifers as a substitute. This is likely to exaggerate the cost differential. The large heifer selling price of $1,887 at organic and transitioning dairy farms was $865 more than the selling price of $1,012 at non-organic farms. Across individual farm size categories, however, this difference in prices between organic and non-organic selling prices varied across size categories, ranging from $750 (farms with 0–49 cows) to $937 (200+ cows). Based on the data, our analysis assumes that before the imposition of any of the proposed changes, a transitioned heifer costs $1,000 and an organic heifer costs $2,000 so that the difference in price between the two animal types is slightly higher than the largest difference observed in the data.

Related data and public comments support these assumptions on price relationships. The approximately $1,000 price of non-organic bred heifers (our substitute for the price of a transitioned animal) is supported by livestock auction market prices at five sites [29] collected by AMS in November of 2019. These data show that bred heifers in the third trimester (*i.e.,* springers) of supreme and approved quality sold for $1,045.

Additionally, the assumptions are supported by public comments that indicate it costs between $600 and $1,300 more to raise an organic calf than a nonorganic calf.

The increased demand for 975 additional organic (from last third of gestation) replacement heifers under the 50 percent transitioning assumption (or 488 additional organic replacement heifers under the 25 percent transitioning assumption) is not expected to lead to a large increase in their price because many of the key inputs to producing those organic replacement heifers can be readily expanded. These inputs include organic heifer calves, additional organic feed, and additional organic pasture land. Because heifer calves are often sold for meat rather than milk production, the number of these animals that might be re-directed into milk production is far less than their total availability, a situation providing a strong check on price increases for that input. Moreover, the additional organic pasture and additional feed required for 975 additional organic replacements are relatively small compared to the existing requirements for the 103,000 heifers currently retained by organic farms for their own replacements.

However, this analysis assumes that the increased demand for organic replacement heifers pushes up their price by $500, or 25 percent,[30] to $2,500. In this case, the total cost of purchasing replacement heifers by organic dairy farms would be $4.875 million per year (1,950 replacements animals purchased from off farm at $2,500 per head). This would be the new total cost of purchasing organic heifers rather than the additional cost of purchasing organic heifers, which is considerably less.[31]

Table 4 shows the estimated costs to and intra-industry transfers between organic dairy farms purchasing organic heifers under alternative assumptions on price response and replacement heifer purchases that would follow the proposed rule. Industry transfers are costs to a set of dairy farms that are exactly offset by benefits to another dairy farm. In the case of the proposed rule that would affect organic dairy farms, such transfers would occur because farms that are currently net sellers of organic heifers see sales revenue increase from price increases for organic heifers should the rule be enacted, even as net buyers of organic cattle see their costs increase. If the price of organic heifers does not increase, then no transfer would occur.

AMS expects that organic dairy farms will purchase 1,950 replacement heifers per year based on our analysis of ARMS data. If the price of organic dairy heifers were to be unchanged following the rule, our analysis finds that total costs would increase by $975,000 per year

[29] This includes data collected in the AMS Livestock and Replacement Cattle Reports reported at *https://www.ams.usda.gov/market-news/feeder-and-replacement-cattle-auctions* for the following five auctions: Mid-Georgia Livestock, Jackson, GA; Empire Livestock, Cherry Creek, NY; Mammoth Cave Dairy Auction, Smiths Grove, KY; New Holland Sales Stables, New Holland, PA; and Toppenish Monthly Dairy Replacement Sale, Toppenish, WA.

[30] A 25 percent price increase resulting from a 50 percent increase in quantity supplied is consistent with an elasticity of supply of 2.

[31] These costs reflect only those for dairy cattle. Costs for purchasing dairy sheep and goats are not included in this analysis.

under the assumption that 50 percent of purchased replacement animals had been transitioned animals, or costs increase by $488,000 under the assumption that 25 percent of purchased replacement animals had been transitioned animals. In these cases, there are no transfers. If the price of organic dairy heifers rises to $2,500 and 25 percent of purchased replacements are transitioned, our analysis finds that total costs are $732,000 (reflecting 488 new organic replacement heifers purchased for $1,500 over the conventional price) and transfers are $731,000 (reflecting 1,462 previously purchased organic heifers purchased at price $500 higher).

If the price of organic dairy heifers rises 50 percent, and 50 percent of purchased replacements are transitioned, our analysis finds that total costs would be $1,462,500 (reflecting 975 new organic replacement heifers purchased for $1,500 over the conventional price) and transfers would be $487,500 (reflecting 975 previously purchased organic heifers purchased at price $500 higher). This information is presented in Table 4 below.

TABLE 4—ESTIMATED COSTS UNDER ALTERNATIVE ASSUMPTIONS FOR PRICE RESPONSE AND THE QUANTITY OF TRANSITIONED ANIMALS PURCHASED BY CERTIFIED ORGANIC OPERATIONS ANNUALLY

Assumptions regarding . . .		Estimated additional costs net of transfers	Estimated transfers
. . . Price response	. . . Transitioning heifers		
The price of organic heifers remains at $2,000	25 percent of heifers are transitioning	$488,000	$0
The price of organic heifers remains at $2,000	50 percent of heifers are transitioning	975,000	0
The price of organic heifers rises from $2,000 to $2,500.	25 percent of heifers are transitioning	732,000	731,000
The price of organic heifers rises from $2,000 to $2,500.	50 percent of heifers are transitioning	1,462,500	487,500

If some of the sellers of the 975 additional organic heifers required under the 50 percent assumption (or the 488 additional organic heifers required under the 25 percent assumption) have costs to supplying these animals that are less than $2,500, then industry transfers would exceed the values stated in Table 4. Increased sales are expected to benefit operations that have more flexibility in capacity (*e.g.,* available pasture) to accommodate raising organic replacement heifers for the organic market. Importantly, sales response across individual farms will likely be uneven and depend on site-specific factors such as the farm's ability to access new buyers and increase organic pasture.

Differences in purchase patterns of milk cows and replacement heifers also vary by size in a way that affects the distribution of costs associated with the proposed rule. Ten percent of operations with fewer than 50 cows reported purchasing *milk cows,* and the average number purchased was 6 head. Five percent of operations with between 50 and 99 cows reported purchasing milk cows, and the average number purchased was 14 head. Three percent of operations with between 100 and 199 cows reported purchasing milk cows, and the average number purchased was 10 head. No operations with 200 or more cows reported purchasing milk cows.

The pattern is different for purchasing *heifers.* Eight percent of operations with fewer than 50 cows reported purchasing heifers, and the average number purchased was 7 head. Sixteen (16) percent of operations with between 50 and 99 cows reported purchasing heifers, and the average number purchased was 4 head. Ten (10) percent of operations with between 100 and 199 cows reported purchasing heifers, and the average number purchased was 17 head. Seven (7) percent of operations with 200 or more cows reported purchasing heifers, and the average number purchased was 12 head. Based on a cost differences of $1,500 per head between transitioned replacement heifers and organic replacement heifers, and assuming that half of replacement heifers currently purchased are transitioned, the average dairy with fewer than 50 cows would pay an additional $382–$510; dairies with between 50 and 99 cows would pay an additional $499–$666; dairies with between 100 and 199 cows would pay an additional $1,316–$1,755; and dairies with 200 or more cows would pay an additional $628–$837. The costs by size of operation are summarized in Table 5.

TABLE 5—COSTS BY SIZE OF OPERATION FOR PURCHASING ORGANIC HEIFERS

	Size of operation			
	Fewer than 50 cows	50–99 Cows	100–199 Cows	200 Or more cows
Share of Operations	43%	34%	13%	10%
Percent of operations that purchased replacement heifers	8%	16%	10%	7%
Average number of replacement heifers purchased	6.68	4.06	17.22	12.33
Number of Farms	1,114	879	324	247
Average Cost Per Farm	$382–$510	$499–$666	$1,316–$1,755	$628–$837
Total cost for purchase of replacement heifers across size class	$425,849–$567,798	$438,939–$585,252	$426,377–$568,502	$155,007–$206,676
Cost per operation for operations purchasing replacements	$5,009–$6,678	$3,048–$4,063	$12,919–$17,225	$9,247–$12,330

The costs in Table 5 do not reflect the offsetting effect of transfers. For this reason, the sum of the total costs of replacing heifers across all size categories ($2.41 million and $2.89 million) roughly equals the sum costs (net of transfer) and transfers in Table 4 ($2.44 million and $2.92 million) with minor discrepancies reflecting rounding differences.

Effects on Heifer-Raising Operations

Organic dairy operations that continually source transitioned heifers would need to change their practices to meet the requirements of the proposed

rule. In some cases, organic dairy operations source their transitioned heifers from off-site heifer-raising operations. Here, we discuss the potential effects of the proposed rule on these operations.

A 2011 USDA NAHMS study on heifer-raising operations [32] found that most heifers sent to heifer-raising operations (80 percent) are returned to their dairy of origin. The study also found that most heifer-raising operations receive weaned calves (rather than wet calves) and send them back as pregnant heifers. In the 2015 proposed rule, AMS specifically requested comments and data on the likely impacts on heifer-raising operations. We did not receive any data on the number of heifer-raising operations that continually transition animals for sale to organic dairies or on the number of animals raised by such operations annually. Aside from fragmentary evidence in the AMS Organic Integrity Database, AMS does not currently have specific data on the locations, numbers, or sizes of organic heifer-raising operations.[33]

In the absence of specific information, we considered that organic dairy operations could be using organic heifer-raising operations to transition animals on a continual basis by taking in nonorganic weaned calves (*e.g.,* 12-month old heifers) and providing organic management for 12 months before returning the pregnant organic heifers to an organic dairy.

Under the proposed rule, heifer-raising operations would not be required to change their *animal production practices.* These operations are certified organic and currently manage animals in compliance with the USDA organic regulations as a requirement of their organic certification. However, the proposed rule would not allow any operations, once certified, to continually source nonorganic animals. Therefore, these operations would be able to accept only weaned calves that had been managed organically from the last third of gestation.

[32] USDA, Animal Plant Health Inspection Service. Dairy Heifer Raiser, 2011 (October 2012). Available online at: *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/nahms/nahms_dairy_studies.*

[33] The Organic Integrity Database includes descriptions of the products for which organic farms are certified as recorded by the certifying agent. It lists 220 operations that recorded dairy cattle but not milk production (*i.e.,* a possible indicator for a heifer-raising operation). These operations were often identified as being involved with ''dairy cows,'' ''breeding operations,'' and ''replacements.'' Unfortunately, the database does not provide sufficient information to use in our analysis of heifer-raising operations.

Within our analysis, we have assumed that competitive markets for both transitioning and replacement heifers have resulted in prices for these animals that are sufficiently high enough to allow sellers to recover the cost of raising these animals along with a ''normal'' rate of return on capital investment. The analysis assumes that the 50 percent conjectured increase in price of organic replacement heifers is sufficient to simultaneously ensure that markets clear (*i.e.* quantity supplied equals quantity demanded) at the higher number of transacted animals and offset the increased costs to supplying more animals.

As with other aspects of our analysis regarding supply response, AMS assumes that the ability of individual sellers of replacement heifers to adjust management practices to market conditions will vary with the site-specific characteristics of operations, such as their ability to find new buyers and access to additional organic pasture. Whether heifer-raising operations will increase or decrease sales of organic heifers following the implementation of the rule cannot be determined with the available data.

Effects on Consumers

Most dairies report that they source at least some of their replacement cows from their own calves, and only 11 percent of all dairies purchase replacement heifers, with less than 1 percent of all replacements being purchased from off the farm. The majority of producers that do not purchase replacement heifers would not see an increase in costs. To replace purchased transitioned heifers, dairies would have to either raise their own replacements or buy them from an operation that sells organic (from last third of gestation) replacement heifers. Since the current supply of replacement heifers can be increased without large price increases, as detailed above, it is unlikely that the proposed rule would significantly increase milk production or milk costs to the consumer. Some commenters to the 2015 proposed rule suggested that the limits on transitions would increase the price of organic milk for consumers. They noted that with the proposed limits on transitions, organic growth for existing organic dairy farms would be biologically capped at 5 percent. Any additional growth would need to come from new organic dairy farms or nonorganic dairy farms transitioning to organic milk production. These commenters stated that the price of organic milk for consumers could rise if demand approached the hard limit for dairy cattle growth.

For additional discussion, see our response to comments on ''Effect on consumer milk price'' above.

Benefits of the Proposed Rule

The proposed rule would provide producers and consumers of organic foods with multiple types of benefits. First, the rule would give specificity and clarity to the enforcement of regulations relating to the origin of dairy livestock and the management of breeder stock, Second, the rule would create uniformity in the application of the USDA organic regulations by generally requiring organic management for an animal's entire life. Together, these may enhance the value of organic premiums that consumers are willing to pay for milk certified under the USDA organic regulations by reducing uncertainty.

The 2016 NASS Certified Organic Production Survey show that U.S. farms and ranches produced and sold $7.6 billion in certified organic commodities, up 23 percent from 2015. At the retail level, the OTA 2019 U.S. Industry Survey found that retail sales of organic production totaled $52.5 billion, 6 percent above the previous year. Organic dairy cattle producers who sell organic dairy females may receive a benefit as part of an intra-industry transfer. AMS estimates that on the high side, the price of an organic springer may increase by $500 over current prices due to increased demand. If this price increase were to occur, dairy producers who are net sellers of replacement springers would benefit through the intra-industry transfer.

AMS does not expect the proposed rule to increase demand for organic milk. However, AMS does expect the proposed rule to help support consumer confidence by preventing organic dairies from continuing to transition non-organic animals into organic milk production. The sustained demand should be valuable for organic milk producers and strengthen the value of the organic brand in the mind of consumers; these outcomes are not benefits in themselves, as that term is defined for purposes of Executive Order 12866 and OMB Circular A–4, but to the extent that they disincentivize the (costly) establishment of credentials that are alternative to USDA organic certification, the associated cost savings qualify as rule-induced benefits.

Alternatives Considered

As required by Executive Order 12866, AMS considered alternative regulatory approaches in our development and analysis of the

proposal. AMS considered alternatives that would be both less stringent (less costly) and more stringent (more costly). The alternatives considered are shown in Table 6 and discussed below.

TABLE 6—ALTERNATIVES CONSIDERED

Alternative	Description
(A) Allow Continual Transition	Allow any operation to transition nonorganic dairy animals into organic production over a 12-month period on a continual basis.
(B) Prohibit All Transitions	Remove all exceptions for transition of nonorganic animals.

Alternative A—Allow Continual Transition

AMS considered amending the regulations to specify that any operation could transition dairy animals into organic production over a 12-month period on a continual basis. Under OFPA, a dairy animal from which milk or milk products will be sold or labeled as organically produced must be raised in accordance with OFPA for not less than the 12-month period immediately prior to the sale of such milk and milk products (7 U.S.C. 6509(e)(2)(A)).

AMS could presumably allow transition of any dairy animal into organic production, without further limitation, if the animal were managed organically for the 12-month period prior to the sale of milk as organic. In effect, this would mean that an operation could continually transition nonorganic dairy animals into organic production on an ongoing basis, as opposed to allowing an operation to transition animals into organic production once. In this scenario, organic dairy farms using heifer-raising operations following organic practices would now use heifer-raising operations that treat the young animals with antibiotics and other medications prohibited in organic livestock production and/or provide nonorganic feed until one year before they were expected to produce milk. Also, in the scenario, all purchased replacements would be transitioned heifers. Relatedly, operations wanting to assure consumers that they had raised organic heifers under organic conditions through their entire lives would have to do so under a separate certification program.

ARMS Data indicated that the average organic dairy operation kept 40.4 heifers (or 39.3 percent of its herd) for breeding and 36.6 heifers (or 35.7 percent of its herd) were kept for breeding and raised on the operation. The difference of these values, 3.6 percent, represents the likely proportion of organic heifers raised on outside heifer-raising operations (as a share of the total herd). If all those animals become transitioned heifers, then an additional 9,711 animals (*i.e.,* 267,523 head * 3.6 percent) would be transitioned. AMS assumes that the price difference between organic (last third of gestation) and transitioned heifers accurately reflects the cost difference of $1,000 in raising heifers for milking under those two comparative production systems. In this case, the benefit of allowing for continuous transitioning of heifers is $9,711,000.

While the cost difference might suggest that organic farms would acquire an even larger share of heifer replacements through purchases rather than internally through breeding, AMS feels this is unlikely owing to the asymmetric information problems associated with cattle sales. Asymmetric information problems arise because heifer sellers have more information than heifer buyers about the health, breeding, and temperament of their animals. This has the effect of reducing total transactions in the market (Akerlof, 1970).[34] [35]

The potential cost associated with the adoption of the continuous transition for all organic dairies could be illustrated by a deleterious effect on markups to products marketed under the organic label; although a markup reduction is not a cost, from the society-wide perspective taken for purposes of Executive Order 12866 and OMB Circular A–4, it may be a sign of an increased incentivize for the (costly) establishment of credentials that are alternative to USDA organic certification. Table 1 shows that milk products marketed under the organic label earned an average markup of 47 percent over conventional products that total $1.8 billion in total value. A one percent fall in total markups would be associated with a $18 million reduction in organic premiums at the retail level.

Continual transition could achieve the regulatory objective of establishing a consistent and uniform standard for all operations. The National Organic Standards Board's recommendations and stakeholder comments support AMS' decision to not select this alternative, as comments indicate that at least some consumers expect organic milk be produced without the use of antibiotics (and other substances prohibited under the USDA organic regulations) and expect organic management of all animals on organic operations.

Alternative B—Prohibit All Transitions

A second alternative AMS considered was to remove any allowance for dairy operations to transition animals to organic production, including new and nonorganic dairies seeking to convert to organic production. Under this option, all dairy animals would need to be managed organically from the last third of gestation for milk and dairy products to be sold, labeled, or represented as organic.

The costs of this alternative are threefold. First, producers would bear the increased annual costs of $1,462,500 described in Table 4 and under the one-time transition scenario where 50 percent of heifers are transitioning. Because conventional organic dairy farms transitioning to organic would also need to purchase heifers and milking cows approximately equal to the size of their current operations, AMS believes that the price increase for organic heifers may significantly exceed a 50 percent price increase.

Second, this alternative would limit the ability of the industry to expand to meet growing demand and thereby create price instability within the market. In periods of stable demand, firm entry into the organic market is modest, reflecting factors such as population and income growth. In these stable periods under current rules, the cost of producing organic milk for established producers reflects both the higher cost of production in terms of feed costs, land requirements, and animal husbandry practices, and the higher cost of replacement heifers. In periods of industry growth (*i.e.,* high

[34] George, Akerlof. (1970) The Market for Lemons: Quality Uncertainty and the Market Mechanism. In: The Quarterly Journal of Economics.

[35] Such information asymmetries create a ''lemons problem'' where buyers assume that only the lowest quality heifers would be sold by dairy farms while the best are retained for internal on farm use. Dairies, in turn, sell only their lower quality heifers because the sales price is too low to justify bringing higher quality animals to market.

demand), entrants to this industry bear those costs as well, but also face the significant additional costs of converting land for organic feed and pasture over a 3-year period. Under this alternative, in periods of industry growth (*i.e.,* high demand) new entrants to the industry would face the additional cost of acquiring organic heifers and milking cows under periods of tight supply and this alternative could lengthen the time required for new entrants to begin production. While a subset of organic dairies would see higher returns on sales of heifers, incumbent farms seeking to grow would see higher costs of expanding herds through heifer purchases and the additional time required to certify additional land under the organic program. While some incumbent producers may benefit under this alternative in the short-term, the added costs to entry and expansion would likely foster price volatility for organic heifers and wholesale organic milk, as the supply has a limited ability to expand in response to demand fluctuations.

Organic heifers are an input to wholesale organic milk production, and wholesale milk is an input to retail organic milk products such as organic cheese, yogurt, butter, and retail-level milk. Bringing organic milk products to market requires complementary investments in retail marketing outlets and brand development. Bernanke (1983), Cabellero and Pindyck (1996), and Carruth et al. (2000) find that increasing input price volatility reduces investment since the value of the option to delay the investment rises with increased uncertainty about the investment's return.[36] [37] [38] Such volatility could limit long-term growth in organic milk demand if downstream milk processors (for cheese and other milk products) and retailers require an organic milk supply with stable prices to allow for planning of other investments such as equipment, brand promotion, and retail promotion, which in some cases constitutes building retail stores focused solely on the sale of organic products.

This alternative would simplify enforcement of the requirements by applying a single standard, without exceptions, to all organic dairy operations. It would also align the requirements for dairy animals with the requirements for organic slaughter stock. AMS does not believe this option is necessary for several reasons.

First, AMS believes that certifiers will be able to enforce a rule that allows for a limited and well-defined transition. Second, AMS believes that allowing one-time transitions for organic dairy operations maintains market stability while simultaneously preserving the value of the organic label. Third, AMS notes that other aspects of the USDA organic regulations slow entry into this market and believes that eliminating its historic allowance of dairy animal transitions would unfairly burden downstream organic processors and retailers who have invested in the industry based on the expectation of the continuation of regulations that ensure a stable and responsive market supply. Most comments objected to the presence of different requirements across the industry, depending on how a certifying agent interprets the regulations. Most commenters supported a one-time allowance.

Conclusions

AMS is proposing a regulatory option that retains the opportunity for new operations to transition into organic dairy production once. We are reopening the comment period to solicit views on whether the final rule should prohibit certified organic dairy operations from acquiring transitioned animals to expand or replace animals to produce organic milk. We are also seeking comment on whether AMS should use the term ''operation'' to describe the regulated entity, rather than ''producer.''

A clear and consistent standard for transition of dairy animals into organic production is needed and anticipated by dairy producers, consumers, trade associations, certifying agents, and USDA's OIG. AMS seeks to provide a foundation for compliance and enforcement in support of fair competition among dairy operations through a well-defined and consistently implemented standard.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Pursuant to the requirements set forth in RFA, AMS performed an economic impact analysis on small entities. Small entities include producers and agricultural service firms, such as handlers and accredited certifying agents. AMS has determined that the proposed action would impact small entities but that it would not have a significant economic impact on them.

RFA permits agencies to prepare the regulatory flexibility analysis in conjunction with other analyses required by law, such as RIA. AMS notes that several requirements of the regulatory flexibility analysis overlap with those of RIA. For example, RFA requires a description of the reasons why the action by the agency is being considered and an analysis of the proposed rule's costs to small entities. RIA likewise describes the need for the proposed rule, the alternatives considered, and the potential costs and benefits of the proposed rule. In order to avoid duplication, we combine some analyses as allowed in § 605(b) of RFA. As explained below, AMS expects that the entities that could be impacted by the proposed rule would qualify as small businesses. In RIA, the discussion of alternatives and the potential costs and benefits pertains to impacts upon all entities, including small entities. Therefore, the scope of those discussions in RIA is applicable to regulatory flexibility analysis under RFA. RIA should be referred to for more detail.

Potentially Affected Small Entities

AMS has considered the economic impact of the proposed action on small entities. Small entities include producers transitioning into organic dairy production, existing organic dairy producers, producers that raise replacement animals for organic dairies, and certifying agents. AMS believes that the cost of implementing the proposed rule will fall primarily on organic dairies that currently purchase transitioned heifers, although any organic dairies that purchase organic heifers would be expected to pay higher prices in the short-term due to increased competition for these animals. Farms that sell their excess organic replacement heifers may see an increase in demand for their heifers, and farms that raise their own organic replacement heifers would not likely be affected by the proposal. AMS believes heifer development operations also could be impacted by this action. However, limited information on the number and size of heifer development operations prevents our estimation of the number

[36] Bernanke, Ben S. (1983) ''Irreversibility, Uncertainty and Cyclical Investment'', *Quarterly Journal of Economics* (98) 85–106.

[37] Caballero, Ricardo J. and Pindyck, Robert S. ''Uncertainty, Investment, and Industry Evolution'' *International Economic Review* (1996)37:641–663.

[38] Carruth, A., Dickerson, A., and Henley, A. (2000) ''What do We Know About Investment Under Uncertainty?'' *Journal of Economic Surveys* (14)2: 119–154.

of such entities and any increased costs for those entities.

The Small Business Administration (SBA) defines small agricultural service firms, which include certifying agents, as those having annual receipts of less than $8,000,000 (13 CFR 121.201). There are currently 78 USDA-accredited certifying agents; based on a query of NOP certified organic operations database, there are approximately 47 certifying agents who are currently involved in the certification of organic dairies. Of those 47 certifiers, 14 are State governments, 2 are county governments, and 1 is a large State university. AMS believes that none of these 17 public entities would meet SBA criterion for small agricultural service firms, but that the 29 other private certifying agents would. While certifying agents are small entities that would be affected by the proposed rule, we do not expect that these certifying agents would incur significant costs as a result of this action. Certifying agents already must comply with the current regulations, *e.g.,* maintaining certification records for organic dairy operations.

For the regulatory flexibility analysis, AMS focused on estimating how different size organic dairy operations (small versus large) would be impacted as a result of purchasing all organic dairy replacement animals. As defined by SBA (13 CFR 121.201), small agricultural producers are those having annual receipts of less than $1,000,000. AMS used this SBA criterion to identify large organic dairy operations, those with cash receipts of more than $1,000,000, and small operations, those with cash receipts of $1,000,000 or less.

Data on the exact shares of organic dairy farms that have sales above and below $1,000,000 are not available. However, ARMS data indicates that the average sales revenue of dairy farms from sales of organic milk and animals is $2,855 per milked cow, a figure that indicates that revenues exceed $1,000,000 for farms with more than 350 head.

Within the 2016 ARMS data, 90 percent of dairy farms (300 of the 332) had fewer than 200 milking animals. Lacking more detailed information, we assume that 92 percent of all organic dairy farms (or 2,354 of 2,559) qualify as small businesses under the SBA standard. We also assume that these farms purchase replacement heifers in the same pattern as the average farm with 200 or fewer head. In this case, small organic dairy farms purchase 0.7 replacement heifers on average, with the 11.3 percent of small farms that purchase replacement heifers buying 6.6 head on average. In contrast, large organic dairy farms purchase 0.8 replacement heifers on average, with the 6.8 percent of large farms that purchase replacement heifers buying 12.3 head on average.

For this cost analysis, we assumed that the difference in cost between transitioned replacement heifers and organic (from last third of gestation) replacement heifers is currently $1,000 per head, that half of organic replacement heifers currently purchased are transitioned, and that the increased demand for organic replacement heifers raises their price by $500. Based on our analysis, AMS estimates that, under the proposed rule, small operations would collectively spend an additional $1,312,317 to $1,749,756 for heifers. Large operations would collectively pay an additional $128,649 to $171,532 for heifers. Of the operations that purchase heifers, the average additional cost per operation in the 50 percent price increase scenario would be $4,926 to $6,569 for small operations and $9,247 to $12,330 for large operations.[39] AMS notes that this analysis assumed that there is no difference in the cost per head paid by large and small operations for purchases of replacement heifers and that these costs estimates do not include transfers.[40] Table 7 summarizes the cost analysis using SBA criterion for small businesses (*i.e.,* producers with less than $1,000,000 in cash receipts).

TABLE 7—COST OF ORGANIC REPLACEMENT HEIFERS BY SBA CRITERION FOR SMALL BUSINESSES

	Small operations (<$1,000,000)	Large operations (> = $1,000,000)
Total cost (all operations)	$1,312,317–$1,749,756	$128,649–$171,532
Per operation purchasing replacement heifers (25% to 50% transitioned replacements)	$4,926–$6,569	$9,247–$12,330

To understand the potential costs in context, we used the higher average cost estimate per operation from Table 7 for the purchase of organic replacement heifers (*i.e.,* $6,569 for small; $12,330 for large) and compared it to the average gross cash farm income for farms with 200 head or fewer and for farms with more than 200 head using a revenue estimate from ARMS data that farms earn $2,855 per head. Of farms with 200 head or fewer and $158,003 in sales on average, the 11.3 percent of farms purchasing replacement heifers will have their costs increase 4.2 percent on average. Of large farms with more than 200 head and $1,683,366 in revenue, the 12.33 percent purchasing replacement heifers will see costs increase by 0.7 percent.

It is important to note that these cost figures do not include the potential offsetting effect of transfers, or increased revenue from replacement heifer sales as organic replacement heifer prices increase. This revenue is recorded as a transfer in the benefit-cost analysis.

If implemented, the proposed rule would, as discussed in the benefits portion of RIA, ensure that consumer expectations are met and support the market for these organic products. AMS believes that the long-term economic impact on producers of not implementing the proposal would be greater than the economic impact of a rule due to the need for greater consistency in applying the origin of livestock standard across the organic dairy sector.

AMS has not identified any relevant Federal rules that are currently in effect that duplicate, overlap, or conflict with the proposed rule. The proposed action would provide additional clarity on the origin of livestock requirements that are specific and limited to the USDA organic regulations.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2021–09978 Filed 5–11–21; 8:45 am]

BILLING CODE P

[39] Small operations making purchases buy 6.57 heifers and will pay $1,000 more for half those animals and $2,000 on the others. Large operations making purchases buy 12.33 heifers and will also pay $1,000 more for half those animals and $2,000 on the others.

[40] As with the Table 5 costs breakout by operation size, total costs in Table 7 ($1.440 million and $1.921 million under the 25 and 50 percent transitioning scenarios) roughly equal the Table 4 estimates of costs net of transfers ($1.463 million and $1.950 million). Discrepancies are attributed to rounding errors.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 993

[Doc. No. AMS–SC–20–0104; SC21–993–1 PR]

Dried Prunes Produced in California; Increased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement a recommendation from the Prune Marketing Committee (Committee) to increase the assessment rate established for the 2020–21 and subsequent crop years. The proposed assessment rate would remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Comments must be received by June 11, 2021.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; or internet: *https://www.regulations.gov*. Comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *https://www.regulations.gov*. All comments submitted in response to this rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Bianca Bertrand, Management and Program Analyst, or Andrew Hatch, Acting Director, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (559)356–8202 or email: *BiancaM.Bertrand@usda.gov* or *Andrew.Hatch@usda.gov*.

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or email: *Richard.Lower@usda.gov*.

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, proposes to amend regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposed rule is issued under Marketing Agreement and Order No. 993, as amended (7 CFR part 993), regulating the handling of dried prunes produced in California. Part 993 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the Order and is comprised of producers and handlers of dried prunes operating within the production area, and a public member.

The Department of Agriculture (USDA) is issuing this proposed rule in conformance with Executive Orders 13563 and 13175. In accordance with Executive Order 13175, AMS has not identified any tribal implications as a result of this proposed rule. This proposed rule falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the Order now in effect, California dried prune handlers are subject to assessments. Funds to administer the Order are derived from such assessments. It is intended that the assessment rate would be applicable to all assessable dried prunes for the 2020–21 crop year and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed no later than 20 days after the date of the entry of the ruling.

This proposed rule would increase the assessment rate from $0.25 per ton of salable dried prunes, the rate that was established for the 2019–20 and subsequent crop years, to $0.28 per ton of salable dried prunes for the 2020–21 and subsequent crop years.

The Order authorizes the Committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members are familiar with the Committee's needs and with the costs of goods and services in their local area and are in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2019–20 and subsequent crop years, the Committee recommended, and USDA approved, an assessment rate of $0.25 per ton of salable dried prunes. That assessment rate continues in effect from crop year to crop year unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other information available to USDA.

The Committee met on December 10, 2020, and unanimously recommended expenditures of $24,550 and an assessment rate of $0.28 per ton of salable dried prunes handled for the 2020–21 and subsequent crop years. In comparison, last year's budgeted expenditures were $24,500. The proposed assessment rate of $0.28 is $0.03 higher than the rate currently in effect. The Committee recommended increasing the assessment rate due to a smaller crop, and to provide adequate income along with carryforward/contingency funds and interest income to cover all of the Committee's budgeted expenses for the 2020–21 crop year.

The major expenditures recommended by the Committee for the 2020–21 crop year include $13,700 for personnel expenses, and $10,850 for operating expenses. Budgeted expenses for these items for the 2019–20 crop year were $13,300 for personnel expenses, and $11,200 for operating expenses.

The Committee derived the recommended assessment rate by considering anticipated expenses, and an estimated crop of 50,000 tons of salable dried prunes. Income derived from handler assessments, calculated at $14,000 (50,000 tons salable dried prunes multiplied by $0.28 assessment rate), along with carryforward/contingency funds and interest income ($11,682), would be adequate to cover budgeted expenses of $24,550.

The assessment rate proposed in this rule would continue in effect indefinitely unless modified, suspended, or terminated by USDA

upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate would be in effect for an indefinite period, the Committee will continue to meet prior to or during each crop year to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA would evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Committee's 2020–21 crop year budget, and those for subsequent crop years, would be reviewed and, as appropriate, approved by USDA.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this proposed rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 800 producers of dried prunes in the production area and 20 handlers subject to the regulation under the Order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts of less than $1,000,000, and small agricultural service firms have been defined as those whose annual receipts are less than $30,000,000 (13 CFR 121.201).

According to the National Agricultural Statistics Service (NASS), the national average producer price for California dried prunes for the 2019–20 crop year was $1,510 per ton. Committee data indicates that the California dried prune total production was 110,000 tons in the 2019–20 crop year. The total 2019–20 crop year value of California dried prunes was $166,100,000 (110,000 tons times $1,510 per ton equals $166,100,000). Dividing the crop value by the estimated number of producers (800) yields an estimated average receipt per producer of $207,625.

According to USDA Market News data, the reported terminal price for 2019 for California dried prunes ranged between $30.02 to $32.59 per 28-pound carton. The average of this range is $31.31 ($30.02 plus $32.59 divided by 2 equals $31.31). Dividing the average value by the 28-pound carton yields an estimated average price per pound of $1.12 ($31.31 average value for 28-pound carton divided by 28). The handler price for prunes is $2,240 per ton ($1.12 per pound multiplied by 2000 pounds per ton equals $2,240 per ton). Multiplying the 2019–20 California dried prune total production of 110,000 tons by the estimated average price per ton of $2,240 equals $246,400,000.

Dividing this figure by 20 regulated handlers yields estimated average annual handler receipts of $12,320,000. Therefore, using the above data, the majority of producers and handlers of California dried prunes may be classified as small entities.

As noted above, the average price received per ton by producers in the preceding crop year was $1,510 per ton of salable dried prunes. Given the estimated tonnage of 50,000 tons salable dried prunes for the 2020–21 crop year, the total producer revenue is estimated to be $75,500,000. The total assessment revenue is expected to be $14,000 (50,000 tons multiplied by $0.28 per ton). Thus, the total assessment revenue compared to total producer revenue is 0.019 percent.

This proposal would increase the assessment rate collected from handlers for the 2020–21 and subsequent crop years from $0.25 to $0.28 per ton of salable California dried prunes. The Committee unanimously recommended 2020–21 expenditures of $24,550 and an assessment rate of $0.28 per ton of salable dried prunes. The proposed assessment rate of $0.28 per ton salable dried prunes is $0.03 higher than the current rate. The volume of assessable dried prunes for the 2020–21 crop year is estimated to be 50,000 tons. Thus, the $0.28 per ton of salable dried prunes should provide $14,000 in assessment income (50,000 multiplied by $0.28). Income derived from handler assessments, along with carryforward/contingency funds and interest income, would be adequate to cover budgeted expenses for the 2020–21 crop year.

The major expenditures recommended by the Committee for the 2020–21 crop year include $13,700 for personnel expenses, and $10,850 for operating expenses. Budgeted expenses for these items in the 2019–20 crop year were $13,300, and $11,200 respectively.

The Committee recommended increasing the assessment rate due to a smaller crop, and to provide adequate income along with carryforward/contingency funds and interest income to cover the Committee's budgeted expenses for the 2020–21 crop year. Prior to arriving at this budget and assessment rate recommendation, the Committee discussed various alternatives, including maintaining the current assessment rate of $0.25 per ton of salable dried prunes, and increasing the assessment rate by a different amount. However, the Committee determined that the recommended assessment rate, along with carryforward/contingency funds and interest income would fund budgeted expenses.

This proposed rule would increase the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to producers. However, these costs would be offset by the benefits derived by the operation of the Order.

The Committee's meeting was widely publicized throughout the California prune industry. All interested persons were invited to attend the meeting and encouraged to participate in Committee deliberations on all issues. Like all Committee meetings, the December 10, 2020, meeting was a public meeting, and all entities, both large and small, were able to express views on this issue. Interested persons are invited to submit comments on this proposed rule, including the regulatory and information collection impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0178, Vegetable and Specialty Crops. No changes in those requirements would be necessary as a result of this proposed rule. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would not impose any additional reporting or recordkeeping requirements on either small or large California prune handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *https://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 30-day comment period is provided to allow interested persons to respond to this proposed rule. All written comments timely received will be considered before a final determination is made on this matter.

List of Subjects in 7 CFR Part 993

Marketing agreements, Plum, Prunes, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 993 is proposed to be amended as follows:

PART 993—DRIED PRUNES PRODUCED IN CALIFORNIA.

■ 1. The authority citation for 7 CFR part 993 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 993.347 is revised to read as follows:

§ 993.347 Assessment rate.

On and after August 1, 2020, an assessment rate of $0.28 per ton of salable dried prunes is established for California dried prunes.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2021–10018 Filed 5–11–21; 8:45 am]

BILLING CODE 3410–02–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[NRC–2018–0290]

RIN 3150–AK22

American Society of Mechanical Engineers 2019–2020 Code Editions; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule; correction.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is correcting a notice that was published in the **Federal Register** on March 26, 2021, regarding its proposed amendment to the regulations to incorporate by reference the 2019 Editions of the American Society of Mechanical Engineers Boiler and Pressure Vessel Code and the 2020 Edition of the American Society of Mechanical Engineers Operation and Maintenance of Nuclear Power Plants, Division 1: OM Code: Section IST, for nuclear power plants. This action is necessary to correct several typographical errors.

DATES: The correction takes effect on May 12, 2021.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2018–0290. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Victoria V. Huckabay, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–5183, email: *Victoria.Huckabay@nrc.gov;* or Keith Hoffman, Office of Nuclear Reactor Regulation, telephone: 301–415–1294, email: *Keith.Hoffman@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION: In the **Federal Register** (FR) on March 26, 2021, at 86 FR 16087 in FR Doc. 2021–06085, the following corrections are made:

1. On page 16094, in the second column, under the heading Section 50.55a(b)(2)(xxxii) Section XI Condition: Summary Report Submittal, in the first two sentences, the two occurrences of the phrase ''repair replacement activities'' are corrected to read ''repair/replacement activities.''

2. On page 16102, in the third column, under the heading *Overall Backfitting Considerations: Section XI of the ASME BPV Code and the ASME OM Code,* in the first paragraph, the last sentence is corrected to read ''In this rulemaking, the NRC's proposal to eliminate some older Section XI editions and addenda from the regulations would not be a backfit because the editions and addenda of codes being removed are no longer in use or available for use by licensees.''

3. On page 16103, in the second column, under the heading *ASME BPV Code, Section XI,* item 1, the first sentence is corrected to read ''Revise § 50.55a(a)(1)(ii) to remove the incorporation by reference of the 1975 Winter Addenda, 1976 Summer Addenda, 1976 Winter Addenda, and the Division 1 1977 Edition through 1994 Addenda and 1998 Edition through 2000 Addenda because they incorporate by reference older editions and addenda of Section XI that are no longer in use or available for use by licensees.''

4. On page 16110, in the third column, in the middle of the column, paragraph (b)(2)(xviii)(D)(*1*), is corrected to read ''(*1*) As an alternative to Note (c) in Table VII–4110–1 of ASME BPV Code, Section XI, 2010 Edition, the 250 hours of Level I experience time may be reduced to 175 hours, if the experience time includes a minimum of 125 hours of field experience and 50 hours of

laboratory practice beyond the requirements for training in accordance with Appendix VII Subarticle 4220, provided those practice hours are dedicated to the Level I or Level II skill areas as described in ANSI/ASNT CP–189.''

5. On page 16111, in the second column, in the middle of the column, in paragraph (b)(2)(xxv)(A), *Mitigation of defects by modification: First person,* the paragraph heading is corrected to read ''*Mitigation of defects by modification: First provision*''.

6. On page 16112, in the second column, near the bottom of the column, in paragraph (b)(2)(xliii), *Section XI condition: Section XI Condition: Regulatory Submittal Requirements,* the paragraph heading is corrected to read ''*Section XI Condition: Regulatory Submittal Requirements*''.

Dated: May 5, 2021.

For the Nuclear Regulatory Commission.

Cindy K. Bladey,

Chief, Regulatory Analysis and Rulemaking Support Branch, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2021–09997 Filed 5–11–21; 8:45 am]

BILLING CODE 7590–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2020–0412; FRL–10023–85–Region 5]

Air Plan Approval; Michigan; Part 18 and Part 19 Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve Michigan Department of Environment, Great Lakes, and Energy (EGLE) promulgated revisions to its Part 18 Prevention of Significant Deterioration of Air Quality rule and the Part 19 New Source Review for Major Sources Impacting Nonattainment Areas rule. The revisions made to Parts 18 and 19 were adopted to ensure consistency with Federal rule language and other parts of the Michigan air quality rules. The proposed rule changes are administrative and are intended to provide clarity to the already approved rule language.

DATES: Comments must be received on or before June 11, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2020–0412 at *http://www.regulations.gov* or via email to *damico.genevieve@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically 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, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: YeChan Lim, Environmental Engineer, Air Permits Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–7259, *lim.yechan@epa.gov.* The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19.

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives such comments, the direct final rule will be withdrawn, and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: May 7, 2021.

Cheryl Newton,

Acting Regional Administrator, Region 5.

[FR Doc. 2021–10043 Filed 5–11–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 21–177; RM–11904; DA 21–461; FR ID 26049]

Television Broadcasting Services Redding, California

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission has before it a petition for rulemaking filed by Sinclair Media Licensee, LLC (Petitioner), the licensee of KRCR–TV (ABC), channel 7, Redding, California. The Petitioner requests the substitution of channel 15 for channel 7 at Redding, California in the DTV Table of Allotments.

DATES: Comments must be filed on or before June 11, 2021 and reply comments on or before June 28, 2021.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 45 L Street NE, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for the Petitioner as follows: Paul A. Cicelski, Esq., Lerman Senter, PLLC, 2001 L Street NW, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Shaun Maher, Media Bureau, at (202) 418–2324; or Shaun Maher, Media Bureau, at *ShaunMaher@fcc.gov*.

SUPPLEMENTARY INFORMATION: In support of its channel substitution request, the Petitioner states that the Commission has recognized that VHF channels have certain propagation characteristics which may cause reception issues for some viewers, and also that the reception of VHF signals requires larger antennas, that are generally not well suited to the mobile applications expected under flexible use, relative to UHF channels. According to the Petitioner, KRCR has received numerous

complaints from viewers unable to receive an over-the-air signal, despite being able to receive signals from other stations. In addition, the Petitioner submitted an analysis, using the Commission's *TVStudy* software analysis program, demonstrating that the proposed channel change from channel 7 to 15 would result in a minimal loss of service to only 299 people currently predicted to receive KRCR's signal. In addition, the Petitioner states that KRCR's proposed channel 15 facility is predicted to serve a total of 517,605 people, a net gain of 30,175 potential viewers over the existing KRCR channel 7 licensed facility.

This is a synopsis of the Commission's *Notice of Proposed Rulemaking,* MB Docket No. 21–177; RM–11904; DA 21–461, adopted April 21, 2021, and released April 21, 2021. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats (braille, large print, computer diskettes, or audio recordings), please send an email to *FCC504@fcc.gov* or call the Consumer & Government Affairs Bureau at (202) 418–0530 (VOICE), (202) 418–0432 (TTY).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

Members of the public should note that all *ex parte* contacts are prohibited from the time a Notice of Proposed Rulemaking is issued to the time the matter is no longer subject to Commission consideration or court review, *see* 47 CFR 1.1208. There are, however, exceptions to this prohibition, which can be found in § 1.1204(a) of the Commission's rules, 47 CFR 1.1204(a).

See §§ 1.415 and 1.420 of the Commission's rules for information regarding the proper filing procedures for comments, 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Proposed Rule

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICE

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

■ 2. In § 73.622 in paragraph (i), amend the Post-Transition Table of DTV Allotments under California by revising the entry for Redding to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(i) * * *

Community	Channel No.
* * * * *	
California	
* * * * *	
Redding	*9, 15.
* * * * *	

[FR Doc. 2021–10022 Filed 5–11–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 21–155; RM–11900; DA 21–436; FR ID 22597]

Television Broadcasting Services Medford, Oregon

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission has before it a petition for rulemaking filed by KTVL Licensee, LLC (Petitioner), the licensee of KTVL (CBS), channel 10, Medford, Oregon. The Petitioner requests the substitution of channel 16 for channel 10 at Medford, Oregon in the DTV Table of Allotments.

DATES: Comments must be filed on or before June 11, 2021 and reply comments on or before June 28, 2021.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 45 L Street NE, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for the Petitioner as follows: Paul A. Cicelski, Esq., Lerman Senter, PLLC, 2001 L Street NW, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Andrew Manley, Media Bureau, at (202) 418–0596; or Andrew Manley, Media Bureau, at Andrew *Manley@fcc.gov.*

SUPPLEMENTARY INFORMATION: In support of its channel substitution request, the Petitioner states that the reception of VHF signals require larger antennas relative to UHF channels, and that studies suggest a large variability in indoor antennas, with most receiving fairly well at UHF and the substantial majority not so well to very poor for high-VHF channels. Petitioner further states that KTVL has received numerous complaints from viewers unable to receive that Station's over-the-air signal, despite being able to receive signals from other stations. In its Amended Engineering Exhibit, the Petitioner demonstrated that while the proposed channel 16 noise limited contour does not completely encompass the channel 10 noise limited contour, there are three other CBS affiliated stations that serve all but 9,355 persons in the noise limited contour loss area. The Petitioner also submitted an analysis, using the Commission's *TVStudy* software analysis program, demonstrating that after taking into account service provided by other CBS stations, all of the population located within KTVL's channel 10 noise limited contour will continue to receive CBS service, resulting in no loss of network service.

This is a synopsis of the Commission's *Notice of Proposed Rulemaking,* MB Docket No. 21–155; RM–11900; DA 21–436, adopted April 16, 2021, and released April 16, 2021. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats (braille, large print, computer diskettes, or audio recordings), please send an email to *FCC504@fcc.gov* or call the Consumer & Government Affairs Bureau at (202) 418–0530 (VOICE), (202) 418–0432 (TTY).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C.

3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

Members of the public should note that all *ex parte* contacts are prohibited from the time a Notice of Proposed Rulemaking is issued to the time the matter is no longer subject to Commission consideration or court review, *see* 47 CFR 1.1208. There are, however, exceptions to this prohibition, which can be found in Section 1.1204(a) of the Commission's rules, 47 CFR 1.1204(a).

See Sections 1.415 and 1.420 of the Commission's rules for information regarding the proper filing procedures for comments, 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan

Chief of Staff, Media Bureau.

Proposed Rule

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICE

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

§ 73.622 [Amended]

■ 2. In § 73.622 in paragraph (i), amend the Post-Transition Table of DTV Allotments under Oregon by revising the entry for Medford to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(i) * * *

Community	Channel No.
* * * * *	
Oregon	
* * * * *	
Medford	5, *8, 12, 16, 26
* * * * *	

[FR Doc. 2021–10062 Filed 5–11–21; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Parts 531 and 533

[Docket No. NHTSA–2021–0030]

RIN 2127–AM33

Corporate Average Fuel Economy (CAFE) Preemption

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes to repeal ''The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule Part One: One National Program,'' published Sept. 27, 2019 (SAFE I Rule), in which NHTSA codified regulatory text and made additional pronouncements regarding the preemption of state and local laws related to fuel economy standards. Specifically, this document proposes to fully repeal the regulatory text and appendices promulgated in the SAFE I Rule. In addition, this document proposes to repeal and withdraw the interpretative statements made by the Agency in the SAFE I Rule preamble, including those regarding the preemption of particular state Greenhouse Gas (GHG) Emissions standards or Zero Emissions Vehicle (ZEV) mandates. As such, this document proposes to establish a clean slate with respect to NHTSA's regulations and interpretations concerning preemption under the Energy Policy and Conservation Act (EPCA).

DATES: Comments must be received by June 11, 2021.

ADDRESSES: You may submit comments to the docket number identified in the heading of this document by any of the following methods:

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

FOR FURTHER INFORMATION CONTACT: Hunter B. Oliver, Office of Chief Counsel, NHTSA, telephone (202) 366–5263, facsimile (202) 366–3820, 1200 New Jersey Ave., SE. Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Table of Contents

A. Public Participation
B. Executive Summary
C. Statutory and Regulatory Background
D. Reconsideration Authority
E. Proposed Repeal of Regulations in the SAFE I Rule
F. Proposed Repeal of Preemption Interpretations in the SAFE I Rule
G. Repealing the Regulations and Positions Announced in the SAFE I Rulemaking Remains Appropriate Even if NHTSA Possessed the Authority for the Rulemaking
H. Rulemaking Analyses and Notices
1. Executive Order 12866, Executive Order 13563, and DOT Regulatory Policies and Procedures
2. Regulatory Flexibility Act
3. Executive Order 13132 (Federalism)
4. Unfunded Mandates Reform Act of 1995
5. National Environmental Policy Act
6. Executive Order 12988 (Civil Justice Reform)
7. Paperwork Reduction Act
8. Privacy Act

A. Public Participation

NHTSA requests comment on all aspects of this proposed rule. This section describes how you can participate in this process.

(1) How do I prepare and submit comments?

Your comments must be written. To ensure that your comments are correctly filed in the docket, please include the docket number NHTSA–2021–0030 in your comments. If you are submitting comments electronically as a PDF (Adobe) file, we ask that the documents submitted be scanned using the Optical Character Recognition (OCR) process, thus allowing NHTSA to search and copy certain portions of your submissions.[1] Please note that pursuant to the Data Quality Act, in order for the substantive data to be relied upon and used by NHTSA, it must meet the information quality standards set forth in the Office of Management and Budget (OMB) and Department of Transportation (DOT) Data Quality Act guidelines. Accordingly, we encourage you to consult the guidelines in preparing your comments. OMB's guidelines may be accessed at *https://www.whitehouse.gov/omb/information-*

[1] OCR is the process of converting an image of text, such as a scanned paper document or electronic fax file, into computer-editable text.

regulatory-affairs/information-policy/. DOT's guidelines may be accessed at *https://www.transportation.gov/dot-information-dissemination-quality-guidelines.*

(2) Tips for Preparing Your Comments

When submitting comments, please remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified in the **DATES** section above.

(3) How can I be sure that my comments were received?

If you submit your comments by mail and wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

(4) How do I submit confidential business information?

If you wish to submit any information under a claim of confidentiality, you should submit your complete submission, including the information you claim to be confidential business information (CBI), to the NHTSA Chief Counsel. When you send a comment containing CBI, you should include a cover letter setting forth the information specified in our CBI regulation.[2] In addition, you should submit a copy from which you have deleted the claimed CBI to the Docket by one of the methods set forth above.

To facilitate social distancing due to COVID–19, NHTSA is treating electronic submission as an acceptable method for submitting CBI to the Agency under 49 CFR part 512. Any CBI submissions sent via email should be sent to an attorney in the Office of Chief Counsel at the address given above under **FOR FURTHER INFORMATION CONTACT**. Likewise, for CBI submissions via a secure file transfer application, an attorney in the Office of Chief Counsel must be set to receive a notification when files are submitted and have access to retrieve the submitted files. At this time, regulated entities should not send a duplicate hardcopy of their electronic CBI submissions to DOT headquarters.

Please note that these modified submission procedures are only to facilitate continued operations while maintaining appropriate social distancing due to COVID–19. Regular procedures for part 512 submissions will resume upon further notice, when NHTSA and regulated entities discontinue operating primarily in telework status.

If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

(5) How can I read the comments submitted by other people?

You may read the materials placed in the docket for this document (*e.g.,* the comments submitted in response to this document by other interested persons) at any time by going to *http://www.regulations.gov.* Follow the online instructions for accessing the dockets. You may also read the materials at the NHTSA Docket Management Facility by going to the street addresses given above under **ADDRESSES**.

B. Executive Summary

In September 2019, NHTSA and the Environmental Protection Agency (EPA) finalized a joint agency action relating to the state regulation of GHG emissions from motor vehicles and ZEV mandates. In that action, NHTSA codified numbered regulatory text that repeated the existing statutory provisions and, in codified appendices, expressly declared that certain types of state regulation were preempted due to a perceived irreconcilable conflict with the Agency's fuel economy standards. In addition, the Agency made further statements throughout the rule's preamble that attempted to categorically label existing state regulations—particularly those from the State of California—as preempted under the codified regulations and associated statutory text. As part of the SAFE I action, EPA also revoked a waiver that EPA had previously extended to the State of California, under Section 209 of the Clean Air Act, to regulate motor vehicle emissions through GHG standards and a ZEV mandate.[3]

The SAFE I Rule represented the first time, in the nearly 50-year history of the CAFE program, that NHTSA had adopted regulations expressly defining the Agency's views on the scope of preemption of state laws that relate to fuel economy. Until 2019, the self-executing express preemption provisions in the governing fuel economy statute, 49 U.S.C. 32919, had always provided the sole codified language on CAFE preemption. Since this statutory language is self-executing, Federal courts, as well as Federal agencies, states, and local governments,[4] had come to understand the fundamental operation of CAFE preemption and applied it on a case-by-case basis, resulting in the development of a significant body of case law, without the need for any corresponding regulations from NHTSA.

Nevertheless, NHTSA finalized the SAFE I Rule in 2019 to prevent what the Agency then perceived to be a risk of regulatory uncertainty and disharmony resulting from an overlap in state motor vehicle GHG emissions regulations and ZEV mandates and NHTSA's fuel economy standards. In an effort to foreclose such perceived instability, NHTSA promulgated regulations that attempted to preempt ''any law or regulation of a State or a political subdivision of a State regulating or prohibiting tailpipe carbon dioxide emissions from automobiles,'' [5] including state GHG standards and ZEV mandates. In the SAFE I Rule, the Agency described the authority for this sweeping act of preemption as primarily drawn from NHTSA's general mandate to establish national fuel economy standards, rather than from any particular delegation of rulemaking authority in Section 32919.[6] In the same document, EPA withdrew California's then-existing waiver under the Clean

[2] *See* 49 CFR part 512.

[3] This proposed rule is being issued only by NHTSA. As such, to the extent EPA subsequently undertakes an action to reconsider the revocation of California's Section 209 waiver, such action would occur through a separate, independent proceeding.

[4] For ease of reference, unless otherwise distinguished herein, the varying levels of State regulatory entities encompassed by the phrase State or a political subdivision of a State are encapsulated in the term ''States'' as used in the remainder of this document.

[5] *See* 49 CFR part 531, app. B (a)(2); 49 CFR part 533, app. B (a)(2).

[6] *See* NHTSA, EPA, The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule Part One: One National Program, Final Rule, 84 FR 51310, 51312 (Sept. 27, 2019) (''To ensure that the fuel economy standards NHTSA adopts constitute the uniform national requirements that Congress intended, NHTSA must address the extent to which State and local laws and regulations are preempted by EPCA.'').

Air Act, relying, in part, on NHTSA's conclusions that those programs were preempted by Section 32919. The final rule was immediately challenged in Federal court by numerous stakeholders, including California, many of whom argued that NHTSA exceeded its authority in promulgating the preemption regulations.[7]

On January 20, 2021, President Biden signed Executive Order 13990, ''Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis,'' which, among other actions, directed DOT and NHTSA to immediately review and consider suspending, revising, or rescinding the SAFE I Rule. Accordingly, NHTSA has conducted a comprehensive review of the SAFE I Rule and, in particular, the legality of and need for the regulations and positions that the Agency announced in the SAFE I Rule. As a result of this review, NHTSA now has substantial doubts about whether the SAFE I Rule was a proper exercise of the Agency's statutory authority with respect to CAFE preemption, particularly as to whether NHTSA had authority to define the scope of EPCA preemption through legislative rules, carrying the force and effect of law. Accordingly, in this document, NHTSA proposes to fully repeal and withdraw the codified regulations, as well as any associated interpretations or views on EPCA preemption contained in the SAFE I Rule, including in the regulatory text of §§ 531.7, 533.7, appendices B to parts 531 and 533, and the Preambles.

First, NHTSA has significant concerns that the regulations finalized in the SAFE I Rule likely exceeded the Agency's rulemaking authority under EPCA. In the final rule, NHTSA codified regulations in the Code of Federal Regulations, which attempted to categorically prohibit certain state programs by proclaiming them preempted under EPCA. However, neither EPCA's express preemption provision nor any other statutory source appears to permit NHTSA to adopt legislative rules implementing express preemption under EPCA. Although NHTSA's administration of EPCA enables the Agency to provide its interpretation of EPCA's preemption provisions, NHTSA appears to lack the authority to conclusively determine the scope or meaning of the EPCA preemption clauses with the force and effect of law. Therefore, NHTSA now has substantial doubts about whether the Agency possessed the authority to issue binding legislative rules on the issue of EPCA preemption. Accordingly, NHTSA proposes to withdraw the regulatory text finalized in the SAFE I Rule. This approach realigns NHTSA to its historical practice: For the entire history of the program until SAFE I was finalized, NHTSA had administered the CAFE program without codifying any such preemption regulations.

In addition, to the extent that the Preambles in the SAFE I Rule contained interpretative views that would not be repealed if the Agency rescinded the codified text, NHTSA is also proposing to withdraw those positions. The Agency believes that withdrawing and repealing these statements is appropriate to reaffirm the proper scope of NHTSA's preemption authority and to remove the uncertainty created by the SAFE I rule. Thus, the Agency proposes to categorically repeal both the codified regulatory text and the interpretative views contained in the SAFE I rule.[8] Similarly, to the extent other NHTSA Preambles, which preceded the SAFE I Rule, also espoused views directly defining EPCA preemption under Section 32919 or the Agency's role in such preemption, NHTSA proposes to withdraw and repeal those statements as well.[9] If finalized, the Agency believes that this proposal would restore a clean slate for the Agency's position on EPCA preemption, which the Agency views as a necessary step to ensure that such prior statements do not overstate NHTSA's authority with respect to EPCA preemption issues.

In addition, this approach will ensure that any overstated or legally tenuous statements from the SAFE I Rule do not impede NHTSA from carefully reassessing its substantive views on EPCA preemption and, if warranted, to subsequently announce those views in a new setting. Restoring a clean slate is critical because the Agency now has significant doubts about the accuracy and prudence of the substantive views espoused in the SAFE I rulemaking, including the validity of the preemption analysis and the manner in which it failed to account for a variety of considerations, including factual circumstances specific to policies that would be affected by the Rule and important federalism interests.

Finally, even if NHTSA had authority to issue binding legislative rules on preemption, NHTSA still proposes to fully repeal and withdraw both these regulations and any interpretative positions. After observing the SAFE I Rule's effect on interested stakeholders, ranging from states, regulated entities, and the public, and considering the temporally-limited and program-specific factual predicates underlying NHTSA's prior assertion of permanent and comprehensive preemption, NHTSA no longer believes that the Agency must or should expressly regulate preemption with the force and effect of law. As such, the Agency prefers for its codified regulations to return to a state of silence regarding EPCA preemption, particularly as the views on preemption expressed in the Appendices and preamble no longer necessarily reflect the views of the Agency on these questions.[10] NHTSA may decide to issue interpretations or guidance at a later point, if warranted, after further consideration.

C. Statutory and Regulatory Background

In 1975, Congress enacted the Energy Policy and Conservation Act (EPCA), which among other goals, sought to

[7] *See generally Union of Concerned Scientists, et al.* v. *NHTSA, et al.,* No. 19–1230 (D.C. Cir.) (on February 8, 2021, the D.C. Circuit granted the Agencies' motion to hold the case in abeyance in light of the reconsideration of the SAFE I action).

[8] The Agency anticipates that many stakeholders may comment, urging the Agency to go further—not merely to repeal the preemption determination, but to affirmatively announce a view that State GHG and ZEV programs are not preempted under EPCA. Nevertheless, the Agency deems any such conclusions as outside the scope of this Proposal. When an agency determines that its past action transcends the legally permissible scope, the agency is obliged to realign its regulatory activities to its properly authorized scope posthaste. *See, e.g., EME Homer City Generation, L.P.* v. *E.P.A.,* 795 F.3d 118, 134 (D.C. Cir. 2015) (noting the need for a corrective rulemaking following a determination that a prior rulemaking exceeded the agency's statutory authority). A repeal is the fastest way to do so and is appropriate in this context, as explained below. Reassessing the scope of preemption under EPCA and announcing new interpretative views regarding Section 32919 entails a more substantive inquiry that necessitates additional consideration and deliberation. While NHTSA may decide to undertake such a deliberation in the future, the Agency's imminent concern is realigning its regulatory statements to their legally proper scope and removing the uncertainty caused by the SAFE I rule.

[9] For instance, NHTSA has particularly identified the Preambles cited at the end of this footnote as containing such statements. NHTSA seeks public comments on whether there are additional preamble statements that contain related statements, which should be included in this list. To be clear though, the Agency is proposing to withdraw all of such statements that may appear in prior NHTSA Preambles, regardless of whether they are expressly cited herein. *See, e.g.,* DOT, NHTSA, Light Truck Average Fuel Economy Standards Model Years 2005–07, Final Rule, 68 FR 16868, 16895 (Apr. 7, 2003) (describing NHTSA's views on EPCA preemption in the preamble to a final rule setting CAFE standards); DOT, NHTSA, Average Fuel Economy Standards for Light Trucks Model Years 2008–2011; Final Rule, 71 FR 17566, 17654 (Apr. 6, 2006) (describing NHTSA's views of EPCA preemption in the preamble to a final rule setting CAFE standards).

[10] As the codified text in §§ 531.7 and 533.7 simply repeats the statute, those provisions cannot be considered to convey any distinct meaning from the verbatim language of Section 32919.

''conserve energy supplies through energy conservation programs, and where necessary, the regulation of certain energy uses.'' [11] Congress included the ''improved energy efficiency of motor vehicles'' among the energy conservation and independence objectives specifically enumerated in the Act.[12] To facilitate the enhanced energy efficiency of motor vehicles, EPCA charged the DOT to ''prescribe, by rule, average fuel economy standards'' for various classifications of motor vehicles.[13]

In establishing a statutory framework for fuel economy regulation, Congress incorporated a provision into EPCA that expressly described the preemptive effect of resulting fuel economy standards and requirements.[14] The wording of this provision was slightly modified in a recodification of EPCA in 1994. Overall though, both contemporaneous legislative sources and courts considering fuel economy matters have stressed that ''the 1994 recodification was intended to ''revise[ ], codif[y], and enact[ ]'' the law ''without substantive change.'' [15] As such, EPCA's original express preemption provision remains codified in substantially the same form in 49 U.S.C. 32919. The express language of subsection (a) of Section 32919 provides that ''[w]hen an average fuel economy standard prescribed under this chapter is in effect, a State or a political subdivision of a State may not adopt or enforce a law or regulation related to fuel economy standards or average fuel economy standards for automobiles covered by an average fuel economy standard under this chapter.'' [16] The provision contains an exception, which allows that a State or local government ''may prescribe requirements for fuel economy for automobiles obtained for its own use.'' [17] In addition, when a Federal fuel economy labeling or information requirement is in effect, pursuant to 49 U.S.C. 32908, a State or local government may adopt or enforce an identical requirement on ''disclosure of fuel economy or fuel operating costs.'' [18]

For nearly 50 years after EPCA's enactment, NHTSA's own regulations remained silent regarding the scope or effect of preemption established by Section 32919. The Agency has, on occasion, spoken directly on various aspects of the scope of EPCA preemption in an interpretative or advisory format—most commonly in preambles of CAFE standards rulemakings, as well as in briefings in litigation over specific state or local laws.[19] On multiple occasions throughout the Agency's history, NHTSA has also incorporated an assessment of state motor vehicle emissions programs—including those from California—into the substantive analysis of CAFE standards rulemakings. For instance, these assessments have often occurred through NHTSA's analysis of the regulatory landscape and existing automotive industry practices, which NHTSA considers when assessing the ''maximum feasible'' fuel economy that can be achieved by manufacturers.[20] However, until the SAFE I Rule, NHTSA's commentary on EPCA preemption occurred exclusively in an interpretative context, and the Agency had never established legally binding requirements on states through regulatory text.[21]

Thus, the SAFE I Rule represented the first Agency action to ever finalize and codify rules that purported to create a binding effect on the scope of EPCA preemption. The Agency initially proposed the preemption regulations finalized in the SAFE I Rule as part of the broader joint EPA and NHTSA rulemaking entitled, ''The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021–2026 Passenger Cars and Light Trucks.'' [22] As part of this proposal, EPA also ''propos[ed] to withdraw the waiver granted to California in 2013 for the GHG and ZEV requirements of its Advanced Clean Cars program.'' [23] This proposed rule also encompassed NHTSA's proposed CAFE and EPA's proposed GHG emissions standards for model years 2021–2026 and various regulations regarding administrative aspects of the CAFE and GHG programs.[24] Subsequently, NHTSA and EPA decoupled the NHTSA preemption regulations and EPA's revocation of California's Clean Air Act waiver from the standards rulemaking. The Agencies jointly published the SAFE I Rule on September 27, 2019, with NHTSA finalizing the proposed preemption regulations, and EPA revoking California's waiver. The Agencies later jointly published a separate final rule that set CAFE and GHG emissions standards for model years 2021–2026 passenger cars and light trucks.[25]

The preemption language promulgated by NHTSA in the SAFE I Rule appears in several locations in the CFR: 49 CFR 531.7, appendix B to 49 CFR part 531, 49 CFR 533.7, and appendix B to 49 CFR part 533. The provisions in §§ 531.7 and 533.7, as well as in each appendix B, mirror one another. The only distinction in the two sets of regulations is that part 531 applies to passenger automobiles and part 533 applies to light trucks. Moreover, the language in §§ 531.7 and 533.7 uses nearly verbatim language as the express preemption statutory provision, 49 U.S.C. 32919.[26] Each

[11] The Energy Policy and Conservation Act of 1975, Public Law 94–163, 89 Stat. 871, section 2(4) (''Statement of Purposes'').

[12] *Id.* section 2(5) (''Statement of Purposes'').

[13] *Id.* section 502(3) (''Average Fuel Economy Standards Applicable to Each Manufacturer'').

[14] *Id.* section 509 (''Effect on State Law'').

[15] *Green Mountain Chrysler Plymouth Dodge Jeep* v. *Crombie,* 508 F. Supp. 2d 295, 346 (D. Vt. 2007) (quoting Pub. L. 103–272, 108 Stat. 745, 745 (1994); H.R. Rep. No. 103–180, at 1 (1994), reprinted in 1994 U.S.C.C.A.N. 818, 818; S. Rep. No. 103–265, at 1 (1994)).

[16] 49 U.S.C. 32919(a).

[17] 49 U.S.C. 32919(c).

[18] 49 U.S.C. 32919(b).

[19] *See, e.g.,* DOT, NHTSA, Light Truck Average Fuel Economy Standards Model Years 2005–07, Final Rule, 68 FR 16868, 16895 (Apr. 7, 2003) (describing NHTSA's views on EPCA preemption in the preamble to a final rule setting CAFE standards); DOT, NHTSA, Average Fuel Economy Standards for Light Trucks Model Years 2008–2011; Final Rule, 71 FR 17566, 17654 (Apr. 6, 2006) (describing NHTSA's views of EPCA preemption in the preamble to a final rule setting CAFE standards).

[20] *See, e.g.,* NHTSA, part 533 Average Fuel Economy Standards for Nonpassenger Automobiles, Final Rule, 42 FR 13807, 13814 (Mar. 14, 1977); NHTSA, Light Truck Average Fuel Economy Standards Model Years 2005–2007, Final Rule, 68 FR 16868, 16895 (Apr. 7, 2003).

[21] NHTSA did, in 2008, propose language very similar to that in the SAFE I Rule. *See* NHTSA, Average Fuel Economy Standards, Passenger Cars and Light Trucks; Model Years 2011–2015, Notice of Proposed Rulemaking, 73 FR 24351 (May 2, 2008). However, NHTSA finalized only standards for model year 2011 through that rulemaking action and chose not to finalize the proposed text regarding preemption, explaining that NHTSA ''will re-examine the issue of preemption in the content of its forthcoming rulemaking to establish Corporate Average Fuel Economy standards for 2012 and later model years.'' 74 FR 14196, 14200 (Mar. 30, 2009). NHTSA's subsequent joint rulemakings with EPA prior to the SAFE rule continued to defer substantive consideration of preemption due to the existence of the National Program that involved NHTSA, EPA, and California. *See* 75 FR 25324, 25546 (May 7, 2010); 77 FR 62624, 63147 (Oct. 15, 2012).

[22] *See generally* NHTSA, EPA, The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021–2026 Passenger Cars and Light Trucks, Notice of Proposed Rulemaking, 83 FR 42986 (Aug. 24, 2018).

[23] *Id.* at 42999.

[24] *Id.*

[25] NHTSA, EPA, The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021–2026 Passenger Cars and Light Trucks, Final Rule, 85 FR 24174 (Apr. 30, 2020).

[26] Since the language in 49 CFR 531.7 and 533.7 merely parrots the applicable statutory text, NHTSA questions whether either provision even has a unique effect apart from Section 32919. *See Gonzales* v. *Oregon,* 546 U.S. 243, 257 (2006) (''the existence of a parroting regulation does not change

Continued

appendix B expressly codifies a prohibition on various state activities—particularly those regulating motor vehicle carbon dioxide emissions—that the Agency proclaimed were unlawful due to ''express preemption'' and ''implied preemption.'' [27]

Following the promulgation of the SAFE I Rule, the actions of both NHTSA and EPA were challenged by a number of petitioners in both the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) and the United States District Court for the District of Columbia.[28] The litigation has substantially divided the regulated industry and interested stakeholders, as the D.C. Circuit litigation encompasses ten consolidated petitions brought by a number of states, cities, and environmental organizations challenging the rule. On the other side of the litigation, several automakers, other states, and fuel and petrochemical manufacturers have intervened in support of the rule. In addition to the litigation, one public interest organization, the Chesapeake Bay Foundation, filed a petition for reconsideration with NHTSA following the SAFE I Rule's publication.[29] The Chesapeake Bay Foundation subsequently filed a petition for review in the D.C. Circuit, which challenges NHTSA's denial of this petition for reconsideration.[30] In light of the Agencies' reconsideration of the SAFE I action, the D.C. Circuit granted requests to hold both the consolidated litigation and Chesapeake Bay Foundation's subsequent lawsuit in abeyance.

On January 20, 2021, President Biden signed Executive Order 13990, which directed DOT and NHTSA to immediately undertake an assessment of the SAFE I Rule.[31] Specifically, Executive Order 13990 directed DOT and NHTSA to, ''as appropriate and consistent with applicable law, consider suspending, revising, or rescinding'' the SAFE I Rule.[32] For the SAFE I Rule, the Executive order also instructed that the Agency, ''as appropriate and consistent with applicable law, shall consider publishing for notice and comment a proposed rule suspending, revising, or rescinding the agency action . . . by April 2021.'' [33]

D. Reconsideration Authority

NHTSA, like any other Federal agency, is afforded an opportunity to reconsider prior views and, when warranted, to adopt new positions. Indeed, as a matter of good governance, agencies *should* revisit their positions when appropriate, especially to ensure that their actions and regulations reflect legally sound interpretations of the agency's authority and remain consistent with the agency's views and practices. As a matter of law, ''an Agency is entitled to change its interpretation of a statute.'' [34] Nonetheless, ''[w]hen an Agency adopts a materially changed interpretation of a statute, it must in addition provide a 'reasoned analysis' supporting its decision to revise its interpretation.'' [35]

''Changing policy does not, on its own, trigger an especially 'demanding burden of justification.' '' [36] Providing a reasoned explanation ''would ordinarily demand that [the Agency] display awareness that it *is* changing position.'' [37] Beyond that, however, ''[w]hen an agency changes its existing position, it 'need not always provide a more detailed justification than what would suffice for a new policy created on a blank slate.' '' [38] While the Agency ''must show that there are good reasons for the new policy,'' the Agency ''need not demonstrate to a court's satisfaction that the reasons for the new policy are *better* than the reasons for the old one.'' [39] ''[I]t suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the Agency *believes* it to be better, which the conscious change of course adequately indicates.'' [40] For instance, ''evolving notions'' about the appropriate balance of varying policy considerations constitute sufficiently good reasons for a change in position.[41] Moreover, it is ''well within an Agency's discretion'' to change policy course even when no new facts have arisen: Agencies are permitted to conduct a ''reevaluation of which policy would be better in light of the facts,'' without ''rely[ing] on new facts.'' [42]

NHTSA views this need to reassess its stated positions as particularly appropriate and imperative when the issues either implicate the limits of the Agency's statutory authority or concern positions on critical policy issues that no longer necessarily reflect that agency's views. This is especially important in matters regarding the preemption of state law, given both the federalism interests at stake and because ''agencies have no special authority to pronounce on pre-emption absent delegation by Congress.'' [43] NHTSA believes that upon tentatively determining that legal authority previously claimed likely does not exist, the most responsible and legally essential course of action is for the Agency to exercise its reconsideration authority to explore and, if necessary, rectify the potential overstep. This is the precise action that NHTSA proposes here.

---

the fact that the question here is not the meaning of the regulation but the meaning of the statute''). Based upon the comments received on the SAFE I Rule, on further reflection, NHTSA's view is that this question merely augmented the uncertainty among stakeholders about the scope of EPCA preemption, and further demonstrates that this codification was unnecessary and unhelpful.

[27] *See* 49 CFR part 531, app. B; 49 CFR part 533, app B.

[28] *See generally Union of Concerned Scientists, et al.* v. *NHTSA, et al.,* No. 19–1230 (D.C. Cir.). *See also California* v. *Chao,* No. 19–cv–2826–KBJ (D.D.C.) (filed Sept. 20, 2019).

[29] *See generally* Chesapeake Bay Foundation, Petition for Reconsideration of NHTSA's Final Rule—The Safer Affordable Fuel Efficient (SAFE) Vehicles Rule Part One: One National Program (Nov. 8, 2019).

[30] *See generally Chesapeake Bay Foundation, Inc.* v. *NHTSA,* No. 20–2091 (D.C. Cir.).

[31] Executive Order 13990, *Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis,* 86 FR 7037 (Jan. 25, 2021).

[32] *Id.* at Sec. 2.

[33] *Id.* at Sec. 2–2(ii).

[34] *Phoenix Hydro Corp.* v. *F.E.R.C.,* 775 F.2d 1187, 1191 (D.C. Cir. 1985).

[35] *Alabama Educ. Ass'n* v. *Chao,* 455 F.3d 386, 392 (D.C. Cir. 2006) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc.* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 57 (1983)); *see also Encino Motorcars, LLC* v. *Navarro,* 136 S. Ct. 2117, 2125 (2016) (''Agencies are free to change their existing policies as long as they provide a reasoned explanation for the change.'') (citations omitted).

[36] *See Mingo Logan Coal Co.* v. *E.P.A.,* 829 F.3d 710, 718 (D.C. Cir. 2016) (quoting *Ark Initiative* v. *Tidwell,* 816 F.3d 119, 127 (D.C. Cir. 2016)).

[37] *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009) (emphasis in original) (''An agency may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books.'').

[38] *Encino Motorcars, LLC,* 136 S. Ct. at 2125–26 (quoting *Fox Television Stations, Inc.,* 556 U.S. at 515).

[39] *Fox Television Stations, Inc.,* 556 U.S. at 515 (emphasis in original).

[40] *Id.* (emphasis in original).

[41] *N. Am.'s Bldg. Trades Unions* v. *Occupational Safety & Health Admin.,* 878 F.3d 271, 303 (D.C. Cir. 2017) (quoting the agency's rule). To be sure, providing ''a more detailed justification'' is appropriate in some cases. *See Fox Television Stations, Inc.,* 556 U.S. at 515 (2009) (''Sometimes [the agency] must [provide a more detailed justification than what would suffice for a new policy created on a blank slate]—when, for example, its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account.''). This is not one of those cases: NHTSA's reconsidered understanding of the governing legal framework does not ''rest[ ] upon factual findings that contradict those which underlay its prior policy.'' Moreover, the reconsideration does not undermine ''engendered serious reliance interests that must be taken into account.,'' The uncertainty associated with the SAFE I rulemaking, which is described further herein, has not created an environment in which any interested stakeholders could reasonably rely upon a framework that presupposed the continuance of the SAFE I Rule.

[42] *Nat'l Ass'n of Home Builders* v. *E.P.A.,* 682 F.3d 1032, 1037–38 (D.C. Cir. 2012).

[43] *See Wyeth* v. *Levine,* 555 U.S. 555, 577 (2009).

E. Proposed Repeal of Regulations in the SAFE I Rule

After a comprehensive reconsideration of the SAFE I Rule, NHTSA now has substantial doubts about whether Congress provided the Agency with the authority necessary to engage in legislative rulemaking [44] to define the scope of preemption in 49 U.S.C. 32919.[45] Ultimately, ''agencies have no special authority to pronounce on preemption absent delegation by Congress.'' [46] Neither the language of Section 32919 nor the broader regulatory structure of Chapter 329 provide NHTSA with the authority to promulgate regulations with the force and effect of law on EPCA preemption. Moreover, contrary to the indications in the SAFE I Rule, NHTSA provisionally considers a general delegation of authority to the Secretary to ''carry out'' his ''duties and powers'' to be insufficient to support a legislative rulemaking that expressly administers preemption under Section 32919. Consequently, NHTSA now proposes to conclude that it likely overstepped its authority in issuing binding legislative rules on preemption.[47] Therefore, NHTSA proposes to repeal each of these provisions in full to ensure that its actions are unquestionably within the legally permissible boundaries of the Agency's authority. Repealing these rules would also restore the Agency's previous practice, in which NHTSA did not codify interpretations of EPCA preemption in regulations.

1. NHTSA Is Concerned That the SAFE I Rule's Issuance of Binding, Legislative Rules on EPCA Preemption Exceeded the Agency's Authority

The preemption analysis begins with consideration of the governing statute. However, while EPCA already contains an express preemption provision in Section 32919, the Appendices promulgated in the SAFE I Rule expressed, in more specific terms than Section 32919, precise types of state regulation that would be preempted—namely, state efforts to regulate carbon dioxide emissions from motor vehicles or to establish requirements for ZEVs.[48] These regulations purported to expressly prohibit the conduct in question through their force as Federal regulations.

The Agency has tentatively determined that these regulations are legislative rules, which seek to preempt state regulations in more specific terms than the express preemption provision already present in EPCA. As noted above, Congress included an express preemption provision in EPCA in Section 32919. This statute expressly preempts state laws or regulations ''related to fuel economy standards or average fuel economy standards for automobiles,'' ''when an average fuel economy standard prescribed under [Chapter 329] is in effect.'' [49] Both the Agency and courts have repeatedly understood Section 32919 as self-executing and capable of direct application to state regulatory activity.[50] Specifically, such a direct application involves the consideration of whether the state regulation in question ''relate[s] to'' fuel economy standards established elsewhere in Chapter 329.[51] The statute does not require any supplemental agency regulations to implement this standard, nor does the text and structure of the statute appear to provide NHTSA any special legislative role in dictating the scope of Section 32919's preemption.

Accordingly, NHTSA tentatively believes that the SAFE I Rule, which codified additional binding standards for express EPCA preemption, represented an additional act of express preemption beyond the self-contained language of Section 32919. Through the SAFE I Rule, NHTSA codified four provisions in the CFR, each of which purported to directly regulate the scope of preemption under EPCA. Specifically, NHTSA promulgated 49 CFR 531.7 and 533.7, both of which were nearly verbatim codifications of the statutory text, and an identical appendix B to both parts 531 and 533, which included a description of certain state regulations also described as preempted. None of these provisions instituted any new compliance or enforcement standards relating to NHTSA's CAFE program. Instead, the provisions, by their own terms, solely sought to codify into NHTSA's regulations a binding framework to govern the scope of EPCA preemption.

As the Preamble to the SAFE I Final Rule described, these provisions sought to ''ma[ke] explicit that state programs to limit or prohibit tailpipe GHG emissions or establish ZEV mandates are preempted.'' [52] In announcing the SAFE I Rule, NHTSA repeatedly described the final rules in terms that appeared to confer upon them legally binding connotations. For instance, the Agency noted that through the final rule, ''NHTSA intends to assert preemption'' [53] and characterized the regulations as ''implementing'' [54] a preemption requirement. Subpart ''a'' of each appendix B to parts 531 and 533 even labels the regulatory text as ''Express Preemption'' provisions, before proceeding to categorically assert, in mandatory terms, what types of state laws were preempted.[55] Such a direct declaration of preemption, which purported to carry the force and effect of law, seeks to provide an authoritative interpretation of the language of Section 32919, and the regulations represented an act of legislative rulemaking that attempted to impose more specific, binding requirements on State and local governments. In order to properly engage in such legislative rulemaking, NHTSA must have adequate authority to do so from Congress. However, after reconsidering the matter, NHTSA has substantial doubts about whether it has the requisite authority to validly promulgate such requirements.

[44] As used in this document, the term ''legislative rulemaking'' refers to an agency's authority to promulgate regulations that carry the force and effect of law. *See, e.g., Batterton* v. *Francis,* 432 U.S. 416, 425 (1977) (noting that when a Federal agency promulgates a rule within the scope of its congressionally delegated authority, the agency ''adopts regulations with legislative effect'').

[45] NHTSA, EPA, The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule Part One: One National Program, Final Rule, 84 FR 51310, 51320 (Sept. 27, 2019).

[46] *Wyeth* v. *Levine,* 555 U.S. 555, 577 (2009).

[47] The Agency acknowledges that there may be some potential ambiguity as to whether the SAFE I Rule established binding legislative rules or interpretative rules, as the Agency described the effect of the rule in varying ways in that final rule, particularly in its preamble. As described below, NHTSA believes the SAFE I Rule was intended to be a legislative rule. However, to the extent it is considered an interpretative rule, NHTSA believes it would still be appropriate to rescind the rule for the reasons described in Part F, *infra.*

[48] *See* 49 CFR part 531, app. B; 49 CFR part 533, app. B.

[49] 49 U.S.C. 32919(a).

[50] *See, e.g., Green Mountain Chrysler Plymouth Dodge Jeep,* 508 F. Supp. at 295 (undertaking a detailed analysis of Section 32919 to determine whether state law was preempted under the express language of the statute).

[51] *See Cent. Valley Chrysler-Jeep, Inc.* v. *Goldstene,* 529 F. Supp. 2d 1151, 1175 (E.D. Cal. 2007), as corrected (Mar. 26, 2008) (conducting such an analysis before concluding that preemption did not exist ''[g]iven the narrow scope the court must accord EPCA's ''related to'' language'').

[52] NHTSA, EPA, The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule Part One: One National Program, Final Rule, 84 FR 51310 (Sept. 27, 2019).

[53] *Id.* at 51317.

[54] *Id.* at 51318.

[55] *See, e.g.,* 49 CFR part 533, app. B(a)(2) (''As a law or regulation of a State or a political subdivision of a State related to fuel economy standards, any state law or regulation regulating or prohibiting tailpipe carbon dioxide emissions from automobiles is expressly preempted under 49 U.S.C. 32919.'').

2. Congress Must Have Provided NHTSA With Authority To Engage in Legislative Rulemaking on Matters of EPCA Preemption if That Rulemaking Is To Be Valid

The legitimacy of an agency's exercise of preemption power through legislative rulemaking is principally a question of the extent of authority delegated to the agency. This is because all rulemaking authority of an agency ultimately derives from Congress.[56] As such, ''in a situation where state law is claimed to be pre-empted by Federal regulation, a narrow focus on Congress' intent to supersede state law [is] misdirected.'' [57] Instead, when considering an agency's preemptive authority, ''the inquiry becomes whether the federal agency has properly exercised its own delegated authority rather than simply whether Congress has properly exercised the legislative power.'' [58] Consequently, an agency ''may act only when and how Congress lets [it].'' [59] This restriction extends to all aspects of an agency's regulatory activity—including a rulemaking. The matters upon which an agency may promulgate rules imbued with the force and effect of law are based on its delegated authority.[60]

These limitations particularly apply with respect to matters of preemption. As the Supreme Court has made clear:

> A federal agency may pre-empt state law only when and if it is acting within the scope of its congressionally delegated authority. This is true for at least two reasons. First, an agency literally has no power to act, let alone pre-empt the validly enacted legislation of a sovereign State, unless and until Congress confers power upon it. Second, the best way of determining whether Congress intended the regulations of an administrative agency to displace state law is to examine the nature and scope of the authority granted by Congress to the agency.[61]

Since an agency lacks plenary authority, the delegation of one power to an agency does not necessarily include other powers, even if they are related.[62] This applies even when the authority is analogous. For instance, the D.C. Circuit has rejected an agency's argument ''that it possesses plenary authority,'' holding instead ''that the fact that the Board is empowered'' in a particular circumstance does not ''mean[] the Board therefore enjoys such power in every instance'' in which a similar question arises.[63] Accordingly, construing an agency's authority requires a close examination of the precise power delegated by Congress and how such authority may differ, even if slightly, from other authority that Congress may reserve.

That is, in order for an agency to issue binding rules on preemption, the agency must have the authority to *directly regulate preemption itself,* rather than merely to establish the substantive law that leads to preemption.[64] Therefore, in evaluating an agency's authority to issue legislative rules on preemption, the proper question is whether Congress intended the agency to define, through its binding regulations, when a state law is preempted. Only if Congress has granted an agency that power does the agency have the authority to speak with the force of law directly on preemption. NHTSA's tentative conclusion, as described below, is that Congress does not appear to have granted NHTSA such authority, and that in light of this doubt, the Agency should not have issued such regulations in the first instance.

3. NHTSA Has Substantial Doubts That EPCA Authorizes NHTSA To Issue Legislative Rules on Preemption

EPCA does not appear to expressly provide the authority to DOT or NHTSA to promulgate legislative rules implementing or defining the scope of the statute's preemption. Throughout its rulemakings over the long history of the CAFE program, NHTSA has consistently declined to construe either Section 32919 or any other provision of EPCA as expressly delegating DOT or NHTSA the authority to promulgate preemption regulations. This approach even extends to the SAFE I rulemaking, in which the Agency cited other statutory provisions for its authority to issue the rules.[65] The Agency continues to hold this view of the statute.

Section 32919, the express preemption provision of EPCA, states that ''a State or a political subdivision of a State may not adopt or enforce a law or regulation related to fuel economy standards'' as long as a Federal fuel economy standard is in place.[66] Thus, this preemption provision offers the best evidence of any possible congressional intent to confer preemption rulemaking authority upon NHTSA. However, the provision is notably silent as to any role of the agency in administering—much less defining—a preemption scheme. At most, the statute merely refers to the substantive tasks of the agency to establish ''fuel economy standard[s]'' and ''requirements'' as set forth elsewhere in Chapter 329.[67] Such references only connote the core duties borne by the agency to administer the substance of the fuel economy program, such as by setting ''maximum feasible average fuel economy'' standards under Section 32902 or establishing fuel economy labeling requirements under Section 32908. These responsibilities are within the agency's traditional substantive regulatory functions, which draw from NHTSA's technical automobile expertise rather than any special agency authority over federalism. In the Agency's tentative view, it seems more reasonable to conclude that if Congress had intended to give NHTSA such direct regulatory authority over EPCA preemption, it would have done so explicitly, and likely within Section 32919 or at least in direct reference to preemption.

Thus, the Agency is now of the view that, under the language of Section 32919, the express preemption instituted by the statute is self-executing and self-contained. This is consistent with NHTSA's longstanding reading of Section 32919. For instance, even the Preamble to the SAFE I Final Rule acknowledged that the EPCA preemption provision of Section 32919 was ''self-executing,'' and that ''state or local requirements related to fuel economy standards are void *ab initio*''—by operation of statute not regulation.[68] Likewise, in the National Environmental Policy Act of 1969 (NEPA) section of the SAFE I Rule, NHTSA expressly disclaimed any discretion to alter the preemption paradigm established by Section 32919 due to the self-sufficiency of the statute, stressing that ''[a]ny preemptive effect resulting from this final action is not the result of the exercise of Agency discretion, but rather reflects the operation and application of the Federal statute.'' [69] As such, the

[56] *Cent. United Life Ins. Co.* v. *Burwell,* 827 F.3d 70, 73 (D.C. Cir. 2016).

[57] *City of New York* v. *F.C.C.,* 486 U.S. 57, 64 (1988).

[58] *Id.*

[59] *Cent. United Life Ins. Co.,* 827 F.3d at 73.

[60] *See, e.g., Adams Fruit Co.* v. *Barrett,* 494 U.S. 638, 650 (1990) (determining that a Department of Labor regulation exceeded the scope of authority delegated by a statute the agency administered).

[61] *Louisiana Pub. Serv. Comm'n* v. *F.C.C.,* 476 U.S. 355, 374 (1986).

[62] *Ry. Labor Executives' Ass'n.,* 29 F.3d at 670 (en banc).

[63] *Id.*

[64] *See, e.g., City of New York,* 486 U.S. at 64 (clarifying that ''the correct focus is on the federal agency that seeks to displace state law and on the proper bounds of its lawful authority to undertake such action.'').

[65] *See* NHTSA, EPA, The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule Part One: One National Program, Final Rule, 84 FR 51310, 51320 (Sept. 27, 2019) (citing other statutory provisions applicable to DOT for the requisite rulemaking authority).

[66] 49 U.S.C. 32919.

[67] *See* 49 U.S.C. 32919(a)–(b).

[68] NHTSA, EPA, The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule Part One: One National Program, Final Rule, 84 FR 51310, 51325 (Sept. 27, 2019).

[69] *Id.* at 51353–54.

Agency again characterized any ''preempted standards [as] void *ab initio*'' due to the non-discretionary and independent application of Section 32919.[70] Due to the express language of Section 32919, NHTSA continues to believe that the provisions of Section 32919 are self-executing. Consequently, the Agency has substantial doubts about the validity of its prior conclusion that Congress provided rulemaking authority to the Agency to further codify preemption requirements. In reaching this tentative conclusion, NHTSA notes that the structures of other parts of EPCA, as well as other Federal statutes, expressly charge an agency to administer preemption through regulations, and no such charge exists for NHTSA. For example, a precursor to the Department of Energy, the Federal Energy Administration, was expressly directed elsewhere in EPCA to ''prescribe . . . rule[s]'' that preempt state and local appliance-efficiency standards.[71] Likewise, other DOT statutes expressly provide a regulatory, or even adjudicatory, role for the Department in the preemption analysis. For instance, in the transportation of hazardous materials context, 49 U.S.C. 5125 directs the Secretary to adjudicate applications on whether a particular state standard is ''substantially the same'' as Federal law and, as such, exempted from statutory preemption.[72] Similarly, 49 U.S.C. 31141 establishes a very detailed role for DOT in reviewing and preempting state law pertaining to commercial motor vehicle safety.[73] Many of the seminal cases in the Supreme Court's preemption jurisprudence also concerned statutory schemes that expressly delegated preemption authorities to the agencies in question.[74]

As these other statutory provisions demonstrate, Congress understands how to incorporate legislative rulemaking authority for an agency expressly and directly into a statutory framework for preemption—and, in fact, exercised this prerogative elsewhere in EPCA. These responsibilities range from charging an agency to promulgate clarifying regulations on the applicability of preemption to instructing an agency to establish an administrative procedure to adjudicate exemptions of state law. Moreover, as 49 U.S.C. 31141 demonstrates, when Congress decides to incorporate an agency into the preemption determination process, the grant of authority is often not accomplished through an indeterminate delegation, but instead, through an intricate and comprehensive description of the agency's precise role in administering the preemption provision.

Within this statutory landscape, the total silence of Section 32919 as to any role for NHTSA in the implementation of preemption seems instructive. In this context, it now appears to the Agency that construing Section 32919 to permit NHTSA to issue regulations with the force of law that regulate and define the scope of preemption, as the Agency did in the SAFE I Rule, would be akin to reading an entirely new subsection into the statutory provision. Congress' failure to explicitly provide DOT authority to define or otherwise regulate the scope of CAFE preemption—despite specifically incorporating an express preemption provision into EPCA in Section 32919—casts significant doubts upon the Agency's prior determination that NHTSA has legislative rulemaking authority in matters of fuel economy preemption. NHTSA requests comment on these provisional views.

Finally, contrary to the arguments made in the SAFE I Rule, NHTSA tentatively believes there is no other statutory source conferring legislative rulemaking authority on the Agency in matters of fuel economy preemption. In the SAFE I rulemaking, NHTSA did not claim that its authority to issue preemption regulations derived from Section 32919.[75] Instead, NHTSA concluded that its authority arose implicitly from EPCA, because the Agency argued that it could not carry out its CAFE standard-setting responsibilities in the face of state regulation that undermined its authority.[76] In the SAFE I Final Rule's most direct discussion of the issue of authority to promulgate regulations concerning preemption, NHTSA linked the perceived conflict between EPCA's purposes and state regulation to the general delegation of authority to the Secretary to carry out his duties. Specifically, after describing Section 322 as an express authorization for the Secretary of Transportation ''to prescribe regulations to carry out her duties and powers,'' and noting that Chapter 329 of Title 49 delegated the Secretary's authority to NHTSA for EPCA purposes, the Agency concluded in the SAFE I Rule that it ''ha[d] clear authority to issue this regulation under 49 U.S.C. 32901 through 32903 to effectuate a national automobile fuel economy program unimpeded by prohibited State and local requirements.'' [77] This is because the Agency characterized the rulemaking as simply ''carry[ing] out'' the preemption scope of Section 32919.[78]

Upon reconsideration, NHTSA is concerned that this rationale was improper. Section 322 contains statutory language of broad applicability that extends well beyond the CAFE program and, indeed, well beyond NHTSA. In light of the preceding discussion, it seems especially peculiar to derive preemption authority from Section 322 when EPCA already contains an express preemption provision, which does not provide NHTSA with a role in further defining that preemption with the force and effect of law. Since Congress already crafted a specific provision to describe EPCA preemption in Section 32919, the more general terms of Section 322 would seem of much clearer applicability if Section 32919 had otherwise delegated NHTSA certain authorities or responsibilities to carry out. But as discussed above, Congress did not, in EPCA, appear to charge NHTSA with any authority or responsibility with respect to preemption regulations. Construing Section 322's general terms to independently provide NHTSA with the authority to issue legislative rules on EPCA preemption that override Section 32919's notable silence as to any role for NHTSA would require an extraordinarily expansive reading of Section 322.

Moreover, even apart from Section 322, general inferences drawn from the broad purposes of EPCA do not seem capable of contravening a clear reading

[70] *Id.*

[71] The Energy Policy and Conservation Act of 1975, Public Law 94–163, 89 Stat. 871, section 327(b), recodified as amended at 42 U.S.C. 6297(d).

[72] 49 U.S.C. 5125(d). The Secretary has delegated this responsibility to another DOT operating administration, the Pipeline and Hazardous Materials Safety Administration (PHMSA).

[73] *See* 49 U.S.C. 31141 (expressly stating that ''[a] State may not enforce a State law or regulation on commercial motor vehicle safety that the Secretary of Transportation decides under this section may not be enforced'' before enumerating multiple subsections that define an adjudicatory role for the DOT, complete with preemption standards and procedures). The Secretary has delegated this responsibility to another DOT operating administration, the Federal Motor Carrier Safety Administration (FMCSA).

[74] For example, in a set of cases evaluating the preemption of certain state tort law relating to medical device product liability, the Supreme Court analyzed U.S. Food and Drug Administration (FDA) regulations that specifically defined when preemption occurred under the applicable statute, the Medical Device Amendments (MDA). *See generally Lohr,* 518 U.S. at 470 (plurality opinion); *Riegel* v. *Medtronic, Inc.,* 552 U.S. 312 (2008). *See also* 21 U.S.C. 360k; 21 CFR 808.1.

[75] *See generally* NHTSA, EPA, The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule Part One: One National Program, Final Rule, 84 FR 51310, 51320 (Sept. 27, 2019).

[76] *See, e.g., id.* at 51317.

[77] *Id.* at 51320.

[78] *Id.*

of the express preemption provision in Section 32919. As described above, the SAFE I Rule argued that regulation was needed to resolve a perceived irreconcilable conflict between state GHG emissions regulations and ZEV mandates and EPCA's delegation of authority to NHTSA to set national fuel economy standards.[79] However, even assuming that is true, the statutory provision on preemption provides no role for NHTSA to speak on this issue with the force and effect of law. The Agency does not believe that a proper statutory reading permits this unambiguous silence in Section 32919 to be overridden by intangible inferences extrapolated from EPCA generally.[80]

Likewise, upon reconsideration, NHTSA does not consider any such general inferences as appropriately addressed through the categorical rulemaking actions of the SAFE I Rule. For example, a substantial portion of the SAFE I Rule drew from principles of implied conflict preemption, seeking to label state regulation as preempted due to an irreconcilable conflict with Federal CAFE standards. Moreover, at most, the SAFE I Rule discussed compliance technologies specific to only one example of state standards and one example of Federal standards.[81] Yet the SAFE I Rule sought to extrapolate upon such a limited analysis to justify a pronouncement of preemption for *any* state greenhouse gas standards or ZEV requirements. The Agency now recognizes that implied preemption, which arises primarily in a judicial context, involves principles that are most appropriately applied by reference to specific state programs, rather than in the abstract and categorical manner of the SAFE I Rule's regulations.[82] While NHTSA still retains interpretative authority to set forth its advisory views on whether a state regulation impermissibly conflicts with Federal law, such authority does not support the power to codify binding legislative rules on the matter.

Thus, upon reconsideration, NHTSA has substantial doubts about its authority to issue legislative rules concerning EPCA preemption. Thus, the SAFE I Rule's effort to establish such rules likely exceeded the Agency's authority. For this reason, and for the additional reasons discussed herein, NHTSA is now of the view that the SAFE I Rule rests upon an infirm foundation and should be repealed. We seek comment on this tentative determination.

F. Proposed Repeal of Preemption Interpretations in the SAFE I Rule

In addition to the proposed repeals of the codified provisions promulgated in the SAFE I Rule, NHTSA also proposes to rescind the accompanying substantive analysis in the Preambles of the Proposed and Final SAFE I Rules—including positions on California's GHG and ZEV programs. Descriptions of California's GHG and ZEV regulations, as well as regulations of states adopting those regulations under Section 177 of the Clean Air Act, were repeatedly used throughout the SAFE I rulemaking analysis as illustrative of why the Agency decided to codify the express preemption text in parts 531 and 533 and their accompanying Appendices. For example, after explaining the specific preemption regulations, the Agency noted that ''[i]n the proposal, NHTSA described, *as an example,* California's ZEV mandate, which manufacturers must comply with individually for each state adopting California's mandate.'' [83] Therefore, these substantive positions on state law were presented in the SAFE I rulemaking as exemplary of the need for regulations, and the finalized text sought to preempt these precise state programs. Consequently, NHTSA considers such examples and substantive positions as inextricably linked to the regulatory text and, as such, would also be rescinded upon the proposed removal of the regulations.

However, to be abundantly clear, NHTSA is also proposing in this document to repeal any interpretative positions regarding EPCA preemption that may be contained within the Preambles of the SAFE I NPRM and Final Rule regardless of whether they are linked to the codified text. This includes any views on whether particular state motor vehicle GHG emissions programs or ZEV mandates conflict with or ''relate to'' CAFE standards or are otherwise preempted by Section 32919. Given the Agency's concerns about the lack of legislative rulemaking authority on matters of EPCA preemption, any surviving substantive views on the topic would constitute, at most, interpretative rules.[84] As such, their repeal would not require the notice and comment procedures set forth in 5 U.S.C. 553. Nevertheless, an agency may find it useful and prudent to seek public comment on interpretations or other agency actions as a matter of good government, and NHTSA is doing so here. Due to the anticipated substantial public interest in this action, NHTSA's interest in gaining a broad array of perspectives on its change in course, and the well-established utility of notice and comment procedures, the Agency is still including a repeal of these interpretations as part of the proposal rather than immediately finalizing a repeal of these views in this document.

At this time, the Agency is not proposing to replace any such interpretations with further views on the relationship between state motor vehicle GHG emissions programs or ZEV mandates and EPCA preemption. Instead, the Agency is exercising its rulemaking authority under 5 U.S.C. 551 to propose simply repealing, rather than amending, any such interpretative positions or interpretative rules of the Agency. Several considerations incline the Agency to propose repealing such interpretations, rather than leave them undisturbed or amend them through this rulemaking.

[79] NHTSA, EPA, The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule Part One: One National Program, Final Rule, 84 FR 51310, 51319 (Sept. 27, 2019).

[80] Even if such a conflict existed, it would seem to only bear upon an implied (conflict) preemption analysis, not whether NHTSA had authority to promulgate binding regulations that expressly governed preemption. Express and implied preemption are district legal concepts. *See, e.g., Geier* v. *Am. Honda Motor Co.,* 529 U.S. 861, 872 (2000) (distinguishing between express and implied preemption). Accordingly, the SAFE I Rule's arguments for implied (conflict) preemption cannot be used to bootstrap authority to regulate through legislative rules that expressly codify mandatory preemption requirements.

[81] The terminology used throughout the SAFE I rulemaking analysis mirrors the standards used by courts to apply the judicial doctrine of implied (conflict) preemption. For instance, the SAFE I Preambles repeatedly invoked conflict preemption standards—''frustrates,'' ''conflicts,'' and ''interferes''—to label state programs preempted. *See City of New York,* 486 U.S. at 64 (''The statutorily authorized regulations of an agency will pre-empt any state or local law that *conflicts* with such regulations or frustrates the purposes thereof.'') (emphasis added); *See, e.g., Wyeth,* 555 U.S. at 576 (''This Court has recognized that an agency regulation with the force of law can pre-empt *conflicting* state requirements.'') (emphasis added); *See, e.g., Patriotic Veterans, Inc.* v. *Indiana,* 736 F.3d 1041, 1051 (7th Cir. 2013) (describing how under the doctrine of conflict preemption, state law may be preempted ''if it *interferes*'' with Federal law) (emphasis added).

[82] *See, e.g., Wyeth,* 555 U.S. at 576 (noting that implied preemption principally applies after ''the Court has performed its own conflict determination relying on the substance of state and federal law and not on agency proclamations of pre-emption.'').

[83] NHTSA, EPA, The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule Part One: One National Program, Final Rule, 84 FR 51310, 51314 (Sept. 27, 2019) (emphasis added).

[84] *See, e.g., Am. Tort Reform Ass'n* v. *OSHA,* 738 F.3d 387, 394 (D.C. Cir. 2013). In addition, the following discussion and rationales would also apply to the codified text that NHTSA proposes to repeal above if that text were determined to be an interpretative rule rather than a legislative rule.

1. Repealing the Interpretive Provisions Makes Clear That All Aspects of the SAFE I Rule Have Been Repealed

First, repealing the interpretations treats them consistently with the codified rules, which we are here proposing for repeal. While the Agency possesses authority to issue advisory, interpretative rules on matters pertaining to EPCA preemption, repealing and withdrawing the interpretative positions of the SAFE I rulemaking promotes clarity by ensuring that such views are withdrawn along with their accompanying regulatory text, rather than leaving an ambiguity as to whether a particular statement or provision regarding EPCA preemption remains in effect. The ambiguity regarding the legal nature and effect of the codified text and positions announced in the SAFE I Rule would only amplify confusion if NHTSA proposed to repeal only parts of the rulemaking.

The lack of clarity regarding this distinction is pervasive in the SAFE I Rule, which often blurred the line between when the Agency was attempting to merely articulate views on preemption under Section 32919, which were merely advisory, and when NHTSA sought to categorically forbid state action through Federal preemption. For example, the Preambles to the SAFE I Rule repeatedly labeled certain types of state GHG regulation and ZEV mandates as categorically preempted and prohibited, even if those programs were not expressly enumerated in the plain language of the finalized regulations. Specifically, the Preamble to the SAFE I final rule unequivocally stressed that ''state programs to limit or prohibit tailpipe GHG emissions or establish ZEV mandates are preempted,'' [85] and that the SAFE I Rule was a ''final decision from the agencies that States do not have the authority to set GHG standards or establish ZEV mandates.'' [86] At the same time, the Preamble also contained other statements in which the Agency's position is described more as an interpretation of the scope of Section 32919. For instance, NHTSA articulated in the Preamble a ''view . . . that ZEV mandates are preempted by EPCA'' [87] The intermittent manner in which the Agency described the force of preemption in the Preamble intermingled any interpretative statements regarding Section 32919 with the more binding definitions of preemption the Agency sought to make in the Appendices. The Agency is also concerned that the manner in which the Preamble described the Agency's role with respect to EPCA preemption does not accurately reflect the limits to the Agency's preemption authority described in the preceding section.

2. Repealing All Aspects of the SAFE I Rule Provides the Agency With a Clean Slate on This Issue

Further, repealing all aspects of the SAFE I Rule will restore the Agency to a clean slate to appropriately exercise its interpretative discretion on matters of EPCA preemption. In this respect, the Agency is mindful that an ''administrative interpretation [which] alters the federal-state framework by permitting federal encroachment upon a traditional state power'' merits particularly careful consideration to fully account for the significant federalism interests of states.[88] Likewise, Executive Order 13132 recognizes the importance of considering federalism interests, stressing that ''[t]he national government should be deferential to the States when taking action that affects the policymaking discretion of the States and should act only with the greatest caution where State or local governments have identified uncertainties regarding the constitutional or statutory authority of the national government.'' [89] Here, states have indicated that the standards at issue were developed to protect the states' residents from dangerous air pollution and the states' natural resources from the threats posed by climate change. In a number of cases, these policies also served as components of the states' compliance with air pollution mitigation requirements delegated to states under the Federal Clean Air Act.

Upon reconsideration, NHTSA is concerned that the categorical preemption views announced in the SAFE I Rule were insufficiently tailored to account for these federalism interests because they label an entire segment of state and local regulation as preempted, irrespective of the precise contours of any particular programs, regulations, or technological developments that may arise. This is not to say that the Agency cannot approach the question of whether a particular state or local law is preempted without certain general principles or overarching views, either at the time it is considering a particular matter or in an advance advisory opinion, but it is entirely different to declare that such general views are incontrovertible or absolute in a way that does not account for the nuanced and careful consideration of program-specific facts called for in preemption analyses.

Thus, the Agency believes that a clean slate would more appropriately enable a particularized consideration of how the specifics of state programs may ''relate to'' fuel economy standards under Section 32919. Such an approach would be more reflective of the importance of federalism concerns and of the kind of program-specific factual inquiry often involved in identifying whether a state program is preempted under the statute. This type of factual, case-specific approach is consistent with how courts generally consider both the application of express preemption provisions and, even more so, claims of implied conflict preemption. Such courts remain available to resolve issues that may arise in the context of applying EPCA preemption, such as in legal challenges to particular state programs. In fact, should such a legal challenge arise, this narrower approach affords a better opportunity to provide to the presiding court, if appropriate, a more tailored and relevant perspective on the Agency's view of whether the state law at issue is preempted. To the extent NHTSA sets forth any such advisory views of how EPCA preemption may affect state programs, considering those programs in a more specific and narrow context also enables the Agency to more fully leverage its automotive expertise in understanding the particular vehicle technologies implicated by the respective regulations. These same advantages also apply if the Agency elects, as appropriate, to provide similar views outside of the litigation context as well. The clean slate facilitated by this approach is fully consistent with NHTSA's previous approach to EPCA preemption.

In contrast, establishing a clean slate and clearly communicating that NHTSA's views on EPCA preemption, while advisory, do not independently preempt, encourages states and political subdivisions to more freely devise programs that can potentially coexist with Section 32919. Therefore, the Agency is concerned that retaining the views announced in the SAFE I Rule, and categorically foreclosing consideration of any such programs that states may otherwise pursue, unnecessarily and inappropriately restricts potential policy innovation at the State and local level.

[85] *Id.* at 51311.

[86] *Id.*

[87] *Id.* at 51314.

[88] *See Solid Waste Agency of N. Cook Cty.* v. *U.S. Army Corps of Engineers,* 531 U.S. 159, 173 (2001).

[89] Executive Order 13132, *Federalism,* Sec. 1(a) (Aug. 4, 1999).

Further, the Agency believes that repealing all aspects of the SAFE I Rule and restoring a clean slate is appropriate because the Agency has substantial doubts about the substantive EPCA preemption conclusions reached in the SAFE I Rule. The proposal, final rule, and ensuing litigation for the SAFE I Rule generated an extensive array of public comments, scholarship, and legal briefing regarding both the procedural and substantive matters of EPCA preemption. While NHTSA is not announcing any new substantive views regarding EPCA preemption in this document, the Agency recognizes that many of these writings raised very detailed and thorough arguments advocating for a different reading and application of Section 32919 than was adopted by NHTSA in the SAFE I Rule.[90]

Although the Agency does not propose to adopt any substantive views in this proposal, NHTSA acknowledges that these substantive arguments merit careful consideration and raise significant doubts for the Agency as to the validity of the positions taken in SAFE I. As long as the SAFE I Rule statements remain in place, any opportunity for a more nuanced consideration of particular state programs is significantly diminished. Moreover, if they remained in place, the SAFE I views would inaccurately suggest that the Agency remained certain about substantive issues for which, in reality, the Agency harbored significant doubts and continued to reconsider. Accordingly, NHTSA preliminarily believes that even if it does not yet wish to articulate new substantive views, withdrawing any interpretations from the SAFE I Rule is a necessary and appropriate next step to ensure the Agency can fully exercise its interpretative and policymaking discretion to do so in a more nuanced and careful way at a later point, if warranted.

Due to these concerns, the Agency has tentatively determined that it is appropriate to first repeal the interpretative positions, rather than also to include a new interpretation in this proposal, as doing so enables the most efficient and streamlined removal of NHTSA's express preemption regulations. If the Agency finalizes its view that the express preemption regulations in parts 531 and 533 indeed exceed NHTSA's delegated authority, repealing the *ultra vires* regulations quickly is imperative to restore NHTSA's regulations to their properly authorized scope, which remains NHTSA's paramount objective in this proposal. In contrast, broadening the scope of this proposal to include new substantive interpretations regarding EPCA's application to state motor vehicle emissions regulations may significantly expand both the purview of the Agency's analysis and the scope of public input on the proposal, and the time needed to complete this action. Therefore, repealing but not replacing the Agency's substantive views on preemption provides the additional time needed to fully reconsider the issue without leaving any implication that the statements in the SAFE I rulemaking remain in effect or inappropriately dampening state regulatory activity in the interim.

Accordingly, NHTSA is proposing to fully withdraw any interpretative statements or views espoused in the Preambles of the SAFE I Rule to ensure that no ambiguity exists regarding whether the Agency continues to endorse such statements. Such a rescission and repeal offers the opportunity to establish a clean slate, in which no prior overstatements as to NHTSA's role lead to confusion about a party's legal obligations or the weight the Agency's statements should carry and no interpretative statements with which the Agency may no longer agree could influence state actions.

G. Repealing the Regulations and Positions Announced in the SAFE I Rulemaking Remains Appropriate Even if NHTSA Possessed the Authority for the Rulemaking

Even apart from the Agency's substantial concerns discussed above, the Agency is also proposing a complete repeal of the codified provisions and interpretative views as independently worthwhile steps. Upon reconsideration, even if it could do so lawfully, NHTSA no longer deems it necessary to speak with the force and effect of law on matters of EPCA preemption.

At the outset, the Agency considers the codified text in §§ 531.7 and 533.7 unnecessary, as they merely repeat the statutory text and, thus, have no effect beyond the statute simply by virtue of their codification in NHTSA's regulations. In fact, NHTSA is concerned that their verbatim recitation in the CFR could even be confusing to some, who assume some subtle difference must exist in the statutory and regulatory provisions. As such, the Agency no longer considers the two provisions to offer any utility and proposes their repeal. As for the remaining two Appendices and associated Preamble text, the Agency remains concerned that, even if NHTSA possessed authority for the rulemaking, the categorical manner in which the SAFE I Rule applied preemption does not appropriately account for the importance of a more nuanced approach that considers state programs on a more particularized basis. NHTSA believes this more nuanced approach could better balance federalism interests by avoiding a sweeping and premature prohibition of all state and local programs and instead evaluating such programs more specifically. Further, NHTSA now has significant doubts about the validity of its preemption analysis as applied to the specific state programs discussed in SAFE I. Therefore, for both these reasons and the further discussion on the subject that appears in the preceding section, NHTSA considers a proposal to repeal the regulations and interpretations appropriate irrespective of the Agency's level of authority on preemption.

H. Rulemaking Analyses and Notices

1. Executive Order 12866, Executive Order 13563, and DOT Regulatory Policies and Procedures

NHTSA has considered the impact of this rulemaking action under Executive Order 12866, Executive Order 13563, and the Department of Transportation's regulatory policies and procedures. This rulemaking document has been considered a ''significant regulatory action'' under Executive Order 12866. At this stage, NHTSA does not believe that this rulemaking would be ''economically significant,'' as it would not directly reinstate any state programs or otherwise affect the self-executing statutory preemption framework in 49 U.S.C. 32919.

2. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of proposed rulemaking or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small governmental

[90] For instance, in 2019 and 2020, Professor Greg Dotson with the University of Oregon School of Law published two law review articles dedicated entirely to the Agencies' SAFE I rulemaking. In these articles, Professor Dotson comprehensively analyzed applicable legislative and regulatory history, before suggesting that Congress did not intend to preempt state GHG standards or ZEV mandates under Section 32919. Similar conclusions have been reached by other commenters and litigants in the SAFE I rulemaking and consolidated litigation.

jurisdictions). No regulatory flexibility analysis is required, however, if the head of an agency certifies the proposal will not have a significant economic impact on a substantial number of small entities.

NHTSA has considered the impacts of this document under the Regulatory Flexibility Act and certifies that this rulemaking will not have a significant economic impact on a substantial number of small entities. The following provides the factual basis for this certification under 5 U.S.C. 605(b). This proposed action would only concern the question of preemption; the action does not set CAFE or emissions standards themselves. The preemption regulations at issue in this proposal have no direct effect on any private entities, regardless of size, because the rules do not regulate private entities. Thus, any effect on entities implicated by this regulatory flexibility analysis is merely indirect.

3. Executive Order 13132 (Federalism)

Executive Order 13132 requires NHTSA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' [91] ''Policies that have federalism implications'' is defined in the Executive order to include regulations 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.'' [92] Executive Order 13132 imposes additional consultation requirements on two types of regulations that have federalism implications: (1) A regulation that imposes substantial direct compliance costs, and that is not required by statute; and (2) a regulation that preempts State law.[93]

While this proposal concerns matters of preemption, it does not propose either type of regulation covered by Executive Order 13132's consultation requirements. Rather, the action in this proposal expressly proposes to repeal regulations and positions that sought to preempt State law. Thus, this proposal does not implicate the consultation procedures that Executive Order 13132 imposes on agency regulations that would either preempt state law or impose substantial direct compliance costs on states.

4. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, Public Law 104–4, requires agencies to prepare a written assessment of the cost, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually. Because this rulemaking is not expected to include a Federal mandate, no unfunded mandate assessment will be prepared.

5. National Environmental Policy Act

The National Environmental Policy Act of 1969 (NEPA) [94] directs that Federal agencies proposing ''major Federal actions significantly affecting the quality of the human environment'' must, ''to the fullest extent possible,'' prepare ''a detailed statement'' on the environmental impacts of the proposed action (including alternatives to the proposed action).[95] However, there are some instances where NEPA does not apply to a particular proposed action.

One consideration is whether the action is a non-discretionary action to which NEPA may not apply.[96] In this document, NHTSA has expressed its substantial concerns over whether Congress provided legislative rulemaking authority to the Agency with regard to 49 U.S.C. 32919. To the extent that the SAFE I Rule purported to dictate or proclaim EPCA preemption with the force of law, the Agency expresses a concern throughout this proposal that such actions exceed the Congressional grant of authority to NHTSA under EPCA. If NHTSA in fact exceeded its authority, the Agency believes that the only legally appropriate course of action would be to realign its regulatory activities to their properly authorized scope by removing the regulatory language and appendices from the Code of Federal Regulations and repealing the corresponding analysis of particular state GHG emissions programs in the SAFE I Rule. Courts have long held that NEPA does not apply to nondiscretionary actions by Federal agencies.[97] If NHTSA were to conclude in its final rule that it lacked authority to issue regulations mandating preemption or otherwise categorically proclaiming state regulations to be preempted, it must therefore conclude that NEPA does not apply to this action.

The Agency also notes that the Supreme Court has characterized an express preemption statue's scope as a legal matter of statutory construction, in which ''the purpose of Congress is the ultimate touchstone of pre-emption analysis.'' *Cipollone* v. *Liggett Grp., Inc.,* 505 U.S. 504, 516 (1992). In turn, ''Congress' intent, of course, primarily is discerned from the language of the pre-emption statute and the 'statutory framework' surrounding it.'' *Lohr,* 518 U.S. at 485–86 (plurality opinion). This particularly applies ''[i]f the statute contains an express pre-emption clause[. Then] the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'' *CSX Transp., Inc.* v. *Easterwood,* 507 U.S. 658, 664 (1993).

In light of this background, as both this proposal and the SAFE I Rule itself consistently made clear, the statutory text of 49 U.S.C. Section 32919 governs express preemption through self-executing terms. Specifically, the Preamble to the SAFE I Final Rule stressed that ''[a]ny preemptive effect resulting from this final action is not the result of the exercise of Agency discretion, but rather reflects the operation and application of the Federal statute.'' [98] NHTSA asserted that it did not have authority to waive any aspect of EPCA preemption no matter the potential environmental impacts; rather, ''preempted standards are void *ab initio*.'' [99] On this basis, the Agency concluded that NEPA did not apply to its action.

In this document, NHTSA does not seek to take any new substantive step or announce any new substantive view. Instead, NHTSA proposes only to withdraw the SAFE I Rule, which was an action for which the Agency already determined NEPA did not apply as the operative statute continued to govern any environmental effects from preemption. As before, the express preemption provision of Section 32919

[91] Executive Order 13132, *Federalism,* Sec. 1(a) (Aug. 4, 1999).

[92] *Id.* at Sec. 1(a).

[93] *Id.* at Sec. 6(b), (c).

[94] 42 U.S.C. 4321–4347.

[95] 42 U.S.C. 4332.

[96] *See Dept. of Transp.* v. *Public Citizen,* 541 U.S. 752, 768–69 (2014) (holding that the agency need not prepare an environmental impact statement (EIS) in addition to an environmental assessment (EA) and stating, ''Since FMCSA has no ability categorically to prevent the cross-border operations of Mexican motor carriers, the environmental impact of the cross-border operations would have no effect on FMCSA's decisionmaking—FMCSA simply lacks the power to act on whatever information might be contained in the EIS.'').

[97] *See, e.g., Public Citizen,* 541 U.S. 752; *Milo Cmty. Hosp.* v. *Weinberger,* 525 F.2d 144 (1st Cir. 1975); *State of South Dakota* v. *Andrus,* 614 F.2d 1190 (8th Cir. 1980); *Citizens Against Rails-to-Trails* v. *Surface Transp. Bd.,* 267 F.3d 1144 (D.C. Cir. 2001); *Sierra Club* v. *Babbitt,* 65 F.3d 1502 (9th Cir. 1995).

[98] 84 FR 51310, 51353–54.

[99] *Id.* at 51354.

remains enacted, in full and unchanged, irrespective of the SAFE I Rule, this proposal, or any subsequent final rule. As such, even though NHTSA now expresses doubts about its substantive conclusions in the SAFE I Rule and proposes to withdraw those views here, the Agency continues to believe that it did not and cannot dictate or define by law the self-executing scope of preemption under Section 32919. This is because of the Agency's belief expressed herein that its views on Section 32919, while potentially informative and advisory, do not carry the force and effect of law.[100] Therefore, this proposal likewise would not change the statutorily set scope of express preemption and, as such, the Agency does not consider this proposal to result in any environmental impact that may arise from such preemption.

6. Executive Order 12988 (Civil Justice Reform)

Pursuant to Executive Order 12988, ''Civil Justice Reform,'' [101] NHTSA has determined that this proposed rule does not have any retroactive effect.

7. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980, NHTSA states that there are no requirements for information collection associated with this rulemaking action.

8. Privacy Act

Please note that anyone is able to search the electronic form of all comments received into any of DOT's dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78), or you may visit *http://dms.dot.gov.*

List of Subjects in 49 CFR Parts 531 and 533

Fuel economy.

[100] *See supra* Sec. E(3). If NHTSA did, in fact, have authority to establish the scope of preemption with the force and effect of law, and if the Agency inappropriately failed to incorporate environmental considerations into its decision in the SAFE I Rule, then establishing a clean slate and restoring the scope to the *status quo ante* would rectify this overstep. *See, e.g., supra* Sec. F(2). In the event NHTSA is adjudged to possess such binding authority and decides to exercise it in a future rulemaking, such a clean state will allow NHTSA to include such environmental considerations, if appropriate, at that time.

[101] 61 FR 4729 (Feb. 7, 1996).

Proposed Regulatory Text

For the reasons stated in the preamble, the National Highway Traffic Safety Administration proposes to amend 49 CFR parts 531 and 533 as set forth below.

PART 531—PASSENGER AUTOMOBILE AVERAGE FUEL ECONOMY STANDARDS

■ 1. The authority citation for part 531 continues to read as follows:

Authority: 49 U.S.C. 32902; delegation of authority at 49 CFR 1.95.

§ 531.7 [Removed]

■ 2. Remove § 531.7.

Appendix B [Removed]

■ 3. Remove appendix B to part 531.

PART 533—LIGHT TRUCK FUEL ECONOMY STANDARDS

■ 4. The authority citation for part 533 continues to read as follows:

Authority: 49 U.S.C. 32902; delegation of authority at 49 CFR 1.95.

§ 533.7 [Removed]

■ 5. Remove § 533.7.

Appendix B [Removed]

■ 6. Remove appendix B to part 533.

Issued on April 22, 2021, in Washington, DC, under authority delegated in 49 CFR 1.81, 1.95, and 501.4

Steven S. Cliff,

Acting Administrator.

[FR Doc. 2021–08758 Filed 5–11–21; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 210505–0102]

RIN 0648–BK37

Atlantic Highly Migratory Species; General Category Restricted-Fishing Days

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS is proposing to set Atlantic bluefin tuna (BFT) General category restricted-fishing days (RFDs) for the 2021 fishing year; clarify the regulations regarding applicability of RFDs to highly migratory species (HMS) Charter/Headboat permitted vessels; and correct references to the Atlantic Tunas General category permit in a section of the Atlantic HMS regulations. This proposed rule would establish RFDs for specific days during the months of July through November 2021. On an RFD, Atlantic Tunas General category permitted vessels may not fish for (including catch-and-release or tag-and-release fishing), possess, retain, land, or sell BFT. On an RFD, HMS Charter/Headboat permitted vessels with a commercial sale endorsement also are subject to these restrictions to preclude commercially for BFT under the General category restrictions and retention limits but may still fish for, possess, retain, or land BFT when fishing recreationally under applicable HMS Angling category rules.

DATES: Written comments must be received by June 11, 2021. NMFS will hold a public hearing via conference call and webinar for this proposed rule on May 19, 2021, from 3 p.m. to 5 p.m. For webinar registration information, see the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2021–0040, by electronic submission. Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter ''NOAA–NMFS–2021–0040'' in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Comments sent by any other method, to any other address or individual, or received after the close of the comment period, may not be considered by NMFS. All comments received are a 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).

NMFS will hold a public hearing via conference call/webinar on this proposed rule. For specific location, date and time, see the **SUPPLEMENTARY INFORMATION** section of this document.

Copies of this proposed rule and supporting documents are available from the HMS Management Division website at *https://www.fisheries.noaa.gov/topic/atlantic-highly-migratory-species* or by contacting Larry Redd at *larry.redd@noaa.gov* or 301–427–8503.

FOR FURTHER INFORMATION CONTACT: Larry Redd, Jr., *larry.redd@noaa.gov,* 301–427–8503, or Sarah McLaughlin, *sarah.mclaughlin@noaa.gov,* 978–281–9260.

SUPPLEMENTARY INFORMATION: Atlantic HMS fisheries, including BFT fisheries, are managed under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*). The 2006 Consolidated Atlantic HMS Fishery Management Plan (2006 Consolidated HMS FMP) and its amendments are implemented by regulations at 50 CFR part 635. Section 635.27 divides the U.S. BFT quota, recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) and as implemented by the United States, among the various domestic fishing categories per the allocations established in the 2006 Consolidated HMS FMP and its amendments. Section 635.23 specifies the retention limit provisions for Atlantic Tunas General category permitted vessels and HMS Charter/Headboat permitted vessels, including regarding RFDs.

In 2018, NMFS implemented a final rule that established the U.S. BFT quota and subquotas consistent with ICCAT Recommendation 17–06 (83 FR 51391, October 11, 2018). In 2020, following a stock assessment update, ICCAT adopted Recommendation 20–06, which maintained the total allowable catch of 2,350 metric tons (mt) and the associated U.S. quota. As such, as described in § 635.27(a), the current baseline U.S. quota remains 1,247.86 mt (not including the 25 mt ICCAT allocated to the United States to account for bycatch of BFT in pelagic longline fisheries in the Northeast Distant Gear Restricted Area). The baseline quota for the General category is 555.7 mt. Each of the General category time periods (January, June through August, September, October through November, and December) is allocated a portion of the annual General category quota. Although it is called the ''January'' subquota, the regulations allow the General category fishery under this quota to continue until the subquota is reached or March 31, whichever comes first. The baseline subquotas for each time period are as follows: 29.5 mt for January; 277.9 mt for June through August; 147.3 mt for September; 72.2 mt for October through November; and 28.9 mt for December. Any unused General category quota rolls forward within the fishing year, which coincides with the calendar year, from one time period to the next, and is available for use in subsequent time periods.

Background

An RFD is a day, established ahead of time through a schedule published in the **Federal Register**, on which NMFS sets the BFT retention limit at zero for certain categories of permit holders. Specifically, on an RFD, vessels permitted in the Atlantic Tunas General category are prohibited from fishing for (including catch-and-release and tag-and-release fishing), possessing, retaining, landing, or selling BFT. (§ 635.23(a)(2)). RFDs also apply to HMS Charter/Headboat permitted vessels to preclude fishing commercially under General category restrictions and retention limits on those days but do not preclude such vessels from recreational fishing activity under applicable Angling category regulations, including catch-and-release and tag-and-release fishing (§ 635.23(c)(3)).

NMFS may waive previously scheduled RFDs under certain circumstances. Consistent with § 635.23(a)(4), NMFS may waive an RFD by adjusting the daily BFT retention limit from zero up to five on specified RFDs, after considering the inseason adjustment determination criteria at § 635.27(a)(8). This would include, among other things, review of dealer reports, daily landing trends, and the availability of BFT on fishing grounds. NMFS would announce any such waiver by filing a retention limit adjustment with the Office of the Federal Register for publication. Such adjustments would be effective no less than 3 calendar days after the date of filing for public inspection with the Office of the Federal Register. NMFS also may waive previously designated RFDs effective upon closure of the General category fishery so that persons aboard vessels permitted in the General category may conduct catch-and-release or tag-and-release fishing for BFT under § 635.26(a). NMFS would not modify the previously scheduled RFDs during the fishing year in other ways (such as changing an RFD from one date to another, or adding RFDs).

NMFS originally established regulatory authority to set ''no-fishing'' days for BFT in the General category fishery in a 1995 rule (60 FR 38505, July 27, 1995). In that 1995 rule, NMFS described ''no-fishing'' days as an available effort control that could be used to extend the General category time-period subquotas and provide additional inseason management flexibility with regard to quota use and distribution and season length. NMFS renamed ''no-fishing'' days to be ''RFDs'' in a 1997 rulemaking, which also included annual BFT quota specifications and effort controls (62 FR 38939, July 21, 1997). From 1995 through 2007, NMFS set RFDs on an annual basis. NMFS has not used such RFDs since 2007.

In 2019 and 2020, NMFS received numerous requests from Atlantic tuna dealers, General category participants, and members of the Atlantic HMS Advisory Panel to resume the use of RFDs. These requests indicated that increasing BFT catch rates in the General category have shortened the time it takes to fill the relevant subquotas, which has resulted in unstable markets. NMFS has also received a number of questions about RFDs and concerns that using them could hinder the market from operating naturally, unnecessarily restrict fishing opportunities during the fishing year, and may negatively affect HMS fishing tournaments for BFT by potentially reducing General category registered tournament participation.

NMFS is proposing to resume the use of RFDs for the 2021 fishing year to prevent recurrence of certain issues that affected the fishery in 2019 and 2020. These issues include the shortened time to fish under the General category subquotas that occurs when quota is filled quickly, increasing numbers of BFT that are landed but cannot be sold by fishermen fishing under the General category quota when there are large volumes of landings in a short period, and the resulting decreasing prices of BFT. NMFS is proposing an RFD schedule for the 2021 fishing year, balancing these issues with other concerns expressed about RFDs affecting market operations and fishing opportunities noted above. NMFS has existing regulatory authority to annually publish a notice of RFDs and to implement them. § 635.23(a)(2). Given the length of time that has passed since NMFS last implemented RFDs in these fisheries, however, NMFS is also requesting comments on resuming the use of RFDs more generally and on the need for RFDs in the 2021 fishing year.

Proposed RFD Schedule for the 2021 Fishing Year

For 2021, NMFS proposes that persons aboard vessels permitted in the

General category would be prohibited from fishing for (including catch-and-release and tag-and-release fishing), possessing, retaining, landing, or selling BFT on the following days: all Tuesdays, Fridays, and Saturdays from July 20, 2021, through November 30, 2021, while the fishery is open. On these designated RFDs, persons aboard HMS Charter/Headboat permitted vessels with a commercial sale endorsement also would be prohibited from fishing commercially for BFT. Persons aboard all HMS Charter/Headboat permitted vessels could fish recreationally for BFT under the applicable Angling category restrictions and retention limits.

NMFS is proposing a schedule of days from July through November based on its review of average daily catch rate data for recent years and a review of past years' RFD schedules and how they worked to extend the use of the General category quota, considering past closure dates. We also considered input from Atlantic tuna dealers, General category participants, and members of the Atlantic HMS Advisory Panel. Considering this information, NMFS believes that this schedule of Tuesday, Friday, and Saturday RFDs should increase the likelihood of pacing General category landings to extend fishing opportunities through a greater portion of the subquota periods (similar to past RFD schedules). It would also allow for two-consecutive-day periods twice each week (Sunday–Monday; Wednesday–Thursday) for BFT product to move through the market and also allow for some commercial fishing activity each weekend (Sunday).

As described above, based on consideration of regulatory criteria at § 635.27(a)(8), NMFS may waive certain RFDs consistent with § 635.23(a)(4), either by adjusting the retention limit upwards on a previously-scheduled RFD or by waiving an RFD to allow recreational fishing under the Angling category restrictions and retention limits when the General category closes. Once the schedule is set, however, NMFS would not modify RFDs in other ways (*e.g.,* switching days or adding RFDs).

Regulatory Clarification Regarding Applicability of RFDs to HMS Charter/Headboat Permitted Vessels

Section 635.23(c) specifies the BFT retention limits for HMS Charter/Headboat permitted vessels, including when such vessels with a commercial sale endorsement may fish under either the General category (commercial) or Angling category (recreational) retention limits and restrictions. However, the regulations do not clearly state which retention rules apply to such vessels on an RFD. Rather, the regulations contain various cross-references to establish which retention limit applies to a vessel with an Atlantic HMS Charter/Headboat permit with a commercial endorsement on an RFD. As such, NMFS proposes to make minor changes at § 635.23(c) to explicitly clarify in the regulations that when the General category is closed or on an RFD, Charter/Headboat permitted vessels may only fish under the Angling category limits. NMFS is also proposing to correct two references to ''General category Atlantic Tunas'' permits in this section to ''Atlantic Tunas General category'' permits, consistent with the permit title name in other sections of the Atlantic HMS regulations.

Request for Comments

NMFS is requesting comments on an RFD schedule for the 2021 fishing year, proposed under its existing regulatory authority to annually publish a notice of RFDs and to implement them accordingly given the length of time that has passed since NMFS last implemented RFDs. However, NMFS is also requesting comments on resuming the use of such RFDs more generally and the need for RFDs in the 2021 fishing year. Comments on this proposed rule may be submitted via *www.regulations.gov* or at a public conference call/webinar. NMFS solicits comments on this action by June 11, 2021 (see **DATES** and **ADDRESSES**).

During the comment period, NMFS will hold a public hearing via conference call and webinar for this proposed action. Requests for sign language interpretation or other auxiliary aids should be directed to Larry Redd at *larry.redd@noaa.gov* or 301–427–8503, at least 7 days prior to the meeting.

The webinar/conference call will take place on May 19, 2021. Information for registering and accessing the webinars can be found at *https://www.fisheries.noaa.gov/action/proposed-rule-implement-general-category-restricted-fishing-days-2021-atlantic-bluefin-tuna.*

The public is reminded that NMFS expects participants at public webinars/conference calls to conduct themselves appropriately. At the beginning of each webinar/conference call, the moderator will explain how the webinar/conference call will be conducted and how and when participants can provide comments. NMFS representative(s) will structure the webinars/conference calls so that all members of the public will be able to comment, if they so choose, regardless of the controversial nature of the subject(s). Participants are expected to respect the ground rules, and those that do not may be asked to leave the webinars/conference calls.

Classification

The NMFS Assistant Administrator has determined that the proposed rule is consistent with the 2006 Consolidated HMS FMP and its amendments, other provisions of the Magnuson-Stevens Act, ATCA, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

An Initial Regulatory Flexibility Analysis (IRFA) was prepared, as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action are contained at the beginning of this section in the preamble and in the **SUMMARY** section of the preamble. A summary of the analysis follows. A copy of this analysis is available from NMFS (see **ADDRESSES**).

Section 603(b)(1) requires agencies to describe the reasons why the action is being considered. The purpose of this proposed rulemaking is, consistent with the objectives of the 2006 Consolidated HMS FMP and its amendments, the Magnuson-Stevens Act, ATCA, and other applicable law, to potentially set a schedule of RFDs for the 2021 fishing year as an effort to control for the General category quota, and to extend General category fishing opportunities through a greater portion of the General category time-period subquotas than have been available in recent years. Implementation of the proposal would further the management goals and objectives stated in the 2006 Consolidated HMS FMP and its amendments.

Section 603(b)(2) of the RFA requires agencies to state the objectives of, and legal basis for, the proposed action. The objective of this proposed rulemaking is to set a schedule of RFDs for the 2021 fishing year to increase the likelihood of pacing General category landings to extend fishing opportunities through a greater portion of the subquota periods (similar to past RFD schedules). Additionally, this proposed rule would clarify the regulations regarding applicability of RFDs to vessels permitted in the HMS Charter-Headboat category. The legal basis for the proposed rule is the Magnuson-Stevens Act and ATCA.

Section 603(b)(3) of the RFA requires agencies to provide an estimate of the number of small entities to which the rule would apply. NMFS established a small business size standard of $11 million in annual gross receipts for all businesses in the commercial fishing industry (NAICS 11411) for RFA compliance purposes. The Small Business Administration (SBA) has established size standards for all other major industry sectors in the United States, including the scenic and sightseeing transportation (water) sector (NAICS code 487210), which includes for-hire (charter/party boat) fishing entities. The SBA has defined a small entity under the scenic and sightseeing transportation (water) sector as one with average annual receipts (revenue) of less than $8.0 million. Therefore, NMFS considers all HMS permit holders, both commercial and for-hire, to be small entities because they had average annual receipts of less than their respective sector's standard of $11 million and $8 million. The 2019 total ex-vessel annual revenue for the BFT fishery was $9.8 million. Since a small business is defined as having annual receipts not in excess of $11.0 million, each individual BFT fishing entity would fall within the small business definition. Thus, all of the entities affected by this rule are considered to be small entities for the purposes of the RFA. The numbers of relevant annual Atlantic Tunas or Atlantic HMS permits as of October 2020 are as follows: 2,645 General category permit holders and 3,839 HMS Charter/Headboat permit holders, of which 1,681 hold HMS Charter/Headboat permits with a commercial sale endorsement.

Section 603(b)(4) of the RFA requires agencies to describe any new reporting, record-keeping, and other compliance requirements. This proposed rule does not contain any new collection of information, reporting, or record-keeping requirements. This proposed rule would set a schedule of RFDs for 2021 as an effort control for the General category quota and would clarify existing regulatory text about the applicability of RFDs to HMS Charter/Headboat permitted vessels.

Under section 603(b)(5) of the RFA, agencies must identify, to the extent practicable, relevant Federal rules which duplicate, overlap, or conflict with the proposed action. Fishermen, dealers, and managers in these fisheries must comply with a number of international agreements, domestic laws, and other fishery management measures. These include, but are not limited to, the Magnuson-Stevens Act, ATCA, the High Seas Fishing Compliance Act, the Marine Mammal Protection Act, the Endangered Species Act, the National Environmental Policy Act, the Paperwork Reduction Act, and the Coastal Zone Management Act. This proposed action has been determined not to duplicate, overlap, or conflict with any Federal rules.

Under section 603(c) of the RFA, agencies must describe any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. Specifically, the RFA (5 U.S.C. 603(c)(1)–(4)) lists four general categories of significant alternatives to assist an agency in the development of significant alternatives. These categories of alternatives are: (1) Establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) use of performance rather than design standards; and, (4) exemptions from coverage of the rule, or any part thereof, for small entities.

Regarding the first, second, and fourth categories, NMFS cannot establish differing compliance or reporting requirements for small entities or exempt small entities from coverage of the rule or parts of it, because all of the businesses impacted by this rule are considered small entities, and thus the requirements are already designed for small entities. Regarding the third category, NMFS does not know of any performance or design standards that would satisfy the aforementioned objectives of this rulemaking.

This proposed rule would not change the U.S. Atlantic BFT quotas or implement any new management measures not previously considered under the 2006 Consolidated HMS FMP and its amendments. This proposed rule would instead resume use of RFDs and provide the regulated community the opportunity to comment on this proposal; propose a schedule of RFDs for 2021; clarify existing regulatory text about the applicability of RFDs to HMS Charter/Headboat permitted vessels; and make a minor change to correct two permit title references in a section of the regulations. Under the regulations, when a General category time period subquota is reached or projected to be reached, NMFS closes the General category fishery. Retaining, possessing, or landing BFT under that quota category is prohibited on and after the effective date and time of a closure notice for that category, for the remainder of the fishing year, until the opening of the subsequent quota period or until such date as specified. In recent years, these closures, if needed, have generally occurred toward the end of any particular subquota time period. According to communications with dealers and fishermen, several of the high-volume HMS Atlantic tunas dealers in 2019 and 2020 were limiting their purchases of BFT and buying no or very few BFT (such as harpooned fish only) on certain days during the beginning portion of the June through August subquota time period in order to extend the available quota until later in the subperiod given market considerations. However, while these actions may have prevented large numbers of BFT from entering the market at the same time and may have lengthened the time before any particular subquota was closed, because these actions were not pre-scheduled or consistently implemented across the fishery, there were negative impacts experienced by some General category and Charter/Headboat permitted fishermen, who could not find buyers for their BFT. As a result, a number of BFT that normally would have been sold were not, and opportunities may not have been equitably distributed among all permitted vessels. Table 1 shows the number and total metric tons (mt) of BFT that were landed but not sold by fishermen fishing under the General category quota for 2017 through 2020. The number and weight of unsold BFT has been increasing since 2017, and increased substantially (from 20 to 173 BFT and 3.8 to 31.4 mt) between 2019 and 2020.

TABLE 1—THE NUMBER (COUNT) AND WEIGHT (mt) OF BFT THAT WERE LANDED BUT UNSOLD BY GENERAL CATEGORY PARTICIPANTS BY YEAR

Year	Count	Weight (mt)
2017	0	0
2018	14	2.6
2019	20	3.8
2020	173	31.4
Total	207	37.8

In addition to reviewing the data regarding the amount of unsold BFT, NMFS also reviewed the average ex-vessel price. Table 2 shows the average ex-vessel price per pound of BFT during each General category subquota time period for the years 2017 through 2020. On an annual basis, the ex-vessel price tends to be lower for the June through August subquota time period, with an

average (2017 through 2020) price of $6.04, and increases over the summer and fall period ($6.30 for September period and $6.49 for the October through November period). NMFS understands that several factors influenced dealers' decisions to not purchase BFT in 2019 (*e.g.,* fish conditions, daily retention limits, and market conditions) and that in 2020, the worsening of global market conditions was an additional factor impacting the number of BFT unsold. These conditions generally occurred in June through August 2019, and were repeated in June through August 2020, with conditions and prices improving by the fall. However, in 2020, the average price per pound was lower for the June through December subquota time periods than in any of the three prior years.

TABLE 2—AVERAGE EX-VESSEL PRICE PER POUND ($) OF BFT BY GENERAL CATEGORY SUBQUOTA TIME PERIOD

[2017–2020]

Year	Subquota time period				
	January through March	June through August	September	October through November	December
2017	$7.37	$6.72	$7.08	$7.56	$9.83
2018	7.43	6.92	6.55	7.58	9.56
2019	6.06	5.61	6.36	5.53	12.25
2020	6.13	4.91	5.21	5.30	5.76
2017 through 2020 average	6.75	6.04	6.30	6.49	9.35

To help address these issues, NMFS is proposing to establish a schedule of RFDs for the 2021 fishing year that would regulate specific days on which fishing and sales will not occur. Specifically, the proposed schedule allows for two-consecutive-day periods twice each week for BFT product to move through the market while also allowing some commercial fishing activity to occur each weekend (*i.e.,* Sundays). Because this schedule of RFDs would apply to all participants equally, NMFS anticipates that this schedule would extend fishing opportunities through a greater proportion of the subquota time periods in which they apply by spreading fishing effort out over time. Further, to the extent that the ex-vessel revenue for a BFT sold by a General or HMS Charter/Headboat permitted vessel (with a commercial endorsement) may be higher when a lower volume of domestically-caught BFT is on the market at one time, the use of RFDs may result in some increase in BFT price, and the value of the General category subquotas could increase. Thus, although NMFS anticipates that the same overall amount of the General category quota would be landed as well as the same amount of BFT landed per vessel, there may be some positive impacts to the General category and Charter/Headboat (commercial) BFT fishery. Using RFDs may more equitably distribute opportunities across all permitted vessels for longer durations within the subquota time periods.

If NMFS does not implement a schedule, without any other changes, it is possible that the trends of increasing numbers of unsold BFT (Table 1) and decreasing ex-vessel prices (Table 2) would continue. If these trends continue, all participants could continue to experience negative economic impacts.

This proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR Part 635

Fisheries, Fishing, Fishing vessels, Foreign relations, Imports, Penalties, Reporting and recordkeeping requirements, Statistics, Treaties.

Dated: May 6, 2021.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 635 is proposed to be amended as follows:

PART 635—ATLANTIC HIGHLY MIGRATORY SPECIES

■ 1. The authority citation for part 635 continues to read as follows:

Authority: 16 U.S.C. 971 *et seq.;* 16 U.S.C. 1801 *et seq.*

■ 2. In § 635.2, revise the definition of ''Restricted-fishing day (RFD)'' to read as follows:

§ 635.2 Definitions.

* * * * *

Restricted-fishing day (RFD) is a day, beginning at 0000 hours and ending at 2400 hours local time, during which a person aboard a vessel issued:

(1) An Atlantic Tunas General category permit may not fish for, possess, retain, land, or sell a BFT; and

(2) A Charter/Headboat permit with a commercial endorsement may not fish commercially for BFT under the General category rules, but may fish for, possess, retain, or land BFT under the Angling category restrictions and retention limits.

* * * * *

■ 3. In § 635.23, revise paragraphs (a)(1) and (3) and (c)(1) through (3) and add paragraph (c)(4) to read as follows:

§ 635.23 Retention limits for bluefin tuna.

* * * * *

(a) * * *

(1) No person aboard a vessel that has an Atlantic Tunas General category permit may possess, retain, land, or sell a BFT in the school, large school, or small medium size class.

* * * * *

(3) Regardless of the length of a trip, no more than a single day's retention limit of large medium or giant BFT may be possessed or retained aboard a vessel that has an Atlantic Tunas General category permit. On days other than RFDs, when the General category is open, no person aboard such vessel may continue to fish, and the vessel must immediately proceed to port, once the applicable limit for large medium or giant BFT is retained.

* * * * *

(c) * * *

(1) When fishing in the Gulf of Mexico, the restrictions and retention limits applicable to the Angling category specified in paragraph (b)(1) of the section apply.

(2) When fishing other than in the Gulf of Mexico when the fishery for the General category is closed or on an RFD, the restrictions and retention limits applicable to the Angling category

specified in paragraphs (b)(1) through (3) of this section apply.

(3) When fishing other than in the Gulf of Mexico when the General category fishery is open and not on an RFD, a person aboard a vessel that has been issued an HMS Charter/Headboat permit with a commercial sale endorsement may fish under either the General category restrictions and retention limits as specified in paragraphs (a)(1) through (3) of this section or the Angling category restrictions and retention limits as specified in paragraphs (b)(1) through (3) of this section. The size category of the first BFT retained will determine whether the General category or Angling category restrictions and retention limits apply to the vessel that day.

(4) When fishing other than in the Gulf of Mexico when the General category fishery is open and not on an RFD, a person aboard a vessel that has been issued an HMS Charter/Headboat permit without a commercial sale endorsement permit may only fish for, possess, retain, or land BFT under the Angling category restrictions and retention limits as specified in paragraphs (b)(1) through (3) of this section.

* * * * *

[FR Doc. 2021–10028 Filed 5–11–21; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 86, No. 90
Wednesday, May 12, 2021

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

Animal and Plant Health Inspection Service

[Docket No. APHIS–2020–0061]

Notice of Availability of a Pest Risk Analysis for the Importation of Fresh Mango Fruit From Colombia Into the United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that we have prepared a pest risk analysis that evaluates the risks associated with importation of fresh mango fruit from Colombia into the United States. Based on the analysis, we have determined that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of fresh mango fruit from Colombia. We are making the pest risk analysis available to the public for review and comment.

DATES: We will consider all comments that we receive on or before July 12, 2021.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov*. Enter APHIS–2020–0061 in the Search field.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2020–0061, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *www.regulations.gov* or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Claudia Ferguson, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, Imports, Regulations, and Manuals, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737–1231; (301) 851–2352; *claudia.ferguson@usda.gov*.

SUPPLEMENTARY INFORMATION:

Background

Under the regulations in ''Subpart L—Fruits and Vegetables'' (7 CFR 319.56–1 through 319.56–12, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into or disseminated within the United States.

Section 319.56–4 contains a performance-based process for approving the importation of fruits and vegetables that, based on the findings of a pest risk analysis, can be safely imported subject to one or more of the five designated phytosanitary measures listed in paragraph (b) of that section.

APHIS received a request from the national plant protection organization (NPPO) of Colombia to allow fresh mango (*Mangifera indica* L.) fruit into the United States. As part of our evaluation of Colombia's request, we have prepared a pest risk assessment (PRA) to identify pests of quarantine significance that could follow the pathway of importation of fresh mango fruit into the United States from Colombia. Based on the PRA, a risk management document (RMD) was prepared to identify phytosanitary measures that could be applied to the fresh mango fruit to mitigate the pest risk.

We have concluded that fresh mango fruit can be safely imported from Colombia into the United States, using one or more of the five designated phytosanitary measures listed in § 319.56–4(b). The NPPO of Colombia would have to enter into an operational workplan with APHIS that spells out the daily procedures the NPPO will take to implement the measures identified in the RMD. These measures will be listed in APHIS' Fruits and Vegetables Import Requirements (FAVIR) database, available at *https://epermits.aphis.usda.gov/manual/*.

The mitigation measures identified in the RMD include the following:

- Only commercial consignments of mango fruit may be imported.
- All growers must be registered with the NPPO and follow operational workplan requirements for suppression of fruit flies.
- The NPPO must monitor the system for inspection, packing, wrapping, transportation, and loading of the commodity and ensure that participating growers are following the program guidelines.
- Packinghouses must be registered and approved by the NPPO and meet the requirements listed in the operational workplan.
- The NPPO is expected to maintain program records for at least 1 year and provide them to APHIS upon request.
- The NPPO or its designate must conduct a fruit fly trapping program for the detection of *Anastrepha* spp. and Medfly (*Ceratitis capitata*) at each production site. Details of trap placement, checking of traps, trap density, and remedial fruit fly control measures will be included in the operational workplan. The NPPO must maintain an APHIS-approved quality control program to monitor or audit the trapping program and maintain records of trap placement, checking of traps, and any fruit fly captures. The trapping records must be maintained for at least 1 year and provided to APHIS upon request.
- The mangos must be treated with an APHIS-approved treatment for *Anastrepha* spp. fruit flies and Medfly (*Ceratitis capitata*). Either:
- Hot water treatment, T102–a, which is only available for use in a preclearance program in accordance with 7 CFR part 305. Each consignment of fruit treated with the APHIS-approved hot water treatment must be precleared by APHIS inspectors in Colombia. The treatment must be carried out under the supervision and direction of APHIS and each consignment must be inspected jointly by APHIS and the NPPO. Treatment must occur in a pest-exclusionary treatment facility; or
- Irradiation treatment, T105–a–1, which requires the fruit to be irradiated

with a minimum absorbed dose of 150 Gray for fruit flies and follow the requirements of part 305. If the approved irradiation treatment is applied outside the United States, each consignment of fruit must be precleared by APHIS inspectors in Colombia. Treatment must occur in a pest-exclusionary treatment facility or, if irradiation is to be applied upon arrival in the United States, each consignment of fruit must be inspected by the NPPO prior to departure and accompanied by a phytosanitary certificate issued by the NPPO. Mangos intended to be irradiated in the United States must be shipped in APHIS-approved packaging that prevents escape of any *Anastrepha* spp. or Medfly larvae or adults.

- All hot water or irradiation treatment facilities in Colombia to be used for mangos are subject to APHIS approval. APHIS reserves the right to require oversight visits in the event of pest interceptions or other problems.
- Mango fruit must be safeguarded from exposure to *Anastrepha* spp. or Medfly from the time of treatment to export. The package containing mango fruit may not contain any other fruit, including mango fruit not qualified for importation into the United States.
- Each consignment must be inspected jointly by inspectors from APHIS and the NPPO and accompanied by a phytosanitary certificate issued by the NPPO.
- If more than one *Ceratitis capitata* or *Anastrepha* spp. or one *Neosilba glaberrima* is detected in a consignment, the consignment may not be exported to the United States.
- Each consignment is subject to inspection at the U.S. ports of entry.

In addition to these specific measures, fresh mango fruit from Colombia would be subject to the general requirements listed in § 319.56–3 that are applicable to the importation of all fruits and vegetables.

Therefore, in accordance with § 319.56–4(c), we are announcing the availability of our PRA and RMD for public review and comment. Those documents, as well as a description of the economic considerations associated with the importation of fresh mango fruit from Colombia, may be viewed on the *Regulations.gov* website or in our reading room (see **ADDRESSES** above for a link to *Regulations.gov* and information on the location and hours of the reading room). You may request paper copies of these documents by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the subject of the analysis you wish to review when requesting copies.

After reviewing any comments we receive, we will announce our decision regarding the import status of fresh mango fruit from Colombia in a subsequent notice. If the overall conclusions of our analysis and the Administrator's determination of risk remain unchanged following our consideration of the comments, then we will authorize the importation of fresh mango fruit from Colombia into the United States subject to the requirements specified in the RMD.

Authority: 7 U.S.C. 1633, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 7th day of May 2021.

Mark Davidson,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021–10042 Filed 5–11–21; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Federal Economic Statistics Advisory Committee

AGENCY: Bureau of Economic Analysis, U.S. Department of Commerce.

ACTION: Notice of request for nominations.

SUMMARY: The Under Secretary for Economic Affairs requests nominations of individuals to the Federal Economic Statistics Advisory Committee. The Under Secretary for Economic Affairs in coordination with the Directors of the Department's statistical agencies, the Bureau of Economic Analysis and the U.S. Census Bureau, as well as the Commissioner of the U.S. Department of Labor's Bureau of Labor Statistics will consider nominations received in response to this notice, as well as from other sources. The **SUPPLEMENTARY INFORMATION** section of this notice provides Committee and membership criteria.

DATES: Please submit nominations 30 days after publication of this notice. The Bureau of Economic Analysis will retain nominations received after this date for consideration should additional vacancies occur.

ADDRESSES: Please submit nominations by email to *Gianna.marrone@bea.gov* (subject line ''2021 FESAC Nominations'').

FOR FURTHER INFORMATION CONTACT: Gianna Marrone, Committee Management Official, Department of Commerce, Bureau of Economic Analysis, telephone 301–278–9282, email: *gianna.marrone@bea.gov*.

SUPPLEMENTARY INFORMATION: The Federal Economic Statistics Advisory Committee (the ''Committee'') was established in accordance with the Federal Advisory Committee Act (Title 5, United States Code, Appendix 2). The following provides information about the Committee, membership, and the nomination process.

Objectives and Scope of FESAC Activities

The Committee advises the Directors of the Department's statistical agencies, the Bureau of Economic Analysis (BEA) and the U.S. Census Bureau, as well as the Commissioner of the U.S. Department of Labor's Bureau of Labor Statistics (BLS) on statistical methodology and other technical matters related to the design, collection, tabulation, and analysis of federal economic statistics.

Description of the FESAC Member Duties

The Committee functions solely as an advisory committee to the senior officials of BEA, the Census Bureau, and BLS (the agencies). Important aspects of the committee's responsibilities include, but are not limited to:

a. Recommending research to address important technical problems arising in federal economic statistics;

b. Identifying areas in which better coordination of the agencies' activities would be beneficial;

c. Exploring ways to enhance the agencies' economic indicators to make them timelier, more accurate, and more specific to meeting changing demands and future data needs;

d. Improving the means, methods, and techniques to obtain economic information needed to produce current and future economic indicators; and

e. Coordinating, in its identification of agenda items, with other existing academic advisory committees chartered to provide agency-specific advice, for the purpose of avoiding duplication of effort.

The Committee meets once or twice a year, budget permitting. Additional meetings may be held as deemed necessary by the Under Secretary for Economic Affairs or the Designated Federal Official. All Committee meetings are open to the public in accordance with the Federal Advisory Committee Act.

FESAC Membership

FESAC will comprise approximately 16 members who serve at the pleasure of the Secretary. Members shall be

appointed by the Under Secretary for Economic Affairs in consultation with the agencies. Committee members shall be professionals in appropriate disciplines, including economists, statisticians, survey methodologists, and behavioral scientists who are prominent experts in their fields, recognized for their scientific, professional, and operational achievements and objectivity. Membership will represent data users with expertise from the public sector, academia, and the private sector. Members will be chosen to achieve a balanced membership that will meet the needs of the agencies.

Members shall serve as Special Government Employees (SGEs) and shall be subject to ethics rules applicable to SGEs.

A FESAC member term is three years.

Members may serve more than one term as described in the FESAC Charter, available at: *https://apps.bea.gov/fesac/.*

Compensation for Members

Members of the Committee serve without compensation but may receive reimbursement for Committee-related travel and lodging expenses.

Solicitation of Nominations

The Committee is currently filling one or more positions on the FESAC.

The Under Secretary of Economic Affairs, in consultation with the agencies will consider nominations of all qualified individuals to ensure that the Committee includes the areas of experience noted above. Individuals may nominate themselves or other individuals, and professional associations and organizations may nominate one or more qualified persons for membership on the Committee. Nominations shall state that the nominee is willing to serve as a member and carry out the duties of the Committee. A nomination package should include the following information for each nominee:

1. A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.,* what specific attributes recommend him/her for service in this capacity), and the nominee's field(s) of experience;

2. a biographical sketch of the nominee and a copy of his/her curriculum vitae; and

3. the name, return address, email address, and daytime telephone number at which the nominator can be contacted.

The Department of Commerce Under Secretary of Economic Affairs and the agencies encourage nominations for appropriately qualified female, minority, or disabled candidates. The Department of Commerce Under Secretary of Economic Affairs and the agencies also encourage geographic diversity in the composition of the Committee.

All nomination information should be provided in a single, complete package 30 days after publication of this notice. The Bureau of Economic Analysis will retain nominations received after this date for consideration should additional vacancies occur.

Interested applicants should send their nomination package to Gianna Marrone, Committee Management Official, at *Gianna.Marrone@bea.gov* (subject line ''2021 FESAC Nominations''). The Bureau of Economic Analysis will retain nominations received after this date for consideration should additional vacancies occur.

Sabrina L. Montes,

Designated Federal Official, Bureau of Economic Analysis, Federal Economic Statistics Advisory Committee.

[FR Doc. 2021–10037 Filed 5–11–21; 8:45 am]

BILLING CODE 3510–MN–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–018, C–570–019]

Boltless Steel Shelving Units Prepackaged for Sale From the People's Republic of China: Continuation of Antidumping Duty Order and Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC) that revocation of the antidumping duty (AD) and countervailing duty (CVD) orders on boltless steel shelving units prepackaged for sale from the People's Republic of China (China) would likely lead to continuation or recurrence of dumping, countervailable subsidies, and material injury to an industry in the United States, Commerce is publishing a notice of continuation of the AD and CVD orders.

DATES: Applicable May 12, 2021.

FOR FURTHER INFORMATION CONTACT: Kabir Archuletta, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2593.

SUPPLEMENTARY INFORMATION:

Background

On October 21, 2015, Commerce published the AD and CVD orders on boltless steel shelving from China.[1] On September 1, 2020, the ITC instituted,[2] and Commerce initiated, the first sunset review of the *Orders,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[3] As a result of its review, Commerce determined that revocation of the *Orders* would likely lead to continuation or recurrence of dumping and countervailable subsidies and, therefore, notified the ITC of the magnitude of the margins and net countervailable subsidy rates likely to prevail should the *Orders* be revoked.[4]

On May 5, 2021, the ITC published its determination, pursuant to sections 751(c) and 752(a) 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 scope of the *Orders* covers boltless steel shelving units prepackaged for sale, with or without decks (boltless steel shelving). The term ''prepackaged for sale'' means that, at a minimum, the steel vertical supports (*i.e.,* uprights and posts) and steel horizontal supports (*i.e.,* beams, braces) necessary to assemble a completed shelving unit (with or without decks) are packaged together for ultimate purchase by the end-user. The scope also includes add-on kits. Add-on kits include, but are not limited to, kits that allow the end-user to add an extension shelving unit onto an existing boltless steel shelving unit such that the

[1] *See Boltless Steel Shelving Units Prepackaged for Sale from the People's Republic of China: Antidumping Duty Order,* 80 FR 63741 (October 21, 2015); *see also Boltless Steel Shelving Units Prepackaged for Sale from the People's Republic of China: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 80 FR 63745 (October 21, 2015) (collectively, *Orders*).

[2] *See Boltless Steel Shelving Units Prepackaged for Sale from China; Institution of Five-Year Reviews,* 85 FR 54404 (September 1, 2020).

[3] *See Initiation of Five-Year (Sunset) Reviews,* 85 FR 54348 (September 1, 2020) (*Notice of Initiation*).

[4] *See Boltless Steel Shelving Units Prepackaged for Sale from the People's Republic of China: Final Results of the Expedited Sunset Review of Antidumping Duty Order,* 86 FR 59 (January 4, 2021), and accompanying Issues and Decision Memorandum (IDM); *see also Boltless Steel Shelving Units Prepackaged for Sale from the People's Republic of China: Final Results of the Expedited Sunset Review of the Countervailing Duty Order,* 86 FR 58 (January 4, 2021), and accompanying IDM.

[5] *See Boltless Steel Shelving Units Prepackaged for Sale from China,* 86 FR 23981 (May 5, 2021).

extension and the original unit will share common frame elements (*e.g.,* two posts). The term ''boltless'' refers to steel shelving in which the vertical and horizontal supports forming the frame are assembled primarily without the use of nuts and bolts or screws. The vertical and horizontal support members for boltless steel shelving are assembled by methods such as, but not limited to, fitting a rivet, punched or cut tab or other similar connector on one support into a hole, slot or similar receptacle on another support. The supports lock together to form the frame for the shelving unit and provide the structural integrity of the shelving unit separate from the inclusion of any decking. The incidental use of nuts and bolts or screws to add accessories, wall anchors, tie-bars or shelf supports does not remove the product from scope. Boltless steel shelving units may also come packaged as partially assembled, such as when two upright supports are welded together with front-to-back supports, or are otherwise connected, to form an end unit for the frame. The boltless steel shelving covered by the *Orders* may be commonly described as rivet shelving, welded frame shelving, slot and tab shelving, and punched rivet (quasi-rivet) shelving as well as by other trade names. The term ''deck'' refers to the shelf that sits on or fits into the horizontal supports (beams or braces) to provide the horizontal storage surface of the shelving unit.

The scope includes all boltless steel shelving meeting the description above, regardless of: (1) Vertical support or post type (including but not limited to open post, closed post and tubing); (2) horizontal support or beam/brace profile (including but not limited to Z-beam, C-beam, L-beam, step beam and cargo rack); (3) number of supports; (4) surface coating (including but not limited to paint, epoxy, powder coating, zinc and other metallic coating); (5) number of levels; (6) weight capacity; (7) shape (including but not limited to rectangular, square, and corner units); (8) decking material (including but not limited to wire decking, particle board, laminated board or no deck at all); or (9) the boltless method by which vertical and horizontal supports connect (including but not limited to keyhole and rivet, slot and tab, welded frame, punched rivet and clip).

Specifically excluded from the scope are:

- Wall-mounted shelving, defined as shelving that is hung on the wall and does not stand on, or transfer load to, the floor;
- wire shelving units, which consist of shelves made from wire that incorporates both a wire deck and wire horizontal supports (taking the place of the horizontal beams and braces) into a single piece with tubular collars that slide over the posts and onto plastic sleeves snapped on the posts to create the finished shelving unit;
- bulk-packed parts or components of boltless steel shelving units; and
- made-to-order shelving systems.

Subject boltless steel shelving enters under the United States through Harmonized Tariff Schedule of the United States (HTSUS) statistical subheadings 9403.20.0018, 9403.20.0020, 9403.20.0025, and 9403.20.0026, but may also enter through HTSUS 9403.10.0040. While 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 a continuation or a recurrence of dumping and countervailable subsidies, as well as material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, Commerce hereby orders the continuation of the *Orders.* U.S. Customs and Border Protection will continue to collect AD and CVD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise. The 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 351.281(c)(2), Commerce intends to initiate the next five-year reviews of the *Orders* not later than 30 days prior to the fifth anniversary of the effective date of continuation.

Notification to Interested Parties

These five-year sunset reviews and this notice are in accordance with section 751(c) of the Act and published in accordance with section 777(i)(1) of the Act and 19 CFR 351.218(f)(4).

Dated: May 6, 2021.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2021–09999 Filed 5–11–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–428–850]

Thermal Paper From Germany: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Affirmative Determination of Critical Circumstances in Part, Postponement of Final Determination, and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that thermal paper from Germany is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation is October 1, 2019, through September 30, 2020. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable May 12, 2021.

FOR FURTHER INFORMATION CONTACT: David Goldberger, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4136.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on November 3, 2020.[1] On February 25, 2021, Commerce postponed the preliminary determination of this investigation and the revised deadline is now May 5, 2021.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public

[1] *See Thermal Paper from Germany, Japan, the Republic of Korea, and Spain: Initiation of Less-Than-Fair-Value Investigations*, 85 FR 69580 (November 3, 2020) (*Initiation Notice*).

[2] *See Thermal Paper from Germany, Japan, the Republic of Korea, and Spain: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations*, 86 FR 11502.

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Thermal Paper from Germany,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.*

Scope of the Investigation

The product covered by this investigation is thermal paper from Germany. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted on the record for this investigation, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[6] Commerce is not preliminarily modifying the scope language as it appeared in the *Initiation Notice. See* the scope in Appendix I to this notice.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Constructed export prices have been calculated in accordance with section 772(b) of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

Preliminary Affirmative Determination of Critical Circumstances

In accordance with section 733(e) of the Act and 19 CFR 351.206, Commerce preliminarily finds that critical circumstances exist for Papierfabrik August Koehler SE (Koehler), but not the companies covered by the all-others rate. For a full description of the methodology and results of Commerce's critical circumstances analysis, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that in the preliminary determination Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

Commerce calculated an individual estimated weighted-average dumping margin for Koehler, the only individually examined exporter/producer in this investigation. Because the only individually calculated dumping margin is not zero, *de minimis,* or based entirely on facts otherwise available, the estimated weighted-average dumping margin calculated for Koehler is the margin assigned to all other producers and exporters, pursuant to section 735(c)(5)(A) of the Act.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Papierfabrik August Koehler SE	2.78
All Others	2.78

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin, as follows: (1) The cash deposit rate for the respondent listed above will be equal to the company-specific estimated weighted-average dumping margin determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of any public announcement, or if there is no public announcement, within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination. Normally, Commerce verifies information using standard procedures, including an on-site examination of original accounting, financial, and sales documentation. However, due to current travel restrictions in response to the global COVID–19 pandemic, Commerce is unable to conduct on-site verification in this investigation. Accordingly, we intend to verify the information relied upon in making the final determination through alternative means in lieu of an on-site verification.

Public Comment

Case briefs or other written comments on non-scope issues may be submitted to the Assistant Secretary for Enforcement and Compliance. Interested parties will be notified of the timeline for the submission of case briefs and written comments at a later date. Rebuttal briefs, limited to issues raised in case briefs on non-scope issues, may be submitted no later than seven days after the deadline date for case briefs.[7] The deadlines for submitting case and rebuttal briefs on scope issues are identified in the Preliminary Scope Decision Memorandum. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[8] Pursuant to 19 CFR 351.309(c)(2) and

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice.*

[6] *See* Memorandum, ''Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated concurrently with this notice (Scope Comments Decision Memorandum).

[7] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[8] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

(d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing.[9]

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioners.[10] Pursuant to 19 CFR 351.210(e)(2), Commerce requires that requests by respondents for postponement of a final AD determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On April 14, 2021, Koehler requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[11] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) The preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: May 5, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The scope of this investigation covers thermal paper in the form of ''jumbo rolls'' and certain ''converted rolls.'' The scope covers jumbo rolls and converted rolls of thermal paper with or without a base coat (typically made of clay, latex, and/or plastic pigments, and/or like materials) on one or both sides; with thermal active coating(s) (typically made of sensitizer, dye, and co-reactant, and/or like materials) on one or both sides; with or without a top coat (typically made of pigments, polyvinyl alcohol, and/or like materials), and without an adhesive backing. Jumbo rolls are defined as rolls with an actual width of 4.5 inches or more, an actual weight of 65 pounds or more, and an actual diameter of 20 inches or more (jumbo rolls). All jumbo rolls are included in the scope regardless of the basis weight of the paper. Also included in the scope are ''converted rolls'' with an actual width of less than 4.5 inches, and with an actual basis weight of 70 grams per square meter (gsm) or less.

The scope of this investigation covers thermal paper that is converted into rolls with an actual width of less than 4.5 inches and with an actual basis weight of 70 gsm or less in third countries from jumbo rolls produced in the subject countries.

The merchandise subject to this investigation may be classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 4811.90.8030 and 4811.90.9030. Although HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Scope Comments
V. Scope of the Investigation
VI. Affirmative Preliminary Determination of Critical Circumstances
VII. Discussion of the Methodology
VIII. Date of Sale
IX. Product Comparisons
X. Constructed Export Price
XI. Normal Value
XII. Currency Conversion
XIII. Recommendation

[FR Doc. 2021–09965 Filed 5–11–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–469–824]

Thermal Paper From Spain: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that thermal paper from Spain is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is October 1, 2019, through September 30, 2020. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable May 12, 2021.

FOR FURTHER INFORMATION CONTACT: Abdul Alnoor, 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) 482–4554.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on November 3, 2020.[1] On February 25, 2021, Commerce postponed the deadline for the preliminary

[9] *See* 19 CFR 351.310(d).

[10] The petitioners are Appvion Operations, Inc. and Domtar Corporation.

[11] *See* Koehler's Letter, ''Koehler's Request to Extend the Antidumping Duty Final Determination,'' dated April 14, 2021.

[1] *See Thermal Paper from Germany, Japan, the Republic of Korea, and Spain: Initiation of Less-Than-Fair-Value Investigations,* 85 FR 69580 (November 3, 2020) (*Initiation Notice*).

determination in this investigation; the revised deadline is now May 5, 2021.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics discussed in the Preliminary Decision Memorandum is in Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.*

Scope of the Investigation

The products covered by this investigation are thermal paper from Spain. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

In accordance with the *Preamble* to Commerce's regulations,[4] in the *Initiation Notice* we set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttals submitted on the record of this investigation, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[6] Commerce is not preliminarily modifying the scope language as it appeared in the *Initiation Notice. See* the scope in Appendix I to this notice.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Pursuant to sections 776(a) and (b) of the Act, Commerce has preliminarily relied upon facts otherwise available to assign an estimated weighted-average dumping margin to the sole mandatory respondent in this investigation, Torraspapel S.A. (Torraspapel) because Torraspapel failed to submit a full response to Commerce's antidumping duty questionnaire. Furthermore, Commerce is preliminarily determining that Torraspapel failed to cooperate by not acting to the best of its ability to comply with a request for information and is using an adverse inference when selecting from among the facts otherwise available (*i.e.,* is basing Torraspapel's dumping margin on total adverse facts available (AFA), in accordance with section 776(b) of Act). For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that, in the preliminary determination, Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* dumping margins, and any dumping margins determined entirely under section 776 of the Act.

Pursuant to section 735(c)(5)(B) of the Act, if the estimated weighted-average dumping margins established for all exporters and producers individually examined are zero, *de minimis* or determined based entirely on facts otherwise available, Commerce may use any reasonable method to establish the estimated weighted-average dumping margin for all-other producers or exporters. Commerce has preliminarily determined the estimated weighted-average dumping margin for the sole mandatory respondent, Torraspapel, under section 776 of the Act. Consequently, pursuant to section 735(c)(5)(B) of the Act, Commerce's normal practice under these circumstances has been to calculate the ''all-others'' rate as a simple average of the alleged dumping margins from the petition.[7] For a full description of the methodology underlying Commerce's analysis, *see* the Preliminary Decision Memorandum.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Dumping margin (percent)
Torraspapel S.A	41.45
All others	37.07

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in the Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate, as follows: (1) The cash deposit rate for the respondent listed above will be equal to the company-specific estimated weighted-average dumping margin determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others

[2] *See Thermal Paper from Germany, Japan, the Republic of Korea, and Spain: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations,* 86 FR 11502 (February 25, 2021).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Thermal Paper from Spain,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties; Final Rule,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

[5] *See Initiation Notice,* 85 FR 69580, 69581.

[6] *See* Memorandum, ''Thermal Paper from Germany, Japan, the Republic of Korea, and Spain: Preliminary Scope Decision,'' dated May 5, 2021.

[7] *See, e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value: Sodium Nitrite from the Federal Republic of Germany,* 73 FR 21909, 21912 (April 23, 2008), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: Sodium Nitrite from the Federal Republic of Germany,* 73 FR 38986, 38987 (July 8, 2008), and accompanying Issues and Decision Memorandum at Comment 2; *see also Notice of Final Determination of Sales at Less Than Fair Value: Raw Flexible Magnets from Taiwan,* 73 FR 39673, 39674 (July 10, 2008); *Steel Threaded Rod from Thailand: Preliminary Determination of Sales at Less Than Fair Value and Affirmative Preliminary Determination of Critical Circumstances,* 78 FR 79670, 79671 (December 31, 2013), unchanged in *Steel Threaded Rod from Thailand: Final Determination of Sales at Less Than Fair Value and Affirmative Final Determination of Critical Circumstances,* 79 FR 14476, 14477 (March 14, 2014); Petitioners' Letter, ''Petitions for the Imposition of Antidumping Duties on Imports of Thermal Paper From Germany, Japan, Korea, and Spain,'' dated October 7, 2020 at Volume V; Petitioners' Letter, ''Response of Petitioners to Volumes I–V Supplemental Questionnaires: Thermal Paper from Germany, Japan, Korea, and Spain,'' dated October 16, 2020 at section ''Petitioners' Responses to Supplemental Questions Regarding Volume V''; and Checklist, ''Enforcement and Compliance Office of AD/CVD Operations Antidumping Duty Investigation Initiation Checklist: Thermal Paper from Spain,'' dated October 27, 2020.

estimated weighted-average dumping margin. These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with a preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of preliminary determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce preliminarily applied AFA to the mandatory respondent in this investigation, Torraspapel, in accordance with section 776 of the Act, and the AFA dumping margin is based solely on the petition, there are no calculations to disclose.

Verification

Because the mandatory respondent in this investigation did not act to the best of its ability to provide information requested by Commerce, and Commerce preliminarily determined that the mandatory respondent is uncooperative, we will not conduct verification.

Public Comment

Case briefs or other written comments on non-scope issues may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 21 days after the date of publication of the preliminary determination in the **Federal Register**.[8] Rebuttal briefs on non-scope issues, limited to issues raised in case briefs on non-scope issues, may be submitted no later than seven days after the deadline for case briefs.[9] The deadlines for submitting case and rebuttal briefs on scope issues are in the Preliminary Scope Decision Memorandum. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[10] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice in the **Federal Register**. Requests for a hearing should contain: (1) The requesting party's name, address, and telephone number; (2) the number of individuals from the requesting party's firm that will attend the hearing, including whether any individual is a foreign national; and (3) a list of the issues the party intends to discuss at the hearing. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, and time of the hearing two days before the scheduled hearing date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination in the **Federal Register** if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On April 27, 2021, pursuant to 19 CFR 351.210(e), Torraspapel requested that Commerce postpone the final determination and that provisional measures be extended not more than six months.[11] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) The preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination in the **Federal Register**.

International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its affirmative preliminary determination. If the final determination is affirmative, the ITC will determine, before the later of 120 days after the date of this preliminary determination or 45 days after Commerce's final determination, whether subject imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: May 5, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The scope of this investigation covers thermal paper in the form of ''jumbo rolls'' and certain ''converted rolls.'' The scope covers jumbo rolls and converted rolls of thermal paper with or without a base coat (typically made of clay, latex, and/or plastic pigments, and/or like materials) on one or both sides; with thermal active coating(s) (typically made of sensitizer, dye, and co-reactant, and/or like materials) on one or both sides; with or without a top coat (typically made of pigments, polyvinyl alcohol, and/or like materials), and without an adhesive backing. Jumbo rolls are defined as rolls with an actual width of 4.5 inches or more, an actual weight of 65 pounds or more, and an actual diameter of 20 inches or more (jumbo rolls). All jumbo rolls are included in the scope regardless of the basis weight of the paper. Also included in the scope are ''converted rolls'' with an actual width of less than 4.5 inches, and with an actual basis weight of 70 grams per square meter (gsm) or less.

The scope of this investigation covers thermal paper that is converted into rolls with an actual width of less than 4.5 inches and with an actual basis weight of 70 gsm or less in third countries from jumbo rolls produced in the subject countries.

The merchandise subject to this investigation may be classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings

[8] *See* 19 CFR 351.309(c)(1)(i); *see also* 19 CFR 351.303 (for general filing requirements). Commerce has exercised its discretion under 19 CFR 351.309(c)(1)(i) to alter the time limit for submission of case briefs.

[9] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[10] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[11] *See* Torraspapel's Letter, ''Thermal Paper from Spain; AD Investigation; Request for Postponement of Final Determination and Extension of Provisional Measures Period,'' dated April 27, 2021.

4811.90.8030 and 4811.90.9030. Although HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Scope Comments
V. Scope of the Investigation
VI. Application of Facts Available, Use of Adverse Inferences, and Calculation of All-Others Rate
VII. Recommendation

[FR Doc. 2021–09967 Filed 5–11–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

President's Advisory Council on Doing Business in Africa

AGENCY: U.S. Department of Commerce, International Trade Administration.

ACTION: Notice of an opportunity to apply for membership on the President's Advisory Council on Doing Business in Africa.

SUMMARY: The Department of Commerce is currently seeking applications for membership on the 2021–2023 term of the President's Advisory Council (Advisory Council) on Doing Business in Africa. The purpose of the Advisory Council is to advise the President through the Secretary of Commerce on strengthening commercial engagement between the United States and Africa. This term, the Secretary is particularly interested in advice on advancing President Biden's strategy for Africa.

DATES: All applications for immediate consideration for appointment must be received by the Office of Africa by 5:00 p.m. Eastern Daylight Time (EDT) on June 25, 2021. After that date, the International Trade Administration (ITA) will continue to accept applications under this notice for a period of up to two years from the deadline to fill any vacancies that may arise.

ADDRESSES: Please submit applications by email to *dbia@trade.gov,* attention: Ashley Bubna and Giancarlo Cavallo, Designated Federal Officers, President's Advisory Council on Doing Business in Africa, Office of Africa.

FOR FURTHER INFORMATION CONTACT: Ashley Bubna and Giancarlo Cavallo, Designated Federal Officers, President's Advisory Council on Doing Business in Africa, telephone: 202–250–9798 (Ms. Bubna) and 202–766–8044 (Mr. Cavallo), email: *dbia@trade.gov, Ashley.Bubna@trade.gov*, and *Giancarlo.Cavallo@trade.gov*.

SUPPLEMENTARY INFORMATION: The President's Advisory Council on Doing Business in Africa (Advisory Council) was established pursuant to Executive Order No. 13675 dated August 5, 2014, and continued by Executive Order 13889 until September 30, 2021. The Advisory Council was established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App., to advise the President through the Secretary of Commerce (Secretary) on strengthening commercial engagement between the United States and Africa.

The Department of Commerce, International Trade Administration, Office of Africa, is accepting applications for Advisory Council members. The Advisory Council shall provide information, analysis, and recommendations to the President that address the following, in addition to other topics deemed relevant by the President, the Secretary, or the Advisory Council:

(i) Creating jobs in the United States and Africa through trade and investment;

(ii) developing strategies by which the U.S. private sector can identify and take advantage of trade and investment opportunities in Africa;

(iii) building lasting commercial partnerships between the U.S. and African private sectors;

(iv) facilitating U.S. business participation in Africa's infrastructure development;

(v) contributing to the growth and improvement of Africa's agricultural sector by encouraging partnerships between U.S. and African companies to bring innovative agricultural technologies to Africa;

(vi) making available to the U.S. private sector an accurate understanding of the opportunities presented for increasing trade with and investment in Africa;

(vii) developing and strengthening partnerships and other mechanisms to increase U.S. public and private sector financing of trade with and investment in Africa;

(viii) analyzing the effect of policies in the United States and Africa on U.S. trade and investment interests in Africa;

(ix) identifying other means to expand commercial ties between the United States and Africa; and

(x) building the capacity of Africa's young entrepreneurs to develop trade and investment ties with U.S. partners.

Executive Order 13675, as amended, provides that the Advisory Council shall consist of not more than 26 private sector corporate members, including small businesses and representatives from infrastructure, agriculture, consumer goods, banking, services, and other industries. The Secretary of Commerce intends to make appointments under this notice up to the current number of Advisory Council members, consistent with the Executive Order and the Advisory Council charter.

The Advisory Council shall be broadly representative of the key industries with business interests in the functions of the Advisory Council as set forth above. Each Advisory Council member shall serve as the representative of a U.S. company engaged in activities involving trade, investment, development or finance with African markets. The Department particularly seeks applicants who are active executives (Chief Executive Officer, Executive Chairman, President or comparable level of responsibility); however, for very large companies, a person having substantial responsibility for the company's commercial activities in Africa may be considered.

For eligibility purposes, a ''U.S. company'' is a for-profit firm incorporated in the United States or with its principal place of business in the United States that is (a) majority controlled (more than 50 percent ownership interest and/or voting stock) by U.S. citizens or by another U.S. entity or (b) majority controlled (more than 50 percent ownership interest and/or voting stock) directly or indirectly by a foreign parent company. Members are not required to be a U.S. citizen; however, members may not be registered as a foreign agent under the Foreign Agents Registration Act. Additionally, no member shall represent a company that is majority owned or controlled by a foreign government entity or entities.

Members of the Advisory Council will be selected, in accordance with applicable Department of Commerce guidelines, based on their ability to carry out the objectives of the Advisory Council as set forth above. Members shall be selected in a manner that ensures that the Advisory Council is balanced in terms of points of view, industry subsector, activities in and with African markets, range of products and services, demographics, geography, and company size. Additional factors which will be considered in the selection of Advisory Council members include candidates' proven leadership and experience in the trade, investment, financing, development, or other

commercial activities between the United States and Africa. Priority may be given to active executives (Chief Executive Officer, Executive Chairman, President or comparable level of responsibility). Appointments to the Advisory Council shall be made without regard to political affiliation.

The Secretary appoints the members of the Advisory Council in consultation with the Trade Promotion Coordinating Committee (TPCC), a Federal interagency group led by the Secretary and tasked with coordinating export promotion and export financing activities of the U.S. Government and development of a government-wide strategic plan to carry out such activities. Members shall serve a term of two years, at the pleasure of the Secretary.

Members shall serve in a representative capacity, representing the views and interests of their particular industry sector. Advisory Council members are not special government employees, and will receive no compensation for their participation in Advisory Council activities. Members participating in Advisory Council meetings and events will be responsible for their travel, living and other personal expenses. Meetings will be held regularly and, to the extent practical, not less than twice annually, in Washington, DC, or other locations as feasible. Teleconference meetings may also be held as needed.

To be considered for membership, submit the following information by 5:00 p.m. EDT on June 25, 2021 to the email address listed in the **ADDRESSES** section:

1. Name and title of the individual requesting consideration.

2. A sponsor letter from the applicant on his or her company letterhead containing a brief statement of why the applicant should be considered for membership on the Advisory Council. This sponsor letter should also address the applicant's experience and leadership related to trade, investment, financing, development, or other commercial activities between the United States and Africa.

3. The applicant's personal resume and short bio (less than 300 words).

4. An affirmative statement that the applicant meets all eligibility criteria, including an affirmative statement that the applicant is not required to register as a foreign agent under the Foreign Agents Registration Act of 1938, as amended.

5. Information regarding the ownership and control of the company, including the stock holdings as appropriate, signifying compliance with the criteria set forth above.

6. The company's size, product or service line, and major markets in which the company operates.

7. A profile of the company's trade, investment, development, finance, partnership, or other commercial activities in or with African markets.

8. Brief statement describing how the applicant will contribute to the work of the Advisory Council based on his or her unique experience and perspective (not to exceed 100 words).

Frederique Stewart,

Director, Office of Africa.

[FR Doc. 2021–09979 Filed 5–11–21; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–911]

Thermal Paper From the Republic of Korea: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Affirmative Determination of Critical Circumstances, Postponement of Final Determination, and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that thermal paper from the Republic of Korea (Korea) is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation is October 1, 2019, through September 30, 2020. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable May 12, 2021.

FOR FURTHER INFORMATION CONTACT: Kristen Ju or Aleksandras Nakutis, 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) 482–3699 or (202) 482–3147, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on November 3, 2020.[1] On February 25, 2021, Commerce postponed the deadline for the preliminary determination in this investigation; the revised deadline is now May 5, 2021.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics discussed in the Preliminary Decision Memorandum is in Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.*

Scope of the Investigation

The products covered by this investigation are thermal paper from Korea. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the *Preamble* to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttals submitted on the record of this investigation, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[6] Commerce is not preliminarily modifying the scope language as it

[1] *See Thermal Paper from Germany, Japan, the Republic of Korea, and Spain: Initiation of Less-Than-Fair-Value Investigations,* 85 FR 69580 (November 3, 2020) (*Initiation Notice*).

[2] *See Thermal Paper from Germany, Japan, the Republic of Korea, and Spain: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations,* 86 FR 11502 (February 25, 2021).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Thermal Paper from the Republic of Korea,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

[5] *See Initiation Notic*e, 85 FR at 69581.

[6] *See* Memorandum, ''Thermal Paper from Germany, Japan, the Republic of Korea, and Spain: Preliminary Scope Decision,'' dated May 5, 2021.

appeared in the *Initiation Notice. See* the scope in Appendix I to this notice.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce calculated export prices in accordance with section 772(a) of the Act and constructed export prices in accordance with section 772(b) of the Act. Commerce calculated normal value in accordance with section 773 of the Act. For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

Preliminary Affirmative Determination of Critical Circumstances

In accordance with section 733(e) of the Act and 19 CFR 351.206, Commerce preliminarily finds that critical circumstances exist for Hansol Paper Company (Hansol Paper) and all other producers and exporters in Korea. For a full description of the methodology and results of Commerce's critical circumstances analysis, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that, in the preliminary determination, Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* dumping margins, and any dumping margins determined entirely under section 776 of the Act.

Commerce calculated an individual estimated weighted-average dumping margin for Hansol Paper, the only individually examined exporter/producer in this investigation. Because the only individually calculated dumping margin is not zero, *de minimis,* or based entirely on facts otherwise available, we assigned the estimated weighted-average dumping margin that we calculated for Hansol Paper to all other producers and exporters in Korea, pursuant to section 735(c)(5)(A) of the Act.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Hansol Paper Company	6.19
All-Others	6.19

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise described in Appendix I on and after the date identified below. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate, as follows: (1) The cash deposit rate for the respondent listed above will be equal to the company-specific estimated weighted-average dumping margin determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.

Section 733(e)(2) of the Act provides that, given an affirmative determination of critical circumstances, any suspension of liquidation shall apply to unliquidated entries of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the later of: (a) The date which is 90 days before the date on which the suspension of liquidation was first ordered; or (b) the date on which the notice of initiation of the investigation was published. As noted above, Commerce preliminarily finds that critical circumstances exist for imports of subject merchandise produced and exported by Hansol Paper and all other exporters and producers in Korea. In accordance with section 733(e)(2)(A) of the Act, the suspension of liquidation shall apply to unliquidated entries of shipments of subject merchandise from Hansol Paper and all other exporters and producers in Korea that were entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the date of publication of this notice in the **Federal Register**.

These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose its preliminary calculations and related analysis to interested parties within five days of any public announcement of the preliminary determination or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination. Normally, Commerce verifies information using standard procedures, including an on-site examination of original accounting, financial, and sales documentation. However, due to current travel restrictions in response to the global COVID–19 pandemic, Commerce is unable to conduct on-site verification in this investigation. Accordingly, we intend to verify the information relied upon in making the final determination through alternative means in lieu of an on-site verification.

Public Comment

Case briefs or other written comments on non-scope issues may be submitted to the Assistant Secretary for Enforcement and Compliance. A timeline for the submission of case briefs and written comments on non-scope issues will be provided to interested parties later. Rebuttal briefs, limited to issues raised in case briefs on non-scope issues, may be submitted no later than seven days after the deadline date for case briefs.[7] The deadlines for submitting case and rebuttal briefs on scope issues are identified in the Preliminary Scope Decision Memorandum. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[8] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue;

[7] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[8] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

(2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice in the **Federal Register**. Requests for a hearing should contain: (1) The requesting party's name, address, and telephone number; (2) the number of individuals from the requesting party's firm that will attend the hearing, including whether any participant is a foreign national; and (3) a list of the issues the party intends to discuss at the hearing. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date and time of the hearing two days before the scheduled hearing date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination in the **Federal Register** if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On April 19, 2021, pursuant to 19 CFR 351.210(e), Hansol Paper requested that Commerce postpone the final determination and that provisional measures be extended not more than six months.[9] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) The preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination in the **Federal Register**.

International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its affirmative preliminary determination. If the final determination is affirmative, the ITC will determine, before the later of 120 days after the date of this preliminary determination or 45 days after Commerce's final determination whether subject imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: May 5, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The scope of this investigation covers thermal paper in the form of ''jumbo rolls'' and certain ''converted rolls.'' The scope covers jumbo rolls and converted rolls of thermal paper with or without a base coat (typically made of clay, latex, and/or plastic pigments, and/or like materials) on one or both sides; with thermal active coating(s) (typically made of sensitizer, dye, and co-reactant, and/or like materials) on one or both sides; with or without a top coat (typically made of pigments, polyvinyl alcohol, and/or like materials), and without an adhesive backing. Jumbo rolls are defined as rolls with an actual width of 4.5 inches or more, an actual weight of 65 pounds or more, and an actual diameter of 20 inches or more (jumbo rolls). All jumbo rolls are included in the scope regardless of the basis weight of the paper. Also included in the scope are ''converted rolls'' with an actual width of less than 4.5 inches, and with an actual basis weight of 70 grams per square meter (gsm) or less.

The scope of this investigation covers thermal paper that is converted into rolls with an actual width of less than 4.5 inches and with an actual basis weight of 70 gsm or less in third countries from jumbo rolls produced in the subject countries.

The merchandise subject to this investigation may be classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 4811.90.8030 and 4811.90.9030. Although HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Scope Comments
V. Scope of the Investigation
VI. Critical Circumstances
VII. Discussion of the Methodology
VIII. Date of Sale
IX. Product Comparisons
X. Export Price and Constructed Export Price
XI. Normal Value
XII. Currency Conversion
XIII. Recommendation

[FR Doc. 2021–09966 Filed 5–11–21; 8:45 am]

BILLING CODE 3510–DS–P

[9] *See* Hansol Paper's Letter, ''Thermal Paper Products from the Republic of Korea: Request for Postponement of Final Determination and Extension of Provisional Measures Period,'' dated April 19, 2021.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–920]

Lightweight Thermal Paper From the People's Republic of China: Rescission of Antidumping Duty Administrative Review; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable May 12, 2021.

SUMMARY: The Department of Commerce (Commerce) is rescinding the 2019–2020 antidumping duty (AD) administrative review of lightweight thermal paper (LWTP) from the People's Republic of China (China) based on a timely request for withdrawal. The period of review (POR) is November 1, 2019, through October 31, 2020.

FOR FURTHER INFORMATION CONTACT: Alex Cipolla, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4956.

SUPPLEMENTARY INFORMATION:

Background

On November 3, 2020, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the AD order on LWTP from China.[1] Commerce received a timely-filed request from Appvion, Inc. (Appvion), a domestic interested party and the petitioner in the underlying investigation, for an

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 85 FR 69586 (November 3, 2020).

administrative review of exports of subject merchandise to the United States during the POR with respect to 20 companies, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b).[2] On January 6, 2021, pursuant to this request, and in accordance with 19 CFR 351.221(c)(1)(i), Commerce published a notice initiating an administrative review of the AD order on LWTP from China.[3] On March 26, 2021, Appvion withdrew its request for an administrative review with respect to all companies for which it requested a review.[4]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party or parties that requested a review withdraws the request within 90 days of the publication date of the notice of initiation of the requested review. Appvion timely submitted a request to withdraw its request for an administrative review for all companies for which an administrative review was initiated. No other party requested an administrative review of the order. Therefore, in accordance with 19 CFR 351.213(d)(1), we are rescinding this review, in its entirety.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of LWTP from China. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 35 days after the date of publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as the only reminder to importers whose entries will be liquidated as a result of this rescission notice, of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the presumption that reimbursement of the antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as a reminder to all parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: May 6, 2021.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2021–10034 Filed 5–11–21; 8:45 am]

BILLING CODE 3510–DS–P

[2] *See* Appvion's Letter, ''Request for Administrative Review,'' dated November 30, 2020.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 511 (January 6, 2021).

[4] *See* Appvion's Letter, ''Withdrawal of Request for Administrative Review,'' dated March 26, 2021.

DEPARTMENT OF COMMERCE

International Trade Administration

Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable May 12, 2021.

FOR FURTHER INFORMATION CONTACT: John Hoffner, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Ave. NW, Washington, DC 20230, telephone: (202) 482–3315.

SUPPLEMENTARY INFORMATION: On January 26, 2021, the Department of Commerce (Commerce), pursuant to section 702(h) of the Trade Agreements Act of 1979 (as amended) (the Act), published the quarterly update to the annual listing of foreign government subsidies on articles of cheese subject to an in-quota rate of duty covering the period July 1, 2020, through September 30, 2020.[1] In the *Third Quarter 2020 Update,* we requested that any party that has information on foreign government subsidy programs that benefit articles of cheese subject to an in-quote rate of duty submit such information to Commerce.[2] We received no comments, information, or requests for consultation from any party.

Pursuant to section 702(h) of the Act, we hereby provide Commerce's update of subsidies on articles of cheese that were imported during the period September 1, 2020, through December 31, 2020. The appendix to this notice lists the country, the subsidy program or programs, and the gross and net amounts of each subsidy for which information is currently available.

Commerce will incorporate additional programs which are found to constitute subsidies, and additional information on the subsidy programs listed, as the information is developed. Commerce encourages any person having information on foreign government subsidy programs which benefit articles of cheese subject to an in-quota rate of duty to submit such information in writing through the Federal eRulemaking Portal at *https://www.regulations.gov,* Docket No. ITA–2020–0005, ''Quarterly Update to Cheese Subject to an In-Quota Rate of Duty.'' The materials in the docket will not be edited to remove identifying or contact information, and Commerce cautions against including any information in an electronic submission that the submitter does not want publicly disclosed. Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF formats only. All comments should be addressed to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, 1401 Constitution Ave. NW, Washington, DC 20230.

This determination and notice are in accordance with section 702(a) of the Act.

Dated: May 7, 2021.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[1] *See Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty,* 86 FR 7062 (January 26, 2021) (*Third Quarter 2020 Update*).

[2] *Id.*

Appendix

SUBSIDY PROGRAMS ON CHEESE SUBJECT TO AN IN-QUOTA RATE OF DUTY

Country	Program(s)	Gross [3] subsidy ($/lb)	Net [4] subsidy ($/lb)
27 European Union Member States [5]	European Union Restitution Payments	$0.00	$0.00
Canada	Export Assistance on Certain Types of Cheese	0.46	0.46
Norway	Indirect (Milk) Subsidy	0.00	0.00
	Consumer Subsidy	0.00	0.00
	Total	0.00	0.00
Switzerland	Deficiency Payments	0.00	0.00

[FR Doc. 2021–10036 Filed 5–11–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–880]

Thermal Paper From Japan: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that thermal paper from Japan is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation is October 1, 2019, through September 30, 2020. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable May 12, 2021.

FOR FURTHER INFORMATION CONTACT: Alex Wood, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1959.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on November 3, 2020.[1] On February 25, 2021, Commerce postponed the preliminary determination of this investigation; the revised deadline is now May 5, 2021.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics discussed in the Preliminary Decision Memorandum is included in Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.*

Scope of the Investigation

The products covered by this investigation are thermal paper from Japan. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted on the record for this investigation, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[6] Commerce is not preliminarily modifying the scope language as it appeared in the *Initiation Notice. See* the scope in Appendix I to this notice.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act. Constructed export prices have been calculated in accordance with section 772(b) of the Act. Normal value is calculated in accordance with section 773 of the Act. In addition, Commerce has relied on partial facts available under section 776(a)(1) of the Act. For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that, in the preliminary determination, Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any

[3] Defined in 19 U.S.C. 1677(5).

[4] Defined in 19 U.S.C. 1677(6).

[5] The 27 member states of the European Union are: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden.

[1] *See Thermal Paper from Germany, Japan, the Republic of Korea, and Spain: Initiation of Less-Than-Fair-Value Investigations,* 85 FR 69580 (November 3, 2020) (*Initiation Notice*).

[2] *See Thermal Paper from Germany, Japan, the Republic of Korea, and Spain: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations,* 86 FR 11502 (February 25, 2021).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Thermal Paper from Japan,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice.*

[6] *See* Memorandum, ''Thermal Paper from Germany, Japan, the Republic of Korea, and Spain: Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated concurrently with this notice (Preliminary Scope Decision Memorandum).

zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

Commerce calculated an individual estimated weighted-average dumping margin for Nippon Paper Industries Co., Ltd. (NPI), the only individually examined exporter/producer in this investigation. Because the only individually calculated dumping margin is not zero, *de minimis,* or based entirely on facts otherwise available, the estimated weighted-average dumping margin calculated for NPI is the margin assigned to all other producers and exporters, pursuant to section 735(c)(5)(A) of the Act.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Nippon Paper Industries Co., Ltd./Nippon Paper Papylia Co., Ltd[7]	35.71
All-Others	35.71

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate, as follows: (1) The cash deposit rate for the respondent listed above will be equal to the company-specific estimated weighted-average dumping margin determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination. Normally, Commerce verifies information using standard procedures, including an on-site examination of original accounting, financial, and sales documentation. However, due to current travel restrictions in response to the global COVID–19 pandemic, Commerce is unable to conduct on-site verification in this investigation. Accordingly, we intend to verify the information relied upon in making the final determination through alternative means in lieu of an on-site verification.

Public Comment

Case briefs or other written comments on non-scope issues may be submitted to the Assistant Secretary for Enforcement and Compliance. Interested parties will be notified of the timeline for the submission of case briefs and written comments at a later date. Rebuttal briefs, limited to issues raised in case briefs on non-scope issues, may be submitted no later than seven days after the deadline date for case briefs.[8] The deadlines for submitting case and rebuttal briefs on scope issues are identified in the Preliminary Scope Decision Memorandum. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[9] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing.[10]

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioners.[11] Pursuant to 19 CFR 351.210(e)(2), Commerce requires that requests by respondents for postponement of a final AD determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On April 19, 2021, NPI requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[12] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) The preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of

[7] Commerce preliminarily determines that Nippon Paper Industries Co, Ltd. and Nippon Paper Papylia Co., Ltd. are a single entity. *See* Preliminary Decision Memorandum.

[8] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[9] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[10] *See* 19 CFR 351.310(d).

[11] The petitioners are Appvion Operations, Inc., and Domtar Corporation.

[12] *See* NPI's Letter, ''NPI's Request to Postpone the Final Determination,'' dated April 19, 2021.

publication of this preliminary determination.

International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: May 5, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The scope of this investigation covers thermal paper in the form of ''jumbo rolls'' and certain ''converted rolls.'' The scope covers jumbo rolls and converted rolls of thermal paper with or without a base coat (typically made of clay, latex, and/or plastic pigments, and/or like materials) on one or both sides; with thermal active coating(s) (typically made of sensitizer, dye, and co-reactant, and/or like materials) on one or both sides; with or without a top coat (typically made of pigments, polyvinyl alcohol, and/or like materials), and without an adhesive backing. Jumbo rolls are defined as rolls with an actual width of 4.5 inches or more, an actual weight of 65 pounds or more, and an actual diameter of 20 inches or more (jumbo rolls). All jumbo rolls are included in the scope regardless of the basis weight of the paper. Also included in the scope are ''converted rolls'' with an actual width of less than 4.5 inches, and with an actual basis weight of 70 grams per square meter (gsm) or less.

The scope of this investigation covers thermal paper that is converted into rolls with an actual width of less than 4.5 inches and with an actual basis weight of 70 gsm or less in third countries from jumbo rolls produced in the subject countries.

The merchandise subject to this investigation may be classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 4811.90.8030 and 4811.90.9030. Although HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Scope Comments
V. Scope of the Investigation
VI. Discussion of the Methodology
VII. Application of Facts Available
VIII. Date of Sale
IX. Product Comparisons
X. Export Price and Constructed Export Price
XI. Normal Value
XII. Currency Conversion
XIII. Recommendation

[FR Doc. 2021–09849 Filed 5–11–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB081]

Marine Mammals and Endangered Species

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

ACTION: Notice; issuance of permits and permit amendments.

SUMMARY: Notice is hereby given that permits and permit amendments have been issued to the following entities under the Marine Mammal Protection Act (MMPA) and the Endangered Species Act (ESA), as applicable.

ADDRESSES: The permits and related documents are available for review upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Amy Hapeman (Permit No. 25498), Shasta McClenahan, Ph.D. (Permit Nos. 22306 and 23675), Jennifer Skidmore (Permit No. 23960 and 24395), Courtney Smith, Ph.D. (Permit No. 24378), and Sara Young (Permit No. 23188–01); at (301) 427–8401.

SUPPLEMENTARY INFORMATION: Notices were published in the **Federal Register** on the dates listed below that requests for a permit or permit amendment had been submitted by the below-named applicants. To locate the **Federal Register** notice that announced our receipt of the application and a complete description of the activities, go to *www.federalregister.gov* and search on the permit number provided in Table 1 below.

TABLE 1—ISSUED PERMITS AND PERMIT AMENDMENTS

Permit No.	RTID	Applicant	Previous **Federal Register** notice	Issuance date
22306	0648–XA897	NMFS Southwest Fisheries Science Center, 8901 La Jolla Shores Drive, La Jolla, CA 92037 (Responsible Party: David W. Weller, Ph.D.).	86 FR 11729; February 26, 2021.	April 21, 2021.
23188–01 ...	0648–XA896	Institute of Marine Sciences, University of California at Santa Cruz, 130 McAllister Way, Santa Cruz, CA 95060 (Responsible Party: Daniel Costa, Ph.D.).	86 FR 11930; March 1, 2021	April 27, 2021.
23675	0648–XA897	Brianna Witteveen, Ph.D., University of Alaska Fairbanks, 118 Trident Way, Kodiak, AK 99615.	86 FR 11729; February 26, 2021.	April 13, 2021.
23960	0648–XA912	Minnesota Zoological Gardens, 13000 Zoo Boulevard, Apple Valley, MN 55124 (Responsible Party: Tony Fisher).	86 FR 12918; March 5, 2021	April 30, 2021.
24378	0648–XA897	University of Alaska Southeast—Sitka Campus, 1332 Seward Avenue Sitka, AK 99835 (Responsible Party: Janice Straley).	86 FR 11729; February 26, 2021.	April 29, 2021.
24395	648–XA893	Lorrie Rea, Ph.D., University of Alaska Fairbanks, 1764 Tanana Loop ELIF Suite 240, Fairbanks, AK 99775.	86 FR 11730; February 26, 2021.	April 15, 2021.

TABLE 1—ISSUED PERMITS AND PERMIT AMENDMENTS—Continued

Permit No.	RTID	Applicant	Previous **Federal Register** notice	Issuance date
25498	0648–XA914	Titan Productions, Limited, 51–55 Whiteladies Road Bristol, BS8 2LY, United Kingdom (Responsible Party: Lucy Meadows).	86 FR 12926; March 5, 2021	April 13, 2021.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activities proposed are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

As required by the ESA, as applicable, issuance of these permit was based on a finding that such permits: (1) Were applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) are consistent with the purposes and policies set forth in Section 2 of the ESA.

Authority: The requested permits have been issued under the MMPA of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the ESA of 1973, as amended (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), as applicable.

Dated: May 6, 2021.

Julia Marie Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–09976 Filed 5–11–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Protocol for Access to Tissue Specimen Samples From the National Marine Mammal Tissue Bank

The Department of Commerce will submit 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, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on January 13, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic and Atmospheric Administration.

Title: Protocol for Access to Tissue Specimen Samples from the National Marine Mammal Tissue Bank.

OMB Control Number: 0648–0468.

Form Number(s): None.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 35.

Average Hours per Response: National Marine Mammal Tissue Bank Tissue Request Form, 3 hours; National Marine Mammal Tissue Bank Form, 45 minutes.

Total Annual Burden Hours: 98.

Needs and Uses: The purpose of this collection of information is to enable the National Oceanic and Atmospheric Administration (NOAA) to allow the scientific community the opportunity to request tissue specimen samples from the National Marine Mammal Tissue Bank (NMMTB), as well as for tissue samples to be submitted. This information collection is being renewed to enable the Marine Mammal Health and Stranding Response Program (MMHSRP) of NOAA to assemble information on all specimens submitted to the National Institute of Standards and Technology's National Biomonitoring Specimen Bank (Bank), which includes the NMMTB.

Affected Public: Individuals or households; Business or other for-profit organizations; Not-for-profit institutions; State, Local, or Tribal government; Federal government.

Frequency: Reporting (on occasion).

Respondent's Obligation: Mandatory.

Legal Authority: Under 16 U.S.C. 1421f section 407(d)(1) of the Marine Mammal Protection Act, the NMFS must establish criteria for access to marine mammal tissues in the NMMTB and make those available for public comment and review.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

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 and entering either the title of the collection or the OMB Control Number 0648–0468.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–10048 Filed 5–11–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; U.S. Pacific Highly Migratory Species Hook and Line Logbook

The Department of Commerce will submit 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, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on January 11, 2021 (86 FR 1943) during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic & Atmospheric Administration (NOAA), Commerce.

Title: U.S. Pacific Highly Migratory Species Hook and Line Logbook.

OMB Control Number: 0648–0223.

Form Number(s): NOAA 88–197.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 1,700.

Average Hours per Response: 1 hour.

Total Annual Burden Hours: 3,400.

Needs and Uses: Under the Fishery Management Plan for United States (U.S.) West Coast Fisheries for Highly Migratory Species (HMS), U.S. anglers participating in the Pacific hook-and-line (also known as the albacore troll and poll-and-line), coastal purse seine (vessels less than 400 st carrying capacity), large-mesh drift gillnet, and swordfish harpoon fisheries, are required to obtain an HMS permit. Permit holders are also required to complete and submit logbooks documenting their daily fishing activities, including catch and effort for each fishing trip. Logbook forms must be completed within 24 hours of the completion of each fishing day and submitted to the Southwest Fisheries Science Center (SWFSC) within 30 days of the end of each trip. Federal regulations allow the use of state logbooks to fulfill this requirement; for example, Washington commercial passenger fishing vessels have fulfilled this requirement to date for HMS fisheries. These data and associated analyses help the SWFSC provide critical HMS fisheries information to researchers, fisheries managers, and the needed management advice to the U.S. in its negotiations with foreign fishing nations that fish for HMS.

Affected Public: Business or other for-profit organizations.

Frequency: After each trip.

Respondent's Obligation: Required to Obtain or Retain Benefits, and Mandatory.

Legal Authority: Magnuson-Stevens Fishery Conservation and Management Act.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

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 and entering either the title of the collection or the OMB Control Number 0648–0223.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–10063 Filed 5–11–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Trademark Post Registration

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of information collection; request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651–0055 (Trademark Post Registration). The purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

DATES: To ensure consideration, comments regarding this information collection must be received on or before July 12, 2021.

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- *Email: InformationCollection@uspto.gov.* Include ''0651–0055 comment'' in the subject line of the message.
- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Mail:* Kimberly Hardy, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Catherine Cain, Attorney Advisor, Office of the Commissioner for Trademarks, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–8946; or by email at *Catherine.Cain@uspto.gov* with ''0651–0055 comment'' in the subject line. Additional information about this information collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

The United States Patent and Trademark Office (USPTO) administers the Trademark Act, 15 U.S.C. 1051 *et seq.,* which provides for the Federal registration of trademarks, service marks, collective trademarks and service marks, collective membership marks, and certification marks. Individuals and businesses that use or intend to use such marks in commerce may file an application to register their marks with the USPTO.

This information collection covers various communications submitted by individuals and businesses to the USPTO occurring after registration of a trademark. One type of communication is a request to amend registrations to delete goods or services that are no longer being used by the registrant or registration owner. Registered marks remain on the register for 10 years and can be renewed, but will be cancelled unless the registration owner files with the USPTO a declaration attesting to the continued use (or excusable non-use) of the mark in commerce, and a renewal application, within specific deadlines. Registration owners may also request to amend or divide a registration, respond to a post-registration Office action, and surrender a registration.

The information in this information collection is used to maintain the quality of the trademark register. The register information may be accessed by an individual or by businesses to determine the availability of a mark. By keeping the register current and accurate, parties may reduce the possibility of initiating use of a mark previously adopted by another.

II. Methods of Collection

Items in this information collection must be submitted via online electronic submissions through the Trademark Electronic Application System (TEAS). In limited circumstances, applicants may also be permitted to submit the information in paper form by mail or hand delivery.

III. Data

OMB Control Number: 0651–0055.

Form Numbers:

- PTO Form 1563 (Declaration of Use of Mark in Commerce Under Section 8)
- PTO Form 1573 (Declaration of Incontestability of a Mark Under Section 15)
- PTO Form 1583 (Combined Declaration of Use and

Incontestability Under Sections 8 and 15)
- PTO Form 1597 (Section 7 Request)
- PTO Form 1963 (Combined Declaration of Use of Mark in Commerce and Application for Renewal of Registration of a Mark Under Sections 8 and 9)
- PTO Form 2302 (Response to Office Action for Post-Registration Matters)
- PTO Form 2309 (Surrender of Registration for Cancellation)
- PTO Form 2310 (Request to Divide Registration)
- PTO Form 2311 (Section 12(c) Affidavit)

Type of Review: Extension and revision of a currently approved information collection.

Affected Public: Private sector; individuals or households.

Estimated Number of Respondents: 219,694 respondents per year.

Estimated Number of Responses: 219,694 responses per year.

Estimated Time per Response: The USPTO estimates that it takes the public approximately between 10 minutes (0.17 hours) and 45 minutes (0.75 hours), depending on the complexity of the situation. This includes the time to gather the necessary information, prepare the appropriate documents, and submit the information to the USPTO.

Estimated Total Annual Respondent Burden Hour: 113,620 hours.

Estimated Total Annual Respondent (Hourly) Cost Burden: $45,448,000.

TABLE 1—BURDEN HOUR/BURDEN COST TO PRIVATE SECTOR RESPONDENTS

Item No.	Item	Estimated annual respondents	Estimated annual responses (a)	Estimated time for response (hours) (b)	Estimated burden (hour/year) (a) × (b) = (c)	Rate [1] ($/hour) (d)	Estimated annual respondent cost burden (c) × (d) = (e)
1	Declaration of Use of Mark in Commerce Under Section 8 (PTO Form 1563).	11,932	11,932	0.50 (30 minutes)	5,966	$400	$2,386,400
2	Combined Declaration of Use of Mark in Commerce and Application for Renewal of Registration of a Mark Under Sections 8 & 9 (PTO Form 1963).	70,235	70,235	0.50 (30 minutes)	35,118	400	14,047,200
3	Declaration of Incontestability of a Mark Under Section 15 (PTO Form 1573).	853	853	0.17 (10 minutes)	145	400	58,000
4	Combined Declaration of Use and Incontestability Under Sections 8 and 15 (PTO Form 1583).	72,448	72,448	0.50 (30 minutes)	36,224	400	14,489,600
5	Surrender of registration for cancellation (PTO Form 2309).	390	390	0.17 (10 minutes)	66	400	26,400
6	Section 7 Request (PTO Form 1597).	5,330	5,330	0.58 (35 minutes)	3,091	400	1,236,400
7	Response to Office Action for Post-Registration Matters (PTO Form 2302).	12,001	12,001	0.75 (45 minutes)	9,001	400	3,600,400
8	Request to Divide Registration (PTO Form 2310).	2,566	2,566	0.50 (30 minutes)	1,283	400	513,200
9	Section 12(c) Affidavit (PTO Form 2311).	1	1	0.25 (15 minutes)	1	400	400
	Total	175,756	175,756	.....	90,895	.....	36,358,000

TABLE 2—BURDEN HOUR/BURDEN COST TO INDIVIDUAL OR HOUSEHOLD RESPONDENTS

Item No.	Item	Estimated annual respondents	Estimated annual responses (a)	Estimated time for response (hours) (b)	Estimated burden (hour/year) (a) × (b) = (c)	Rate [2] ($/hour) (d)	Estimated annual respondent cost burden (c) × (d) = (e)
1	Declaration of Use of Mark in Commerce Under Section 8 (PTO Form 1563).	2,983	2,983	0.50 (30 minutes)	1,492	$400	$596,800
2	Combined Declaration of Use of Mark in Commerce and Application for Renewal of Registration of a Mark Under Sections 8 & 9 (PTO Form 1963).	17,559	17,559	0.50 (30 minutes)	8,780	400	3,512,000
3	Declaration of Incontestability of a Mark Under Section 15 (PTO Form 1573).	213	213	0.17 (10 minutes)	36	400	14,400
4	Combined Declaration of Use and Incontestability Under Sections 8 and 15 (PTO Form 1583).	18,112	18,112	0.50 (30 minutes)	9,056	400	3,622,400
5	Surrender of registration for cancellation (PTO Form 2309).	98	98	0.17 (10 minutes)	17	400	6,800
6	Section 7 Request (PTO Form 1597).	1,332	1,332	0.58 (35 minutes)	773	400	309,200

[1] 2019 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); *https://www.aipla.org/detail/journal-issue/2019-report-of-the-economic-survey.*

[2] The USPTO uses the mean rate for attorneys in private firms which is $400 per hour.

TABLE 2—BURDEN HOUR/BURDEN COST TO INDIVIDUAL OR HOUSEHOLD RESPONDENTS—Continued

Item No.	Item	Estimated annual respondents	Estimated annual responses (a)	Estimated time for response (hours) (b)	Estimated burden (hour/year) (a) × (b) = (c)	Rate [2] ($/hour) (d)	Estimated annual respondent cost burden (c) × (d) = (e)
7	Response to Office Action for Post-Registration Matters (PTO Form 2302).	3,000	3,000	0.75 (45 minutes)	2,250	400	900,000
8	Request to Divide Registration (PTO Form 2310).	641	641	0.50 (30 minutes)	321	400	128,400
	Total	43,938	43,938	.....	22,725	.....	9,090,000

Estimated Total Annual (Non-hour) Respondent Cost Burden: $89,646,738. This information collection has no capital startup, maintenance fees, or operating fees. However, this information collection does have filing fees and postage costs. The total annual non-hour respondent cost burden for this information collection in the form of filing fees ($89,646,625) and postage costs ($113) is approximately $89,646,738.

Filing Fees

Filing fees are charged per class of goods or services and can vary depending on the number of classes. The filing fees shown here are based on the minimum fee of one class per document associated with this information collection.

TABLE 3—FILING FEES (NON-HOUR) COST BURDEN TRADEMARK POST REGISTRATION

Item No.	Item	Estimated annual responses (a)	Estimated cost (b)	Estimated non-hour cost burden (a) × (b) = (c)
1	Declaration of Use of Mark in Commerce Under Section 8	14,915	$225	$3,355,875
2	Combined Declaration of Use of Mark in Commerce and Application for Renewal of Registration of a Mark Under Sections 8 & 9 (TEAS).	87,791	525	46,090,275
2	Combined Declaration of Use of Mark in Commerce and Application for Renewal of Registration of a Mark Under Sections 8 & 9 (paper).	3	825	2,475
2	Issuing New Certificate of Registration	200	100	20,000
2	Certificate of Correction, Registrant's Error (TEAS)	6,463	100	646,300
2	Certificate of Correction, Registrant's Error (paper)	1	200	200
3	Declaration of Incontestability of a Mark Under Section 15	1,066	200	213,200
4	Combined Declaration of Use and Incontestability Under Section 8 and 15 (TEAS)	90,557	425	38,486,725
4	Combined Declaration of Use and Incontestability Under Section 8 and 15 (paper)	3	625	1,875
6	Section 7 Request	488	100	48,800
6–7	Deletion of Goods or Services after submission and prior to acceptance of a section 8 affidavit (TEAS).	1,839	250	459,750
6–7	Deletion of Goods or Services after submission and prior to acceptance of a section 8 affidavit (paper).	1	350	350
8	Request to Divide Registration	3,207	100	320,700
9	Section 12(c) Affidavit	1	100	100
	Total	.....	.....	89,646,625

Postage Costs

Although the USPTO requires that the items in this information collection be submitted electronically, the items may, in limited situations, be submitted by mail through the United States Postal Service (USPS). The USPTO estimates that the average postage cost for a mailed submission, using a Priority Mail 2-day flat rate legal envelope, will be $8.05. The USPTO estimates approximately 14 submissions per year may be mailed to the USPTO, for a total postage cost of $113 per year.

Respondent's Obligation: Required to obtain or retain benefits.

IV. Request for Comments

The USPTO is soliciting public comments to:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility;

(b) 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 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.

All comments submitted in response to this notice are a matter of public record. The USPTO will include or summarize each comment in the request to OMB to approve this information

[2] 2019 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); *https://www.aipla.org/detail/journal-issue/2019-report-of-the-economic-survey.* The USPTO uses the mean rate for attorneys in private firms which is $400 per hour.

collection. Before including an address, phone number, email address, or other personal identifying information (PII) in a comment, be aware that the entire comment—including PII—may be made publicly available at any time. While you may ask in your comment to withhold PII from public view, the USPTO cannot guarantee that it will be able to do so.

Kimberly Hardy,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2021–09972 Filed 5–11–21; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2021–SCC–0073]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Early Childhood Longitudinal Study, Kindergarten Class of 2023–24 (ECLS–K:2024) Preschool Round Removal Change Request

AGENCY: National Center for Education Statistics (NCES), Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a no material or nonsubstantive change to a currently approved information collection.

DATES: Interested persons are invited to submit comments on or before June 11, 2021.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Carrie Clarady, 202–245–6347 or email *NCES.Information.Collections@ed.gov.*

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Early Childhood Longitudinal Study, Kindergarten Class of 2023–24 (ECLS–K:2024) Preschool Round Removal Change Request.

OMB Control Number: 1850–0750.

Type of Review: No material or nonsubstantive change of a currently approved information collection.

Respondents/Affected Public: Individuals or households.

Total Estimated Number of Annual Responses: 46,033.

Total Estimated Number of Annual Burden Hours: 8,655.

Abstract: The Early Childhood Longitudinal Study (ECLS) program, conducted by the National Center for Education Statistics (NCES) within the Institute of Education Sciences (IES) of the U.S. Department of Education (ED), draws together information from multiple sources to provide rich, descriptive data on child development, early learning, and school progress. The ECLS program studies deliver national data on children's status at birth and at various points thereafter; children's transitions to nonparental care, early care and education programs, and school; and children's experiences and growth through the elementary grades. The Early Childhood Longitudinal Study, Kindergarten Class of 2022–23 (ECLS–K:2023) is the fourth cohort in the series of early childhood longitudinal studies. The study will advance research in child development and early learning by providing a detailed and comprehensive source of current information on children's early learning and development, transitions into kindergarten and beyond, and progress through school. Collecting parent data beginning in preschool will enable the study to measure influences on children's development before entry into formal schooling, including children's home environments and access to early care and education. The request to conduct a field test of the ECLS–K:2023 preschool data collection activities from January through October 2020, to field test the preschool data collection materials and procedures, was approved in November 2019 (OMB# 1850–0750 v.19), with change requests approved in January and July 2020 (OMB #1850–0750 v.20–21). In April 2021, OMB approved a one year study delay (OMB #1850–0750 v.22), and the study is now the Early Childhood Longitudinal Study, Kindergarten Class of 2023–24 (ECLS–K:2024). This request is to notify OMB and the public that, following analysis of the results of the preschool field test that was carried out in 2020, NCES has decided not to go forward with the national ECLS–K: 2024 preschool round in spring 2023. No other planned procedures or features of the study will change. Approval for the fall 2022 kindergarten-first grade field test and national study recruitment will be requested in a separate submission later in 2021.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021–09977 Filed 5–11–21; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

Notice of Federal Advisory Committee Charter Renewals

AGENCY: U.S. Election Assistance Commission.

ACTION: Notice of Federal Advisory Committee charter renewals.

SUMMARY: In accordance with the Federal Advisory Committee Act, the purpose of this notice is to announce that the Election Assistance Commission (EAC) has renewed the charters for the Board of Advisors, the Standards Board, and the Technical Guidelines Development Committee for a two-year period through April 13, 2023. The Board of Advisors, the Standards Board, and the Technical Guidelines Development Committee are federal advisory committees under the

Federal Advisory Committee Act and created by the Help America Vote Act of 2002.

DATES: Renewed through April 13, 2023.

ADDRESSES: Election Assistance Commission, 633 3rd Street NW, Suite 200, Washington, DC 20001.

To Obtain a Copy of the Charters: A complete copy of the Charters are available from the EAC in electronic format. An electronic copy can be downloaded in PDF format on the EAC's website, *http://www.eac.gov.* In order to obtain a paper copy of the Charters, please mail your request to the U.S. Election Assistance Commission FACA Boards Management at 633 3rd Street NW, Suite 200, Washington, DC 20001. Please note that due to COVID–19 restrictions there are delays in processing mailed requests and responses.

FOR FURTHER INFORMATION CONTACT: Kevin Rayburn, General Counsel, at 866–747–1471 (toll free) or 301–563–3919. Email: *facaboards@eac.gov.*

SUPPLEMENTARY INFORMATION: The Board of Advisors, the Standards Board, and the Technical Guidelines Development Committee are federal advisory committees created by statute whose mission is to advise the EAC through review of the voluntary voting systems guidelines, review of voluntary guidance, and review of best practices recommendations. In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, this notice advises interested persons of the renewal of these Charters.

Amanda Joiner,

Associate Counsel, U.S. Election Assistance Commission.

[FR Doc. 2021–10023 Filed 5–11–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC21–23–000]

Commission Information Collection Activities (FERC–725V); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice 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–725V, Mandatory Reliability Standards: COM Reliability Standards.

DATES: Comments on the collection of information are due July 12, 2021.

ADDRESSES: You may submit copies of your comments (identified by Docket No. IC21–23–000) by one of the following methods:

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:* Deliver to: Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: All 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,* telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC–725V, Mandatory Reliability Standards: COM Reliability Standards.

OMB Control No.: 1902–0277.

Type of Request: Three-year extension of the FERC–725V information collection requirements with no changes to the reporting requirements.

Abstract: On August 15, 2016, the North American Electric Reliability Corporation (NERC) filed a petition for Commission approval, pursuant to section 215(d)(1) of the Federal Power Act (''FPA'') [1] and Section 39.5 [2] of the Federal Energy Regulatory Commission's regulations, for Reliability Standard COM–001–3 (Communications), the associated Implementation Plan, retirement of currently-effective Reliability Standard COM–001–2.1, and Violation Risk Factors (''VRFs'') and Violation Severity Levels (''VSLs'') associated with new Requirements R12 and R13 in Reliability Standard COM–001–3. Reliability Standard COM–001–3 reflects revisions developed under Project 2015–07 Internal Communications Capabilities, in compliance with the Commission's directive in Order No. 888 that NERC ''develop modifications to COM–001–2, or develop a new standard, to address the Commission's concerns regarding ensuring the adequacy of internal communications capability whenever internal communications could directly affect the reliability opera.

Reliability Standards COM–001–3 and COM–002–4 do not require responsible entities to file information with the Commission. COM–001–3 requires that transmission operators, balancing authorities, reliability coordinators, distribution providers, and generator operators must maintain documentation of Interpersonal Communication capability and designation of Alternate Interpersonal Communication, as well as evidence of testing of the Alternate Interpersonal Communication facilities. COM–002–4 requires balancing authorities, distribution providers, reliability coordinators, transmission operators, and generator operators to develop and maintain documented communication protocols, and to be able to provide evidence of training on the protocols and of their annual assessment of the protocols. Additionally, all applicable entities (balancing authorities, reliability coordinators, transmission operators, generator operators, and distribution providers) must be able to provide evidence of three-part communication when issuing or receiving an Operating Instruction during an Emergency.

Type of Respondents: Public utilities.

Estimate of Annual Burden: [3] The Commission estimates the annual public reporting burden for the information collection as:

[1] 16 U.S.C. 824o (2012).

[2] 18 CFR 39.5 (2015).

[3] The Commission defines burden as 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, reference 5 Code of Federal Regulations 1320.3.

FERC–725V—MANDATORY RELIABILITY STANDARDS: COM RELIABILITY STANDARDS

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden and cost per response [4]	Total annual burden hours and total annual cost ($)	Cost per respondent ($)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
(On-going) Maintain evidence of Interpersonal Communication capability [5].	1,313 (BA, DP, GOP, RC & TOP).	1	1,313	4 hrs.; $228	5,252 hrs.; $299,364 ..	$228
(On-going) Maintain evidence of training and assessments [6].	199 (BA, RC & TOP) ..	1	199	8 hrs.; 456	1,592 hrs.; 90,744	456
(On-going) Maintain evidence of training [7]	1,257 (DP & GOP)	1	1,257	8 hrs.; 456	10,056 hrs.; 573,192 ..	456
Total	.....	.....	2,769	.....	16,900 hrs.; 963,300 ..	.....

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 6, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–10008 Filed 5–11–21; 8:45 am]

BILLING CODE 6717–01–P

[4] The estimates for cost per response are loaded hourly wage figure (includes benefits) is based on two occupational categories for 2020 found on the Bureau of Labor Statistics website (*http://www.bls.gov/oes/current/naics2_22.htm*): The hourly estimates for salary plus benefits are: (a) Electrical Engineer (code 17–2071), $70.19; (b) Information and Record Clerk (code 43–4199), $43.38. The average hourly cost (salary plus benefits), weighting both skill sets equally, is $56.79. For these calculations, we round the figure to $57.00 per hour.

[5] For COM–001–3 the BA, RC, TOP, GOP, DP were taken as aggregate to eliminate overlap if the same entity has multiple registrations.

[6] For COM–002–4 the BA, RC and TOP were taken as aggregate to eliminate overlap if the same entity has multiple registration.

[7] For COM–002–4 the DP and GOP were taken as aggregate to eliminate overlap if the same entity has multiple registrations.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP21–813–000]

Spire Marketing Inc. v. Panhandle Eastern Pipe Line Company, LP; Notice of Complaint

Take notice that on April 30, 2021, pursuant to Section 5 of the Natural Gas Act [1] and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 (2020), Spire Marketing Inc. (Complainant) filed a formal complaint against Panhandle Eastern Pipe Line Company, LP (Respondent), alleging that the Respondent's failure to waive operational flow order penalties incurred after February 15, 2021 is unduly discriminatory and inconsistent with Commission policy and precedent, all as more fully explained in its complaint.

The Complainant certify that copies of the complaint were served on the contacts listed for Respondent in the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainant.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. 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://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.

Comment Date: 5:00 p.m. Eastern Time on May 20, 2021.

Dated: May 6, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–10010 Filed 5–11–21; 8:45 am]

BILLING CODE 6717–01–P

[1] 15 U.S.C. 717d.

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:

Docket Numbers: RP21–757–000.

Applicants: Cheyenne Plains Gas Pipeline Company, L.L.C.

Description: § 4(d) Rate Filing: Annual Fuel and LU Update and OPS Report to be effective 6/1/2021.

Filed Date: 4/29/21.

Accession Number: 20210429–5014.

Comments Due: 5 p.m. ET 5/11/21.

Docket Numbers: RP21–758–000.

Applicants: Wyoming Interstate Company, L.L.C.

Description: § 4(d) Rate Filing: Fuel and L&U Quarterly Update to be effective 6/1/2021.

Filed Date: 4/29/21.

Accession Number: 20210429–5015.

Comments Due: 5 p.m. ET 5/11/21.

Docket Numbers: RP21–759–000.

Applicants: Sierrita Gas Pipeline LLC.

Description: § 4(d) Rate Filing: FL&U Quarterly Update Filing to be effective 6/1/2021.

Filed Date: 4/29/21.

Accession Number: 20210429–5016.

Comments Due: 5 p.m. ET 5/11/21.

Docket Numbers: RP21–760–000.

Applicants: Kinetica Energy Express, LLC.

Description: § 4(d) Rate Filing: Section 4 Rate Case to be effective 6/1/2021.

Filed Date: 4/29/21.

Accession Number: 20210429–5021.

Comments Due: 5 p.m. ET 5/11/21.

Docket Numbers: RP21–761–000.

Applicants: Ruby Pipeline, L.L.C.

Description: § 4(d) Rate Filing: FLU and Electric Power Update to be effective 6/1/2021.

Filed Date: 4/29/21.

Accession Number: 20210429–5039.

Comments Due: 5 p.m. ET 5/11/21.

Docket Numbers: RP21–762–000.

Applicants: Gulfstream Natural Gas System, L.L.C.

Description: § 4(d) Rate Filing: 2021 GNGS TUP/SBA Filing to be effective 6/1/2021.

Filed Date: 4/29/21.

Accession Number: 20210429–5041.

Comments Due: 5 p.m. ET 5/11/21.

Docket Numbers: RP21–763–000.

Applicants: Alliance Pipeline L.P.

Description: Alliance Pipeline L.P. submits Annual report for operational purchase and sales for the 12-month period ending December 31, 2020 under RP21–763.

Filed Date: 4/29/21.

Accession Number: 20210429–5062.

Comments Due: 5 p.m. ET 5/11/21.

Docket Numbers: RP21–764–000.

Applicants: Sabal Trail Transmission, LLC.

Description: § 4(d) Rate Filing: 2021 TUP/SBA Annual Filing to be effective 6/1/2021.

Filed Date: 4/29/21.

Accession Number: 20210429–5065.

Comments Due: 5 p.m. ET 5/11/21.

Docket Numbers: RP21–765–000.

Applicants: Colorado Interstate Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rate Non-Conforming TSA (BHSC Elkhart) and Housekeeping Filing to be effective 6/1/2021.

Filed Date: 4/29/21.

Accession Number: 20210429–5140.

Comments Due: 5 p.m. ET 5/11/21.

Docket Numbers: RP21–766–000.

Applicants: Southern Star Central Gas Pipeline, Inc.

Description: § 4(d) Rate Filing: Vol 2—Neg and Conforming Rate Agreements-Southwest Energy PLS to be effective 5/1/2021.

Filed Date: 4/29/21.

Accession Number: 20210429–5156.

Comments Due: 5 p.m. ET 5/11/21.

Docket Numbers: RP21–767–000.

Applicants: Gas Transmission Northwest LLC.

Description: § 4(d) Rate Filing: GTN Neg Rate Agreements to be effective 11/1/2019.

Filed Date: 4/29/21.

Accession Number: 20210429–5225.

Comments Due: 5 p.m. ET 5/11/21.

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: April 30, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–09987 Filed 5–11–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

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

Docket Numbers: EC21–88–000.

Applicants: KES Kingsburg, L.P.

Description: Application for Authorization Under Section 203 of the Federal Power Act of KES Kingsburg, L.P.

Filed Date: 5/5/21.

Accession Number: 20210505–5186.

Comments Due: 5 p.m. ET 5/26/21.

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

Docket Numbers: EG21–140–000.

Applicants: Orangeville Energy Storage LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Orangeville Energy Storage LLC.

Filed Date: 5/4/21.

Accession Number: 20210504–5190.

Comments Due: 5 p.m. ET 5/25/21.

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

Docket Numbers: ER17–1214–004; ER11–3917–003.

Applicants: Mojave Solar LLC, Coso Geothermal Power Holdings, LLC.

Description: Notice of Change in Status of Coso Geothermal Power Holdings, LLC, et al.

Filed Date: 5/6/21.

Accession Number: 20210506–5048.

Comments Due: 5 p.m. ET 5/27/21.

Docket Numbers: ER12–1436–016; ER10–2742–015; ER14–153–009; ER14–154–009; ER15–1604–004; ER16–517–004; ER18–533–003; ER18–534–003; ER18–535–003; ER18–536–003; ER18–537–003; ER18–538–004; ER20–1641–002.

Applicants: Tilton Energy LLC, Dynegy Lee II, LLC, Eagle Point Power Generation LLC, Gibson City Energy Center, LLC, Grand Tower Energy Center, LLC, Lee County Generating Station, LLC, Montepelier Generating Station, LLC, Monument Generating Station, LLC, O.H. Hutchings CT, LLC, Shelby County Energy Center, LLC, Sidney, LLC, Southern Illinois Generation Company, LLC, Tait Electric Generating Station, LLC, Yankee Street, LLC.

Description: Notice of Non-Material Change in Status of Rockland Sellers.

Filed Date: 5/5/21.

Accession Number: 20210505–5185.
Comments Due: 5 p.m. ET 5/26/21.

Docket Numbers: ER19–1073–004; ER10–2460–019; ER10–2461–020; ER10–2463–019; ER10–2466–020; ER10–2895–022; ER10–2917–022; ER10–2918–023; ER10–2920–022; ER10–2921–022; ER10–2922–022; ER10–2966–022; ER10–3167–014; ER11–2201–023; ER11–2383–018; ER11–3941–020; ER11–3942–025; ER11–4029–019; ER12–1311–019; ER12–161–024; ER12–2068–019; ER12–645–025; ER12–682–020; ER13–1139–022; ER13–1346–013; ER13–1613–015; ER13–17–017; ER13–203–014; ER13–2143–015; ER14–1964–013; ER14–25–019; ER14–2630–015; ER16–287–008; ER17–482–007; ER19–1074–007; ER19–1075–007; ER19–1076–004; ER19–2429–005; ER19–529–007; ER20–1447–003; ER20–1806–003.

Applicants: Alta Wind VIII, LLC, Bear Swamp Power Company LLC, BIF II Safe Harbor Holdings, LLC, BIF III Holtwood LLC, Bishop Hill Energy LLC, Black Bear Development Holdings, LLC, Black Bear Hydro Partners, LLC, Black Bear SO, LLC, Blue Sky East, LLC, BREG Aggregator LLC, Brookfield Energy Marketing Inc., Brookfield Energy Marketing LP, Brookfield Energy Marketing US LLC, Brookfield Power Piney & Deep Creek LLC, Brookfield Renewable Energy Marketing US, Brookfield Renewable Trading and Marketing LP, Brookfield Smoky Mountain Hydropower LP, Brookfield White Pine Hydro LLC, California Ridge Wind Energy LLC, Canandaigua Power Partners, LLC, Canandaigua Power Partners II, LLC, Catalyst Old River Hydroelectric Limited Partnership, Carr Street Generating Station, L.P., Erie Boulevard Hydropower, L.P., Erie Wind, LLC, Evergreen Wind Power, LLC, Evergreen Wind Power III, LLC, Granite Reliable Power, LLC, Great Lakes Hydro America, LLC, Hawks Nest Hydro LLC, Imperial Valley Solar 1, LLC, Mesa Wind Power Corporation, Niagara Wind Power, LLC, Prairie Breeze Wind Energy LLC, Regulus Solar, LLC, Rumford Falls Hydro LLC, Safe Harbor Water Power Corporation, Stetson Holdings, LLC, Stetson Wind II, LLC, Vermont Wind, LLC, Windstar Energy, LLC.

Description: Notice of Non-Material Change in Status of Alta Wind VIII, LLC, et al.

Filed Date: 5/5/21.
Accession Number: 20210505–5191.
Comments Due: 5 p.m. ET 5/26/21.

Docket Numbers: ER21–44–002.
Applicants: Altavista Solar, LLC.
Description: Notice of Change in Status of Altavista Solar, LLC.
Filed Date: 5/5/21.
Accession Number: 20210505–5188.
Comments Due: 5 p.m. ET 5/26/21.

Docket Numbers: ER21–1006–000; ER21–1007–000.
Applicants: El Paso Electric Company.
Description: EL Paso Electric Company submits response to the Commission's March 29, 2021 letter.
Filed Date: 4/28/21.
Accession Number: 20210428–5220.
Comments Due: 5 p.m. ET 5/19/21.

Docket Numbers: ER21–1401–001.
Applicants: Northern States Power Company, a Wisconsin corporation, Northern States Power Company, a Minnesota corporation.
Description: Tariff Amendment: 2021 Interchange Agreement Annual Filing-Stay to be effective 12/31/9998.
Filed Date: 5/5/21.
Accession Number: 20210505–5179.
Comments Due: 5 p.m. ET 5/26/21.

Docket Numbers: ER21–1506–001.
Applicants: Shaw Creek Solar, LLC.
Description: Tariff Amendment: Shaw Creek Solar, LLC Amendment to the Application for MBR Authority to be effective 5/23/2021.
Filed Date: 5/5/21.
Accession Number: 20210505–5178.
Comments Due: 5 p.m. ET 5/26/21.

Docket Numbers: ER21–1752–001.
Applicants: Public Service Company of New Mexico.
Description: Tariff Amendment: Supplement to First Revised Service Agreement No. 398 to be effective 5/6/2021.
Filed Date: 5/5/21.
Accession Number: 20210505–5170.
Comments Due: 5 p.m. ET 5/26/21.

Docket Numbers: ER21–1858–000.
Applicants: Northern States Power Company, a Minnesota corporation.
Description: § 205(d) Rate Filing: CapX Brookings OMA–537–0.1.0-Filing to be effective 7/5/2021.
Filed Date: 5/5/21.
Accession Number: 20210505–5153.
Comments Due: 5 p.m. ET 5/26/21.

Docket Numbers: ER21–1859–000.
Applicants: Arizona Public Service Company.
Description: Notice of Cancellation of Rate Schedule No. 214 of Arizona Public Service Company.
Filed Date: 5/5/21.
Accession Number: 20210505–5175.
Comments Due: 5 p.m. ET 5/26/21.

Docket Numbers: ER21–1860–000.
Applicants: CenterPoint Energy Houston Electric, LLC.
Description: § 205(d) Rate Filing: TFO Interim Tariff Rate Revision to Conform with PUCT to be effective 4/30/2021.
Filed Date: 5/6/21.
Accession Number: 20210506–5023.
Comments Due: 5 p.m. ET 5/27/21.

Docket Numbers: ER21–1861–000.
Applicants: BP Energy Company.
Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff Filing to be effective 7/6/2021.
Filed Date: 5/6/21.
Accession Number: 20210506–5060.
Comments Due: 5 p.m. ET 5/27/21.

Docket Numbers: ER21–1862–000.
Applicants: Cedar Creek II, LLC.
Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff Filing to be effective 7/6/2021.
Filed Date: 5/6/21.
Accession Number: 20210506–5067.
Comments Due: 5 p.m. ET 5/27/21.

Docket Numbers: ER21–1863–000.
Applicants: Alabama Power Company.
Description: § 205(d) Rate Filing: RE Sumter (Sumter County Solar) Amended and Restated LGIA Filing to be effective 4/9/2021.
Filed Date: 5/6/21.
Accession Number: 20210506–5094.
Comments Due: 5 p.m. ET 5/27/21.

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 6, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–10007 Filed 5–11–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC21–25–000]

Commission Information Collection Activities (Ferc–552); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice 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–552, (Annual Report of Natural Gas Transactions).

DATES: Comments on the collection of information are due July 12, 2021.

ADDRESSES: You may submit copies of your comments (identified by Docket No. IC21–25–000) by one of the following methods:

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:* Deliver to: Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: All 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,* telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC Form No. 552, Annual Report of Natural Gas Transactions.

OMB Control No.: 1902–0242.

Type of Request: Three-year extension of the FERC Form No. 552 information collection requirements with no changes to the current reporting requirements.

Abstract: The Commission uses the information collected in the FERC Form No. 552 [1] to provide greater transparency into the size of the physical natural gas market and the use of physical fixed-price and index-based natural gas transactions. This information assists the Commission and the public in assessing whether index prices are the result of a robust market of fixed-price transactions.

FERC Form No. 552 had its genesis in the Energy Policy Act of 2005,[2] which added section 23 of the Natural Gas Act (NGA). Section 23 of the NGA, among other things, directs the Commission ''to facilitate price transparency in markets for the sale or transportation of physical natural gas in interstate commerce, having due regard for the public interest, the integrity of those markets, and the protection of consumers.'' [3]

Type of Respondents: Wholesale natural gas market participants.

Estimate of Annual Burden: [4] The Commission estimates the average annual burden and cost [5] for this information collection as follows.

FERC Form No. 552—Annual Report of Natural Gas Transactions

Category	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden hours and cost per response	Total annual burden hours and cost ($)	Annual cost per respondent ($) (rounded)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Wholesale natural gas market participants.	688	1	688	20 hrs.; $1,702.60	13,760 hrs.; $1,171,388.80	$1,702.60

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 6, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–10009 Filed 5–11–21; 8:45 am]

BILLING CODE 6717–01–P

[1] FERC Form No. 552 is prescribed in 18 CFR 260.401.

[2] Energy Policy Act of 2005, Public Law 109–58, sections 1261 *et seq.,* 119 Stat. 594 (2005).

[3] 15 U.S.C. 717t–2(a)(1)(2006).

[4] Burden is defined as 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. Refer to 5 CFR 1320.3 for additional information.

[5] Costs (for wages and benefits) are based on wage figures from the Bureau of Labor Statistics (BLS) for May 2020 (at *https://www.bls.gov/oes/current/naics2_22.htm*) and benefits information (issued March 2020, *https://www.bls.gov/news.release/ecec.nr0.htm*). The staff estimates that 75% of the work is done by a financial analyst (code 13–2098) at an hourly cost of $66.09 (for wages plus benefits), and 25% of the work is done by legal staff members (code 23–0000) at an hourly cost of $142.25 (for wages plus benefits). Therefore, the weighted cost (for wages plus benefits) is calculated to $85.13/hour [or ($66.09/hour * 0.75) + ($142.25/hour * 0.25)].

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2021–0169; FRL–10023–19–OW]

National Pollutant Discharge Elimination System (NPDES) 2022 Issuance of General Permit for Stormwater Discharges From Construction Activities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: All ten Environmental Protection Agency (EPA) Regions are

proposing for public comment on the proposed 2022 National Pollutant Discharge Elimination System (NPDES) general permit for stormwater discharges from construction activities, also referred to as the ''proposed 2022 Construction General Permit (CGP)'' or the ''proposed permit.'' The proposed permit, once finalized, will replace the existing 2017 CGP that will expire on February 16, 2022. EPA proposes to issue this permit for five (5) years, and to provide permit coverage to eligible operators in all areas of the country where EPA is the NPDES permitting authority, including Massachusetts, New Hampshire, New Mexico, most Indian country lands, the District of Columbia, U.S. territories and protectorates except for the U.S. Virgin Islands, and certain federal facilities. EPA seeks comment on the proposed permit and on the accompanying fact sheet, which contains supporting documentation. This **Federal Register** document describes the proposed permit in general and includes specific topics on which the Agency is particularly seeking comment. EPA encourages the public to read the fact sheet to better understand the proposed permit. The fact sheet and proposed permit can be found at *https://www.epa.gov/npdes/stormwater-discharges-construction-activities.*

DATES: Comments on the proposed permit must be received on or before July 12, 2021. EPA will host at least one webcast during the week of June 14, 2021 that will provide an overview of the proposed 2022 CGP and an opportunity for participants to ask questions. EPA will announce details of all webcasts and post webcast recordings at *https://www.epa.gov/npdes/stormwater-discharges-construction-activities.*

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OW–2021–0169 to the *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically 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 FURTHER INFORMATION CONTACT: For further information on the proposed permit, contact the appropriate EPA Regional office listed in Section I.F of this document, or Greg Schaner, EPA Headquarters, Office of Water, Office of Wastewater Management at 202–564–0721 or email: *schaner.greg@epa.gov.*

SUPPLEMENTARY INFORMATION: This section is organized as follows:

Table of Contents

I. General Information
A. Does this action apply to me?
B. How can I get copies of these documents and other related information?
C. What should I consider as I prepare my comments for EPA?
D. Will a public hearing be held on this action?
E. What process will EPA follow to finalize the permit?
F. Who are the EPA regional contacts for this permit?
II. Background of Permit
A. Technology-Based Effluent Limits
B. Water Quality-Based Effluent Limits (WQBELs)
III. Process Used To Identify Proposed Permit Changes
IV. Summary of Proposed Permit Changes
A. Changes to Clarity of the Permit
B. Added Specificity to Permit Requirements
V. Provisions for Which EPA Is Soliciting Comment
VI. Paperwork Reduction Act (PRA)
VII. Proposed 2022 CGP Incremental Cost Analysis and Future Cost-Benefit Considerations
VIII. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
IX. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
X. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
XI. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use
XII. Compliance With the National Environmental Policy Act (NEPA) for the National Pollutant Discharge Elimination System (NPDES) General Permit for Discharges From Construction Activities

I. General Information

A. Does this action apply to me?

1. Entities Covered by This Permit

This proposed permit covers the following entities, as categorized in the North American Industry Classification System (NAICS):

TABLE 1—ENTITIES COVERED BY THIS PROPOSED PERMIT

Category	Examples of affected entities	North American Industry Classification System (NAICS) Code
Industry	Construction site operators disturbing one or more acres of land, or less than one acre but part of a larger common plan of development or sale if the larger common plan will ultimately disturb 1 acre or more, and performing the following activities:	
	Construction of Buildings	236
	Heavy and Civil Engineering Construction	237

EPA does not intend the preceding table to be exhaustive but provides it as a guide for readers regarding the types of activities EPA is now aware of that could potentially be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your site is covered by this action, you should carefully examine the definition of ''construction activity'' and ''small construction activity'' in existing EPA regulations at

40 CFR 122.26(b)(14)(x) and 122.26(b)(15), respectively. If you have questions regarding the applicability of this action to a particular entity, consult one of the persons listed for technical information in the preceding **FOR FURTHER INFORMATION CONTACT** section.

2. Construction Projects for Which Operators Are Eligible for Permit Coverage

Coverage under this permit will be available to operators of eligible projects located in those areas where EPA is the permitting authority. A list of eligible areas is included in Appendix B of the proposed permit. Eligibility for permit coverage is limited to operators of ''new sites,'' operators of ''existing sites,'' ''new operators of new or existing sites,'' and operators of ''emergency-related projects.'' A ''new site'' is a site where construction activities commenced on or after the effective date of the final 2022 CGP. An ''existing site'' is a site where construction activities commenced prior to the effective date of the final 2022 CGP. A ''new operator of a new or existing site'' is an operator that through transfer of ownership and/or operation replaces the operator of an already permitted construction site. An ''emergency-related project'' is a project initiated in response to a public emergency (*e.g.,* mud slides, earthquake, extreme flooding conditions, disruption in essential public services), for which the related work requires immediate authorization to avoid imminent endangerment to human health or the environment, or to reestablish public services.

3. Geographic Coverage

This 2022 CGP can provide coverage to eligible operators for stormwater discharges from construction activities that occur in areas not covered by an approved state NPDES program. The areas of geographic coverage for the 2022 CGP are listed in Appendix B, and include the states of New Hampshire, Massachusetts, and New Mexico, as well as most Indian country lands, and areas in selected states operated by a federal operator. Permit coverage can also be obtained by operators in Puerto Rico, the District of Columbia, and the Pacific Island territories (*i.e.,* Island of American Samoa, Island of Guam, and Johnston Atoll, Commonwealth of the Northern Mariana Islands, Midway Island, and Wake Island). EPA notes that the CGP will no longer offer coverage to construction sites in the state of Idaho, except for sites located on Indian country lands, or to sites located in the state of Texas that involve the exploration, development, or production of oil or gas or geothermal resources, including transportation of crude oil or natural gas by pipeline, as both states are now authorized to issue permits for construction stormwater. Eligible operators in these two states will need to seek permit coverage for their stormwater discharges from their respective state NPDES authority.

B. How can I get copies of these documents and other related information?

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. EPA–HQ–OW–2021–0169. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460. Although all documents in the docket are listed in an index, some information is not publicly available, *i.e.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/* or email, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

2. *Electronic Access.* You may access this **Federal Register** document electronically through the United States government on-line source for Federal regulations at *http://www.regulations.gov.*

Electronic versions of this proposed permit and fact sheet are available on EPA's NPDES website at *https://www.epa.gov/npdes/stormwater-discharges-construction-activities.*

An electronic version of the public docket is available through the EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.* Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the Docket Facility identified in Section I.B.1 of this preamble.

C. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI information to EPA through *www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. As noted previously, CBI information should not be submitted through *regulations.gov* or by email. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify this proposed permit by docket number and other identifying

information (subject heading, **Federal Register** date and page number).

- Where possible, respond to specific questions or organize comments by referencing a section or part of this proposed permit.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- To ensure that EPA can read, understand, and therefore properly respond to comments, the Agency would prefer that commenters cite, where possible, the paragraph(s) or section in the proposed permit or fact sheet to which each comment refers.
- Make sure to submit your comments by the comment period deadline identified.

D. Will a public hearing be held on this action?

EPA has not scheduled a public hearing to receive public comment concerning the proposed permit. All persons will continue to have the right to provide written comments during the public comment period. However, interested persons may request a public hearing pursuant to 40 CFR 124.12 concerning the proposed permit. Requests for a public hearing must be sent or delivered in writing to the same address as provided above for public comments prior to the close of the comment period. Requests for a public hearing must state the nature of the issues proposed to be raised in the hearing. Pursuant to 40 CFR 124.12, EPA shall hold a public hearing if it finds, on the basis of requests, a significant degree of public interest in a public hearing on the proposed permit. If EPA decides to hold a public hearing, a public notice of the date, time and place of the hearing will be made at least 30 days prior to the hearing. Any person may provide written or oral statements and data pertaining to the proposed permit at the public hearing.

EPA is hosting at least one public webcast during the week of June 14, 2021 that will provide an overview of the proposed 2022 CGP and an opportunity for participants to ask questions. EPA will announce details of all webcasts and post webcast recordings at *https://www.epa.gov/npdes/stormwater-discharges-construction-activities.*

E. What process will EPA follow to finalize the permit?

After the comment period closes, EPA intends to issue a final permit prior to the expiration date of the current 2017 CGP. EPA will consider all significant comments and make appropriate changes before issuing this permit. EPA's responses to public comments received will be included in the docket as part of the final permit issuance. Once the final permit becomes effective, eligible operators of existing and new sites may seek authorization under the 2022 CGP. Any construction site operator obtaining permit coverage prior to the expiration date of the 2017 CGP will automatically remain covered under that permit until the earliest of:

- Authorization for coverage under the 2022 CGP following a timely submittal of a complete and accurate Notice of Intent (NOI);
- Submittal of a Notice of Termination (NOT); or
- EPA issues an individual permit or denies coverage under an individual permit for the site's stormwater discharges.

F. Who are the EPA regional contacts for this permit?

For EPA Region 1, contact David Gray: email at *gray.davidj@epa.gov.*

For EPA Region 2, contact Stephen Venezia: email at *venezia.stephen@epa.gov,* or for Puerto Rico, contact Sergio Bosques: email at *bosques.sergio@epa.gov.*

For EPA Region 3, contact Carissa Moncavage: email at *moncavage.carissa@epa.gov.*

For EPA Region 4, contact Michael Mitchell: email at *mitchell.michael@epa.gov.*

For EPA Region 5, contact Krista McKim: email at *mckim.krista@epa.gov.*

For EPA Region 6, contact Suzanna Perea: email at: *perea.suzanna@epa.gov.*

For EPA Region 7, contact Mark Matthews: email at: *matthews.mark@epa.gov.*

For EPA Region 8, contact Amy Clark: email at: *clark.amy@epa.gov.*

For EPA Region 9, contact Eugene Bromley: email at *bromley.eugene@epa.gov.*

For EPA Region 10, contact Margaret McCauley: email at *mccauley.margaret@epa.gov.*

II. Background of Permit

The Clean Water Act (CWA) establishes a comprehensive program ''to restore and maintain the chemical, physical, and biological integrity of the Nation's waters.'' 33 U.S.C. 1251(a). The CWA also includes the objective of attaining ''water quality which provides for the protection and propagation of fish, shellfish and wildlife and * * * recreation in and on the water.'' 33 U.S.C. 1251(a)(2)). To achieve these goals, the CWA requires EPA to control discharges of pollutants from point sources through the issuance of National Pollutant Discharge Elimination System (NPDES) permits.

The Water Quality Act of 1987 (WQA) added section 402(p) to the CWA, which directed EPA to develop a phased approach to regulate stormwater discharges under the NPDES program. 33 U.S.C. 1342(p). EPA published a final regulation in the **Federal Register**, often called the ''Phase I Rule,'' on November 16, 1990, establishing permit application requirements for, among other things, ''storm water discharges associated with industrial activity.'' See 55 FR 47990. EPA defines the term ''storm water discharge associated with industrial activity'' in a comprehensive manner to cover a wide variety of facilities. See *id.* Construction activities, including activities that are part of a larger common plan of development or sale, that ultimately disturb at least five acres of land and have point source discharges to waters of the U.S. were included in the definition of ''industrial activity'' pursuant to 40 CFR 122.26(b)(14)(x). The second rule implementing section 402(p), often called the ''Phase II Rule,'' was published in the **Federal Register** on December 8, 1999. It requires NPDES permits for discharges from construction sites disturbing at least one acre but less than five acres, including sites that are part of a larger common plan of development or sale that will ultimately disturb at least one acre but less than five acres, pursuant to 40 CFR 122.26(b)(15)(i). See 64 FR 68722. EPA is proposing to issue this proposed permit under the statutory and regulatory authorities cited in this section.

NPDES permits for construction stormwater discharges are required under Section 402(a)(1) of the CWA to include conditions to meet technology-based effluent limits established under Section 301 and, where applicable, Section 306. Effluent Limitations Guidelines (ELGs) and New Source Performance Standards (NSPS) are technology-based effluent limitations that are based on the degree of control that can be achieved using various levels of pollutant control technology as defined in Subchapter III of the CWA.

Once a new national standard is established in accordance with these sections, NPDES permits must incorporate limits based on such technology-based standards. See CWA sections 301 and 306, 33 U.S.C. 1311 and 1316, and 40 CFR 122.44(a)(1). On December 1, 2009, EPA published final regulations establishing technology-based ELGs and NSPS for the Construction & Development (C&D) point source category, which became effective on February 1, 2010. See 40 CFR part 450 and 74 FR 62996. EPA amended the Construction & Development Rule, or ''C&D rule,'' on March 6, 2014 to satisfy EPA's agreements pursuant to a settlement of litigation that challenged the 2009 rule. See 79 FR 12661. All NPDES construction permits issued by EPA or states after this date must incorporate the requirements in the C&D rule.

A. Technology-Based Effluent Limits

All NPDES construction stormwater permits issued by EPA or states after March 6, 2014, must incorporate the requirements in the C&D rule, as amended. The non-numeric effluent limitations in the C&D rule are designed to prevent or minimize the mobilization and discharge of sediment and sediment-bound pollutants, such as metals and nutrients, and to prevent or minimize exposure of stormwater to construction materials, debris, and other sources of pollutants on construction sites. In addition, these non-numeric effluent limitations limit the generation of dissolved pollutants. Soil on construction sites can contain a variety of pollutants such as nutrients, pesticides, herbicides, and metals. These pollutants may be present naturally in the soil, such as arsenic or selenium, or they may have been contributed by previous activities on the site, such as agriculture or industrial activities. These pollutants, once mobilized by stormwater, can detach from the soil particles and become dissolved pollutants. Once dissolved, these pollutants would not be removed by down-slope sediment controls. Source control through minimization of soil erosion is, therefore, the most effective way of controlling the discharge of these pollutants.

The non-numeric effluent limits in the C&D rule, upon which certain technology-based requirements in the proposed permit are based, include the following:

• *Erosion and Sediment Controls*—Permittees are required to design, install, and maintain effective erosion controls and sediment controls to minimize the discharge of pollutants. At a minimum, such controls must be designed, installed, and maintained to:

1. Control stormwater volume and velocity to minimize soil erosion in order to minimize pollutant discharges;

2. Control stormwater discharges, including both peak flow rates and total stormwater volume, to minimize channel and streambank erosion, and scour in the immediate vicinity of discharge points;

3. Minimize the amount of soil exposed during construction activity;

4. Minimize the disturbance of steep slopes;

5. Minimize sediment discharges from the site. The design, installation and maintenance of erosion and sediment controls must address factors such as the amount, frequency, intensity and duration of precipitation, the nature of resulting stormwater discharge, and soil characteristics, including the range of soil particle sizes expected to be present on the site;

6. Provide and maintain natural buffers around waters of the United States. Direct stormwater to vegetated areas and maximize stormwater infiltration to reduce pollutant discharges, unless infeasible;

7. Minimize soil compaction. Minimizing soil compaction is not required where the intended function of a specific area of the site dictates that it be compacted; and

8. Unless infeasible, preserve topsoil. Preserving topsoil is not required where the intended function of a specific area of the site dictates that the topsoil be disturbed or removed.

• *Soil Stabilization Requirements*—Permittees are required to, at a minimum, initiate soil stabilization measures immediately whenever any clearing, grading, excavating, or other earth disturbing activities have permanently ceased on any portion of the site or temporarily ceased on any portion of the site and will not resume for a period exceeding 14 calendar days. In arid, semiarid, and drought-stricken areas where initiating vegetative stabilization measures immediately is infeasible, alternative stabilization measures must be employed as specified by the permitting authority. Stabilization must be completed within a period of time determined by the permitting authority. In limited circumstances, stabilization may not be required if the intended function of a specific area of the site necessitates that it remains disturbed.

• *Dewatering Requirements*—Permittees are required to minimize the discharge of pollutants from dewatering trenches and excavations. Discharges are prohibited unless managed by appropriate controls.

• *Pollution Prevention Measures*—Permittees are required to design, install, implement, and maintain effective pollution prevention measures to minimize the discharge of pollutants. At a minimum, such measures must be designed, installed, implemented, and maintained to:

1. Minimize the discharge of pollutants from equipment and vehicle washing, wheel wash water, and other wash waters. Wash waters must be treated in a sediment basin or alternative control that provides equivalent or better treatment prior to discharge;

2. Minimize the exposure of building materials, building products, construction wastes, trash, landscape materials, fertilizers, pesticides, herbicides, detergents, sanitary waste, and other materials present on the site to precipitation and to stormwater. Minimization of exposure is not required in cases where the exposure to precipitation and to stormwater will not result in a discharge of pollutants or where exposure of a specific material or product poses little risk of stormwater contamination (such as final products and materials intended for outdoor use); and

3. Minimize the discharge of pollutants from spills and leaks and implement chemical spill and leak prevention and response procedures.

• *Prohibited Discharges*—The following discharges from C&D sites are prohibited:

1. Wastewater from washout of concrete, unless managed by an appropriate control;

2. Wastewater from washout and cleanout of stucco, paint, form release oils, curing compounds, and other construction materials;

3. Fuels, oils, or other pollutants used in vehicle and equipment operation and maintenance; and

4. Soaps or solvents used in vehicle and equipment washing.

• *Surface Outlets*—When discharging from basins and impoundments, permittees are required to utilize outlet structures that withdraw water from the surface, unless infeasible.

The accompanying fact sheet details how EPA has incorporated these requirements into the proposed permit. The discussion in the fact sheet includes a summary of each provision and the Agency's rationale for articulating the provision in this way.

B. Water Quality-Based Effluent Limits (WQBELs)

EPA's regulations at 40 CFR 122.44(d)(1) require permitting authorities to include additional or more stringent permit requirements when necessary to achieve water quality standards. The 2017 CGP contains several provisions to protect water quality and the proposed permit includes those same provisions. It includes a narrative WQBEL requiring that discharges be controlled as necessary to meet applicable water quality standards. Failure to control discharges in a manner that meets applicable water quality standards is a violation of the permit.

In addition to the narrative WQBEL, the 2017 CGP includes related provisions that act together to protect water quality. These provisions are retained in the proposed 2022 CGP. For example, the 2017 CGP and proposed 2022 CGP permit require permittees to implement stormwater control measures and to take corrective action in response to any exceedance of applicable water quality standards. In addition, the permit requires more stringent site inspection frequencies and stabilization deadlines for construction sites that discharge to sensitive waters, such as those waters that are sediment or nutrient-impaired, which are parameters typically associated with stormwater discharges from construction sites, or waters identified by a state, tribe, or EPA as requiring enhanced protection under antidegradation requirements. EPA is also weighing whether to include an additional water quality-based requirement for dewatering discharges to certain sensitive waters in the form of a requirement to monitor the discharge for turbidity, possibly in comparison to a benchmark value. The proposed permit includes a request for public comment that is focused specifically on the potential turbidity monitoring requirement. See specific requests for comment in Section V of this document.

Additionally, EPA expects that, as with the 2017 CGP, the Agency will receive CWA Section 401 certifications for the final 2022 CGP. Some of those certifications may include additional conditions that are required by states, Indian tribes, and territories, pursuant to relevant provisions of the Clean Water Act or their respective legal authorities, and that, when properly submitted, will be incorporated into the permit as legally binding permit limits and conditions in the specific geographic areas that are located within the jurisdiction of the certifying authority.

III. Process Used To Identify Proposed Permit Changes

EPA made a concerted effort in the early stages of developing this proposed permit to reach out to stakeholders that would be affected by any modifications to the permit requirements. This outreach included meetings with stakeholders representing the construction industry, environmental interests, and state permitting authorities. The purpose of these meetings was to help identify areas of the 2017 CGP that require further clarification or modification to more effectively achieve the pollutant reduction objectives of the permit. EPA also queried its Regional enforcement personnel to determine where the permit could be clarified or where further specifics would help improve compliance. The individual feedback obtained from these meetings informed the types of clarifications and other changes EPA is proposing here, as well as the areas where the Agency is soliciting further feedback during the public comment period.

IV. Summary of Proposed Permit Changes

EPA proposes to make several modifications in the 2022 CGP, which are summarized below and discussed in more detail in the fact sheet. EPA also specifically requests comment on several potential permit modifications, which are summarized in Section V of this document. The fact sheet for the proposed permit explains in more detail each proposed permit condition and the rationale for including those conditions and any changes to those conditions. The fact sheet and proposed permit can be found at *https://www.epa.gov/npdes/stormwater-discharges-construction-activities.* A comprehensive list of all the proposed changes, as well as the corresponding parts of the permit that are modified, is included in a table in Section III.B of the fact sheet.

The types of changes generally fall into one of two categories: (1) Changes to improve the clarity of the permit, and (2) added specificity to the permit requirements. The table of proposed modifications in Section III.B of the fact sheet specifies which changes fall under the type (1) category and which fall into the type (2) category. The following sections briefly describe the proposed changes that are proposed within these two broad categories.

A. Changes to Clarity of the Permit

EPA proposes a number of relatively minor changes that focus on improving the clarity of provisions where permittees, EPA compliance staff, or other stakeholders have raised questions. These changes generally do not change the underlying requirement from the 2017 CGP, but rather attempt to make EPA's original intent clearer. It is EPA's hope that these proposed clarifications improve the overall understanding of the permit's requirements from all perspectives, including the permitting authority, permittees, and the general public.

The proposed changes to improve clarity include the following:

- *Approved stormwater control and stormwater pollution prevention plan products*—EPA includes new language in the permit to clearly state that the Agency does not endorse specific stormwater control or stormwater pollution prevention plan (SWPPP) products or vendors. Industry stakeholders suggested to include such language to help discourage some vendors from misleadingly suggesting that EPA or the permit approves of specific products. See footnotes 12 and 59 in Parts 2.1 and 7.1, respectively, of the proposed permit.
- *Differentiate between routine maintenance and corrective action*—EPA proposes to define routine maintenance as repairs to or replacement of stormwater controls that can be completed within 24 hours of first discovering the need for the repair or replacement. If a repair (or replacement) takes longer than 24 hours, the permit would require that it be treated as a corrective action. This change addresses feedback provided by industry stakeholders who have observed that there is considerable confusion about which maintenance repairs are considered routine versus those that should be treated as corrective actions. See Parts 2.1.4.b and c, and 5.1.1 of the proposed permit.
- *Clarify application of perimeter control and natural buffer requirements*—EPA understands from conversations with stakeholders that there is confusion about whether perimeter controls are necessary on the site when the operator is already providing a natural buffer pursuant to the requirements of the permit. To address this confusion, EPA clarifies that perimeter controls must be installed upgradient of any natural buffers except in situations where the perimeter control is being used by the permittee to fulfill one of the buffer alternative requirements, in which case the permittee would not be required to install a second perimeter control. See Part 2.2.3.a of the proposed permit.
- *Clarify the permit flexibilities for arid and semi-arid areas*—The 2017

CGP establishes alternative stabilization and inspection schedules for arid and semi-arid areas that are reflective of the different climatic and precipitation conditions that exist in those areas. These stabilization and inspection schedule flexibilities apply during the ''seasonally dry period'' of the year when there is less risk of a discharge-producing storm event. The permit did not previously define the term ''seasonally dry period,'' and EPA has received a number of questions from construction operators over the past several years about what this term means. For this reason, the proposed permit establishes a new definition to provide clarity, and includes resources in the form of maps and zip code tables to assist construction operators located in an arid or semi-arid area in determining when they may be operating during a seasonally dry period of the year. See Parts 2.2.14.b, 2.2.14.c, and 4.4.2 of the proposed permit, as well as the definition of ''seasonally dry period'' in Appendix A.

• *Clarified requirements for inspections during snowmelt conditions*—The permit proposes to add a numeric inspection threshold for snowfall precipitation that is equivalent to the 0.25-inch rain event, which triggers the need for an inspection if the operator chooses to inspect its site on a bi-weekly basis pursuant to Part 4.2.2. This change would clarify that where there is a discharge from snowmelt caused by an accumulation of 3.25 inches or greater of snow, an inspection would be required. Permit holders requested this change and explained to EPA that without a numeric threshold, it is difficult for operators to know which snow events may trigger the need to inspect the site during the winter season. EPA relied on information from the National Oceanic and Atmospheric Administration (NOAA) to derive the 3.25-inch snowfall equivalent to the 0.25-inch rain event. See Part 4.2.2 of the proposed permit.

• *Availability of stormwater pollution prevention plan (SWPPP), inspection reports, and corrective action log in electronic form*—The 2017 CGP currently enables operators to keep their SWPPP, inspection reports, and corrective action records in electronic form, as long as it can be accessed and read by the permittee and by any EPA, state, or local inspection authorities in the same manner as a paper copy. EPA heard from permittees, however, who were uncertain about whether the flexibility to keep these documents in electronic form was available to them. EPA acknowledges that part of the problem is that its explanation about retaining documents in electronic form is currently included in a frequently asked question section of its stormwater website (see *https://www.epa.gov/npdes/construction-general-permit-cgp-frequent-questions*), and is not clearly stated in the permit. For this reason, the proposed permit includes text to make it clear that electronic versions of the SWPPP, inspection reports, and corrective action logs may be used as long as they meet certain minimum requirements. See footnotes 54, 55, and 66 to Parts 4.7.3, 5.4.3, and 7.3, respectively, of the proposed permit.

• *Updated process for Endangered Species Act eligibility determinations*—EPA proposes several updates to Appendix D of the CGP, which establishes procedures for operators to follow in determining their eligibility for coverage with respect to the protection of endangered and threatened species. The changes to Appendix D are primarily in the form of clarifications to existing procedures or updates to resources that operators can use to determine whether species are located in the ''action area'' of the construction site. EPA finalized similar changes as part of the Endangered Species Act consultation it completed as part of its issuance of the 2021 Multi-Sector General Permit (MSGP) for discharges from industrial activities (See Appendix E of the 2021 MSGP at *https://www.epa.gov/npdes/stormwater-discharges-industrial-activities-epas-2021-msgp).* See Appendix D of the proposed permit.

B. Added Specificity to Permit Requirements

EPA is proposing select modifications to the permit to address specific problems that have come to the Agency's attention during the permit term or to incorporate enhancements that reflect current best practices. These proposed changes are narrowly focused on specific topics. The following is a summary of these proposed changes:

• *Perimeter control installation and maintenance requirements*—Due to the vital role that sediment controls installed along the downslope side of the construction site perimeter play in minimizing sediment discharges, it is important for the CGP requirements related to these controls to reflect best practices that are available, effective, and practicable. Reviewing a number of state permits and best management practice manuals during the development of the proposed permit, EPA concluded that some targeted proposed changes to the perimeter control requirements in the CGP are appropriate at this time. For this reason, EPA is proposing additional perimeter control installation and maintenance requirements that are focused on ensuring that these controls continue to work effectively. For example, under the proposed provision, if there is evidence of stormwater circumventing or undercutting the perimeter control after a storm event, the operator would be required to extend the length of the perimeter control or repair any undercut areas, whichever applies. This change is intended to ensure that maintenance of these controls is focused on fixing problems as soon as they are found and making sure they work effectively when the next storm event occurs. See Part 2.2.3 of the proposed permit.

• *Pollution prevention requirements for chemicals used and stored on site*—EPA is proposing changes to the pollution prevention requirements for diesel fuel, oil, hydraulic fuels, or other petroleum products, and other chemicals. These proposed changes respond to feedback EPA received from some permittees who recommended reframing the current permit requirements so they are proportionate to the volume of chemicals being used and stored on the site, and relative to the risk of a spill or leak. EPA agrees that the requirements in this section could be improved by strengthening the linkage between the type of pollution prevention control needed and the volume of the pollutant kept on site. Consistent with this principle, the proposed permit establishes control requirements that are appropriate for smaller-sized containers by requiring that the operator use water-tight containers, place them on a spill containment pallet (or similar device) if kept outside, and have a spill kit available at all times and in good working condition, and personnel available to respond quickly to a spill or leak. These controls will be effective at preventing a discharge from a spill or leak, while also having the added advantage of being moved more easily around the site. The proposed permit also includes controls that are more suitable to larger volumes of chemicals on site, such as requiring a temporary roof or secondary containment to prevent a discharge from a leak or spill. See Part 2.3.3.c of the proposed permit.

• *Dewatering discharge requirements*—EPA is proposing several changes to the permit's dewatering requirements to improve compliance and further reduce pollutant loads to waterways. EPA has noted violations with the permit's dewatering requirements at sites with controls that are improperly installed and maintained, resulting in significant

discharges of sediment and other pollutants to receiving waters. Given the high rate at which dewatered water may be discharged, EPA inspection personnel have observed that it is possible that a site may discharge more sediment in several hours of poorly managed dewatering activities than might otherwise be discharged from a site via stormwater discharges over the entire course of the construction project. Additionally, EPA has found there to be good example provisions from state construction stormwater permits and standalone NPDES dewatering permits that can be used to strengthen the CGP's dewatering conditions.

The proposed revisions to the permit add clarity to the existing pollutant control provisions, increase the number of inspections required while the dewatering discharge is occurring, establish a tailored checklist of problems to review during the inspection, and identify specific triggers for when corrective action is required. For example, one new inspection provision would require the operator to check whether a sediment plume, sheen, or hydrocarbon deposit on the bottom or shoreline of the receiving water was observed during a dewatering discharge. If such a plume, sheen, or deposit is observed, the permit would require the operator to, among other things, take immediate steps to suspend the discharge and ensure that the dewatering controls being used are operating effectively. During an inspection of the dewatering operation, the operator would also be required to take photographs of (1) the dewatering water prior to treatment by a stormwater control(s) and the final discharge after treatment; (2) the stormwater control; and (3) the point of discharge to any waters of the U.S. flowing through or immediately adjacent to the site. This documentation will help demonstrate how well the dewatering controls are working and will show where adaptations made after any problems have been found have resulted in improved pollutant control. See Parts 2.4, 4.3.2, 4.5.5, 4.6.3, and 5.1.5 of the proposed permit.

- *Training requirements for personnel conducting site inspections*—EPA is proposing to include modifications to the training requirements for personnel conducting site inspections. EPA considers these changes reasonable to address problems found during many of the Agency's own construction site inspections, in which EPA has observed that while some permittees are properly conducting inspections and documenting their findings in accordance with the permit, a large number are not. EPA proposes to address this problem is by strengthening the training requirements for inspection personnel to ensure their competency to conduct such inspections. For this reason, the proposed permit specifies that anyone carrying out inspections must either (1) have completed the new EPA construction inspection course developed for this permit and passed the exam, or (2) hold a current valid certification or license from a program that covers essentially the same principles as EPA's inspection course. The proposal also includes an exception to the new training requirement if the personnel are working under the supervision of a person who has the met the qualifications described above. These new proposed requirements are essentially an extension of what the 2017 CGP (and 2012 CGP) already required for the ''qualified person'' to conduct inspections. EPA is in the process of developing a construction inspection training program that will be made available as an option to fulfill this new requirement to CGP permittees along with an accompanying exam that, if passed, will provide the person with documentation showing that they have successfully completed the EPA course. EPA plans to have the training program ready for use by the issuance of the final 2022 CGP, or to delay the implementation of the requirement until the EPA training is available. Documentation that the relevant personnel has completed the EPA course and passed the exam will serve as proof that the operator has met the new inspection training requirements. Alternatively, if the relevant personnel elect to obtain the required training through a different program that covers the same basic principles, the operator will need to provide documentation that these personnel have completed the program and are in possession of a current, valid certification or license. See Parts 4.1 and 6.3 of the proposed permit.

- *Documenting signs of sedimentation attributable to construction site discharges*—EPA specifies in the proposed permit that during the inspection, operators must check for signs of sedimentation (*e.g.,* sand bars with no vegetation growing on top) at points downstream from the point of discharge that could be attributable to their discharges. This change is intended to address a frequent problem observed during EPA's compliance inspections that the permittee does not document obvious signs that its discharges have caused sedimentation in the receiving water. The intent of this proposed addition is to emphasize that the site inspection is an ideal time to examine whether there are any obvious signs of sedimentation attributable to the site's discharges, and to require documentation of such sedimentation. EPA does not specify in the permit a specific distance downstream of the site that operators much check for sedimentation that could be attributable to the discharge, given variable site-specific conditions. Instead, EPA expects that operators will account for the amount of sediment leaving the site in determining this distance. EPA notes that the CGP already requires operators to check for signs of visible erosion and sedimentation (*i.e.,* sediment deposits) that have occurred and are attributable to the permittee's discharge at outfalls and, if applicable, on the banks of any waters of the U.S. flowing within or immediately adjacent to the site. See Part 4.6.1.d of the proposed permit.

- *Photo documentation of adequate site stabilization*—EPA's compliance inspectors have observed cases when operators prematurely terminate coverage under the CGP before the site is properly stabilized. The proposed permit adds a new provision requiring operators as part of their Notice of Termination (NOT) to take and submit photographs showing the stabilized areas of the site following completion of construction. EPA proposes this requirement primarily as an additional level of proof that permittees are complying with the stabilization requirements prior to terminating coverage. Given the importance of stabilization to preventing continuing erosion and sedimentation, EPA views the additional proposed photo documentation requirement to be a relatively inexpensive, effective, and straightforward way for the permittee to show the Agency that it has complied with the permit's final stabilization requirements. See Part 8.2.1.a of the proposed permit. Related to this proposed new requirement, EPA is also adding a check box to the NOT form to confirm that the operator has attached photographs as required by Part 8.2.1.a to document compliance with the permit's final stabilization requirements.

- *Notice of Intent (NOI) questions*—EPA proposes to add new questions to the NOI form that construction operators will use to obtain coverage under the 2022 CGP. One question asks operators if dewatering water will be discharged during the course of their permit coverage. While EPA suspects that most CGP-covered projects discharge dewatering water during

construction, it would be useful to the Agency to know what the prevalence of this practice is at its permitted sites. This question will provide a straightforward way of compiling information broadly about permittees and enable EPA to know which permittees may be affected by the permit's new proposed dewatering requirements. Another question asks the operator completing the NOI whether there are other operators who are also covered by the CGP at the same site and, if so, what their NPDES ID numbers are. Because the 2017 CGP NOI does not ask the operator to indicate whether there are multiple operators permitted for the same site, EPA is often unable to easily determine who all the permitted entities are at larger projects. The NOI form will also include a proposed new question that requires the operator to confirm that any personnel conducting inspections at the site will meet the modified training requirements in Part 6 of the permit. EPA also proposes clarifying edits to better explain the types of documentation that are needed for several of the eligibility criteria and edits to provide links to updated available mapping tools to assist operators in determining whether any listed or threatened species are known to occur in the action area of their project.

V. Provisions for Which EPA Is Soliciting Comment

While EPA encourages the public to review and comment on all provisions in the proposed permit, EPA has included in the body of the proposed permit several proposed provisions on which EPA specifically requests feedback. The following list summarizes these specific requests for comment, and where they are included in the permit. EPA notes that these are only summaries of the requests for comment. The Agency recommends that the public see the specific wording of each comment request within the body of the permit. Additionally, the request for comment numbers 1, 3, 4, and 5 are not accompanied by a proposed change to the permit, but rather are inviting input on possible revisions to the CGP.

1. *Permit coverage clarification*—Request for comment on potentially modifying the definition of operator to specifically include parties that determine acceptance of work and pay for work performed. See Request for Comment 1 in Part 1.1.1 of the proposed permit.

2. *Prohibition of dewatering discharges from contaminated sites*—Request for comment on whether additional sites should be prohibited from coverage under this permit due to the possibility of discharging dewatering water that is contaminated, and whether certain sites should be given case-by-case flexibility if stormwater contact with underground contamination has been prevented through implementation of cleanup controls, such as capping. See Request for Comment 2 in Part 1.3.6 of the proposed permit.

3. *Waiting period for discharge authorization*—Request for comment on whether to extend the waiting period between the operator's submittal of the NOI and the authorization to discharge from 14 days to 30 days to facilitate review of the site's eligibility related to the protection of endangered or threatened species. See Request for Comment 3 in Part 1.4.3 of the proposed permit.

4. *Stabilization deadlines*—Request for comment on whether the 5-acre disturbance threshold for stricter stabilization deadlines has the intended effect of encouraging the phasing of construction disturbances. See Request for Comment 4 in Part 2.2.14.a of the proposed permit.

5. *Pollution prevention requirements for construction waste*—Request for comment on whether existing pollution control flexibilities such as those that apply to building materials and products in Part 2.3.3.a should be applied to certain types of construction wastes. See Request for Comment 5 in Part 2.3.3.e of the proposed permit.

6. *Water quality-based requirements for dewatering discharges*—Request for comment on requiring targeted sampling of the dewatering discharges from sites discharging to sediment-impaired waters or waters designated as Tier 2, Tier 2.5 or Tier 3 waters. See Request for Comment 6 in Part 3.3 of the proposed permit.

7. *Training Requirements*—Request for comment on the proposed modifications to the site inspection training requirements, specifically on how EPA can design its own inspection training program and the criteria used to describe the minimum requirements for third-party training programs. See Request for Comment 7 in Part 6.3 of the proposed permit.

8. *Photographic documentation of site stabilization*—Request for comment on the proposed requirement to take photographs of the stabilized areas of the site and submit them with the NOT. See Request for Comment 8 in Part 8.2.1.a of the proposed permit.

VI. Paperwork Reduction Act (PRA)

The information collection activities in this permit have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR No. 2686.01, OMB Control No. 2040–NEW. You can find a copy of the ICR in the docket for this permit (Docket ID No. EPA–HQ–OW–2021–0169), and it is briefly summarized here.

CWA section 402 and the NPDES regulations require collection of information primarily used by permitting authorities, permittees (operators), and EPA to make NPDES permitting decisions. The burden and costs associated with the entire NPDES program are accounted in an approved ICR (EPA ICR number 0229.23, OMB control no. 2040–0004). Certain changes in this permit require revisions to the ICR to reflect changes to the forms and other information collection requirements. EPA is reflecting the paperwork burden and costs associated with this permit in a separate ICR instead of revising the existing ICR for the entire program for administrative reasons.

EPA is proposing to collect new information as part of the 2022 CGP. The NOI form was updated from the 2017 CGP to collect new information related to the following: Added one new question related to whether operators will be discharging construction dewatering water during the course of their permit coverage; added questions about whether there are other operators who are also covered by the CGP at the same site and, if so, what their NPDES ID numbers are; added a check box for the operator to confirm that any personnel conducting inspections at the site will meet the modified training requirements in Part 6 of the permit; and added clarifying edits to better explain the types of documentation that are needed for several of the eligibility criteria related to endangered and threatened species and edits to provide links to updated available mapping tools to assist operators in determining whether any such species are known to occur in the vicinity of their project.

EPA added one check box for operators who are submitting an ''NOT'' because all construction activities have ended and the site has met all of the requirements for terminating permit coverage in Part 8.2.1. The check box confirms that the operator has attached photographs taken to document compliance with the final stabilization requirements pursuant to Part 8.2.1.a.

Respondents/affected entities: Construction operators in the areas where EPA is the NPDES permitting authority.

Respondent's obligation to respond: Compliance with the CGP's information collection and reporting requirements is mandatory for CGP operators.

Estimated number of respondents: EPA estimates that for the duration of the three-year ICR period approximately 7,800 operators will obtain coverage under the 2022 CGP, or 2,600 operators per year.

Frequency of response: Response frequencies in the 2022 CGP vary from once per permit term to quarterly.

Total estimated burden: EPA estimates that the information collection burden of the 2022 CGP is 134,059 hours per year. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: EPA estimates that the final information collection cost of the 2022 CGP is $8,195,357 per year.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9. EPA will respond to ICR-related comments in the final permit.

VII. Proposed 2022 CGP Incremental Cost Analysis and Future Cost-Benefit Considerations

The cost analysis accompanying this proposed permit monetizes and quantifies certain incremental cost impacts of the proposed permit changes as compared to the 2017 CGP. EPA analyzed each change in the proposed 2022 CGP considering the previous permit's (*i.e.,* the 2017 CGP) requirements. The objective of this incremental cost analysis is to show where or to what extent the proposed 2022 CGP requirements impose an incremental increase in administrative and compliance costs (such as the cost to conduct site inspections or to prepare compliance reports) on operators in relation to costs that are already accounted for in the 2017 CGP.

More broadly, EPA notes that additional unquantified costs and benefits result from this action. In developing the next CGP (or another NPDES general permit, as appropriate), EPA plans to estimate the broader impacts arising from these actions, including costs and benefits. Estimates under consideration may include: (1) Assessing how costs and benefits are attributed between the CGP and applicable water quality standards (including TMDLs) that may be in effect; (2) developing a new modeling framework to assess how regulated entities understand and implement pollutant controls related to existing and new permit obligations; (3) examining whether any underlying cost and benefit assumptions need to be updated; (4) examining more broadly how EPA can analyze benefits when developing permits; (5) developing more robust approaches to assessing uncertainties associated with the analytic approaches, including how to quantitatively assess uncertainties of key assumptions; and (6) developing a framework to analyze the effect of cooperative federalism.

EPA expects the incremental cost impact on entities that will be covered under the 2022 CGP, including small businesses, to be minimal. EPA anticipates the approximate average annual incremental cost increase (compared to the 2017 CGP) will be $704 to $714 per permitted project per year. A copy of EPA's incremental cost analysis for the proposed permit, titled ''Incremental Cost Impact Analysis for the Proposed 2022 Construction General Permit (CGP),'' is available in the docket (Docket ID No. EPA–HQ–OW–2021–0169).

VIII. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

The proposed permit is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

IX. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order (E.O.) 12898 (59 FR 7629 (February 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has preliminarily determined that this proposed permit will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because the requirements in the proposed permit apply equally to all construction projects that disturb one or more acres (or are part of a larger common plan of development that disturbs one or more acres) in areas where EPA is the permitting authority, and the erosion and sediment control proposed provisions increase the level of environmental protection for all affected populations over the 2017 CGP. EPA requests comment on this preliminary determination and/or any modifications that EPA could make to the proposed permit to address environmental justice concerns.

X. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

In compliance with Executive Order 13175, EPA consulted with tribal officials to gain an understanding of and, where necessary, to address the tribal implications of the proposed permit. During this consultation, EPA conducted the following activities:

- August 13, 2020—EPA mailed notification letters to all tribal leaders, initiating consultation and coordination on the proposed permit. The consultation period was from August 13, 2020 to October 27, 2020.
- September 9, 2020—EPA participated in the National Tribal Water Council monthly conference call and received written comments in response.
- September 16, 2020—EPA led an informational webinar to provide an overview of the current CGP and information regarding the ongoing consultation to the National Tribal Caucus. A total of 34 tribal representatives attended.

EPA received comments providing input from tribes. These comments are described in EPA's tribal consultation summary, which is can be accessed at *https://www.epa.gov/dockets* in the docket for this permit (refer to Docket No. EPA–HQ–OW–2021–0169). In addition, EPA received comments during the September 16, 2020 informational webinar and a September 9, 2020 National Tribal Water Council monthly conference call with EPA staff.

EPA will provide email notification to tribes of the proposed permit and invite those interested to provide the Agency with comments. EPA also notes that as part of the finalization of this proposed permit, it will complete the Section 401 certification procedures with all applicable tribes where this permit will apply (see Appendix B).

XI. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy and has not otherwise been designated

by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.

XII. Compliance With the National Environmental Policy Act (NEPA) for the National Pollutant Discharge Elimination System (NPDES) General Permit for Discharges From Construction Activities

Pursuant to the National Environmental Policy Act (NEPA) (42 U.S.C. 4321–4307h), the Council on Environmental Quality's NEPA regulations (40 CFR part 15), and EPA's regulations for implementing NEPA (40 CFR part 6), EPA has determined that the 2022 reissuance of the CGP is eligible for a categorical exclusion requiring documentation under 40 CFR 6.204(a)(1)(iv). This category includes ''actions involving reissuance of a NPDES permit for a new source providing the conclusions of the original NEPA document are still valid, there will be no degradation of the receiving waters, and the permit conditions do not change or are more environmentally protective.'' EPA completed an Environmental Assessment/Finding of No Significant Impact (EA/FONSI) for the 2012 CGP. The analysis and conclusions regarding the potential environmental impacts, reasonable alternatives, and potential mitigation included in the EA/FONSI are still valid for the 2022 reissuance of the CGP because the proposed permit conditions are either the same or more environmentally protective. Actions may be categorically excluded if the action fits within a category of action that is eligible for exclusion and the proposed action does not involve any extraordinary circumstances. EPA has reviewed the proposed action and determined that the 2022 reissuance of the CGP does not involve any extraordinary circumstances listed in 6.204(b)(1) through (10). EPA made a similar determination for the 2017 CGP. Prior to the issuance of the final 2022 CGP, the EPA Responsible Official will document the application of the categorical exclusion and will make it available to the public on EPA's website at *https://cdxnodengn.epa.gov/cdx-enepa-public/action/nepa/search.* If new information or changes to the proposed permit involve or relate to at least one of the extraordinary circumstances or otherwise indicate that the permit may not meet the criteria for categorical exclusion, EPA will prepare an EA or Environmental Impact Statement (EIS).

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*

Deborah Szaro,

Acting Regional Administrator, EPA Region 1.

Javier Laureano,

Director, Water Division, EPA Region 2.

Carmen Guerrero-Perez,

Director, Caribbean Environmental Protection Division, EPA Region 2.

Leslie Gillespie-Marthaler,

Deputy Director, Water Division, EPA Region 3.

Jeaneanne Gettle,

Director, Water Division, EPA Region 4.

Tera Fong,

Director, Water Division, EPA Region 5.

Charles Maguire,

Deputy Director, Water Division, EPA Region 6.

Jeffery Robichaud,

Director, Water Division, EPA Region 7.

Humberto Garcia,

Acting Director, Water Division, EPA Region 8.

Tomás Torres,

Director, Water Division, EPA Region 9.

Daniel D. Opalski,

Director, Water Division, EPA Region 10.

[FR Doc. 2021–09961 Filed 5–11–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10021–56–OCFO]

Privacy Act of 1974; System of Records

AGENCY: Office of the Chief Financial Officer, Environmental Protection Agency (EPA).

ACTION: Notice of a new system of records.

SUMMARY: The U.S. Environmental Protection Agency's (EPA) Office of the Controller is giving notice that it proposes to create a new system of records pursuant to the provisions of the Privacy Act of 1974. MoveLINQS Relocation Software was created to assist in the processing of relocation related expenses for government employees. Originally published under EPA SORN–29, which also covers EPA travel, other accounts payable, and accounts receivable files, the EPA proposes this new SORN to transition MoveLINQS from its prior location to a separate Microsoft Azure Government Cloud. The MoveLINQS system provides the capability to allow external relocation customers (EPA employees) to enter and update their own relocation requests. In order to make payments on behalf of the requestor, certain information is collected due to IRS requirements. This information is collected via a form that is submitted by the requestor and contains the requestor's name, Social Security Number (SSN), address, email address, spouse's name, filing status (for tax purposes), and children's names and dates of birth (DOB).

DATES: Persons wishing to comment on this system of records notice must do so by June 11, 2021. New routine uses for this new system of records will be effective June 11, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OMS–2021–0143, by one of the following methods:

Regulations.gov: www.regulations.gov. Follow the online instructions for submitting comments.

Email: docket_oms@epa.gov.

Fax: 202–566–1752.

Mail: OMS Docket, Environmental Protection Agency, Mail Code: 2822T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

Hand Delivery: OMS Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OMS–2021–0143. The EPA policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Controlled Unclassified Information (CUI) or other information for which disclosure is restricted by statute. Do not submit information that you consider to be CUI or otherwise protected through *www.regulations.gov*. The *www.regulations.gov* website is an ''anonymous access'' system for the EPA, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov* 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. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment. If the EPA

cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CUI or other information for which disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the OMS Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington. DC 20460. 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 is (202) 566–1744, and the telephone number for the OMS Docket is (202) 566–1752.

Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/* or email, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Rhonda Gerdsen, Business Development and Services Branch; *Gerdsen.Rhonda@epa.gov*; 1–513–487–2028.

SUPPLEMENTARY INFORMATION: MoveLINQS Relocation Software is an EPA major information system (MIS) that was originally published under the EPA–29 SORN, which also covers EPA travel, other accounts payable, and accounts receivable files. Relocation request data was tracked and coordinated by an EPA-hosted version of the MoveLINQS software. The EPA now proposes this new SORN to reflect a relocation of the MoveLINQS software from an EPA-hosted environment into a separate FedRAMP Government Cloud environment (Microsoft Azure) under the Software as a Service (SaaS) platform. The EPA utilizes the MoveLINQS application to help manage the Federal Employee Relocation Center (FERC), where they process employee relocation moves for the EPA.

SYSTEM NAME AND NUMBER:

MoveLINQS; EPA–87

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

101 Herbert Drive, Boydton, Va. 23917; Microsoft Azure Government Cloud (Azure-Va).

SYSTEM MANAGER(S):

William E. Wiggins Jr., Branch Chief, Business Development & Services Branch (BDSB), EPA's Federal Employee Relocation Center (FERC), *Wiggins.William@epa.gov,* (513) 487–2013, 26 W Martin Luther King Dr., Cincinnati, OH 45268.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 5753; 5 CFR part 575, subpart B.

PURPOSE(S) OF THE SYSTEM:

MoveLINQS, is an EPA major information system (MIS). It was originally published under the EPA–29 SORN, which also covers EPA travel, other accounts payable, and accounts receivable files. However, the EPA proposes to move the MoveLINQS application to a separate Microsoft Azure Government Cloud under the new SORN EPA–87. The EPA utilizes MoveLINQS to help manage the BDSB Federal Employee Relocation Center, where they process employee relocation moves for the EPA.

CATEGORIES OF INDIVIDUALS COVERED BY SYSTEM:

Federal employees and their family members who are eligible for move-related reimbursements will be covered.

CATEGORIES OF RECORDS IN THE SYSTEM:

SSN, name, address, email address, children's names and DOB, spouse's name, filing status (for tax purposes).

RECORD SOURCE CATEGORIES:

The employees are the source of information.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

MoveLINQS is used internally to maintain and store pertinent employee and relocation expense data. It uses its features and flexible controls to automate and streamline the permanent change of station (PCS) travel cost management process, eliminating errors and simplifying the enforcement of complex federal policy throughout the Agency. General routine uses D, E, F, G, K, L, and M apply to this system. Records may also be disclosed: 1. To the Office of Management and Budget, and Department of Treasury for paying taxes on relocation expenses; and 2. to provide information to contracted agencies of the EPA for the purposes of relocation. This information may contain monthly reports such as taxes that were paid, invoices and travel authorizations that were obligated. The routine uses below are both related to and compatible with the original purpose for which the information was collected. The following general routine uses apply to this system (73 FR 2245):

D. Disclosure to Office of Management and Budget: Information may be disclosed to the Office of Management and Budget at any stage in the legislative coordination and clearance process in connection with private relief legislation as set forth in OMB Circular No. A–19.

E. Disclosure to Congressional Offices: Information may be disclosed to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

F. Disclosure to Department of Justice: Information may be disclosed to the Department of Justice, or in a proceeding before a court, adjudicative body, or other administrative body before which the Agency is authorized to appear, when:

1. The Agency, or any component thereof;

2. Any employee of the Agency in his or her official capacity;

3. Any employee of the Agency in his or her individual capacity where the Department of Justice or the Agency have agreed to represent the employee; or

4. The United States, if the Agency determines that litigation is likely to affect the Agency or any of its components,

Is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or the Agency is deemed by the Agency to be relevant and necessary to the litigation provided, however, that in each case it has been determined that the disclosure is compatible with the purpose for which the records were collected.

G. Disclosure to the National Archives: Information may be disclosed to the National Archives and Records

Administration in records management inspections.

K. Disclosure in Connection With Litigation: Information from this system of records may be disclosed in connection with litigation or settlement discussions regarding claims by or against the Agency, including public filing with a court, to the extent that disclosure of the information is relevant and necessary to the litigation or discussions and except where court orders are otherwise required under section (b)(11) of the Privacy Act of 1974, 5 U.S.C. 552a(b)(11).

The two routine uses below (L and M) are required by OMB Memorandum M–17–12.

L. Disclosure to Persons or Entities in Response to an Actual of or Suspected Breach of Personally Identifiable Information: To appropriate agencies, entities, and persons when (1) the Agency suspects or has confirmed that there has been a breach of the system of records, (2) the Agency has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Agency (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Agency's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

M. Disclosure to Assist Another Agency in Its Efforts to Respond to a Breach of Personally Identifiable Information: To another Federal agency or Federal entity, when the Agency determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained electronically on computer storage devices such as servers and cloud storage. The computer storage devices are located at the EPA; MoveLINQS backups will be maintained at a disaster recovery site designated by Microsoft Azure Government. Computer records are maintained in a secure password protected environment. Access to computer records is limited to those who have a need to know. Permission level assignments will allow users access only to those functions for which they are authorized. All records are maintained in secure, access-controlled areas or buildings.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Retrieval of computer records is limited to those who have a need to know. Currently requestors (end users) do not have access to records using the MoveLINQS system. All users are required to have appropriate permission levels assigned before accessing the system. The permission levels are determined by the type of user. The MoveLINQS system is the only method of retrieval. Users input the information themselves and only authorized users can access.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

MoveLINQS is listed on EPA Records Control Schedule 0089 under Chief Financial Officer as Relocation Expense Management System. The disposition is to close when no longer needed for current agency business and destroy immediately after file closure.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Security controls used to protect personal sensitive data in MoveLINQS are commensurate with those required for an information system rated moderate for confidentiality, integrity, and availability, as prescribed in NIST Special Publication, 800–53, ''Recommended Security Controls for Federal Information Systems,'' Revision 4. Administrative controls include the policies and procedures governing the agency program and systems operated within, background investigations for privileged users and rules of behavior. Technical controls include role-based, user access controls, and data encryption. All MoveLINQS servers and software are stored in the Microsoft Azure Va. Datacenter. All security measures for the physical space are the responsibility of Microsoft. Microsoft Azure Government must in addition adhere to FedRAMP regulations and policies set forth by the Joint Authorization Board, which is the primary authority and decision-making board that ensures FedRAMP Cloud System compliance.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information in this system of records about themselves are required to provide adequate identification (*e.g.,* driver's license, military identification card, employee badge or identification card). Additional identity verification procedures may be required, as warranted. Requests must meet the requirements of EPA regulations that implement the Privacy Act of 1974, at 40 CFR part 16.

CONTESTING RECORDS PROCEDURES:

Requests for correction or amendment must identify the record to be changed and the corrective action sought. Complete EPA Privacy Act procedures are described in the EPA's Privacy Act regulations at 40 CFR part 16.

NOTIFICATION PROCEDURE:

Any individual who wants to know whether this system of records contains a record about him or her, should make a written request to the EPA Attn: Agency Privacy Officer, MC 2831T, 1200 Pennsylvania Ave. NW, Washington, DC 20460, *privacy@epa.gov*.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

67 FR 8255—Posted on February 22, 2002—The EPA provided notice that it proposed to establish a new system of records, the EPA Travel, Other Accounts Payable, and Accounts Receivable Files.

Vaughn Noga,

Senior Agency Official for Privacy.

[FR Doc. 2021–10040 Filed 5–11–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0874; FRS 25345]

Information Collections Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's

burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before July 12, 2021. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0874.

Title: Consumer Complaint Center: Informal Consumer Complaints.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Individuals or households; Business or other for-profit entities; Not for profit institutions; State, Local or Tribal Government.

Number of Respondents and Responses: 292,937 respondents; 292,937 responses.

Estimated Time per Response: 15 minutes (.25 hour) to 1 hour.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Voluntary. The statutory authority for this collection is contained in 47 U.S.C. 208 of the Communications Act of 1934, as amended (the Act).

Total Annual Burden: 73,244 hours.

Total Annual Cost: None.

Nature and Extent of Confidentiality: Confidentiality is an issue to the extent that individuals and households provide personally identifiable information, which is covered under the FCC's updated system of records notice (SORN), FCC/CGB–1, ''Informal Complaints, Inquiries and Requests for Dispute Assistance.'' As required by the Privacy Act, 5 U.S.C. 552a, the Commission also published a SORN, FCC/CGB–1 ''Informal Complaints, Inquiries, and Requests for Dispute Assistance,'' in the **Federal Register** on August 15, 2014 (79 FR 48152) which became effective on September 24, 2014. It may be reviewed at *https://www.fcc.gov/general/privacy-act-information#systems.*

Privacy Impact Assessment: The FCC completed a Privacy Impact Assessment (PIA) on June 28, 2007. It may be reviewed at *http://www.fcc.gov/omd/privacyact/Privacy-Impact-Assessment.html.*

Needs and Uses: The Commission consolidated all of the FCC informal consumer complaint intake into an online consumer complaint portal, which allows the Commission to better manage the collection of informal consumer complaints. Informal consumer complaints consist of informal consumer complaints, inquiries and comments. This revised information collection requests OMB approval for the addition of a layer of consumer reported complaint information related to the National Deaf-Blind Equipment Distribution Program rules. The information collection burdens associated with these complaints is being transferred from OMB Control Number 3060–1225 (National Deaf-Blind Equipment Distribution Program) to OMB Control Number 3060–0874 to enable consumers to file complaints related to the National Deaf-Blind Equipment Distribution Program rules through the Commission's Consumer Complaint Center.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–10002 Filed 5–11–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

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 paragraph 7 of the Act.

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 May 27, 2021.

A. *Federal Reserve Bank of Dallas* (Karen Smith, Director, Applications) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *The Trust Department at FirstBank Southwest, Amarillo, Texas;* to retain voting shares of FirstPerryton Bancorp, Inc. (''Company''), Perryton, Texas, by becoming trustee of the Carl Ellis Separate Property FPB Stock Revocable Trust, Amarillo, Texas, which owns Company stock and thereby indirectly owns First Bank Southwest, Perryton, Texas. Additionally, *the Ellis Family Trust—Julie Ellis FirstBank Southwest Trust S, and the Trust Department at FirstBank Southwest, as trustee,* to acquire voting shares of the Company and to join the Ellis Family Group, a group acting in concert, all of Amarillo, Texas.

Board of Governors of the Federal Reserve System, May 7, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–10016 Filed 5–11–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request

that the Office of Management and Budget (OMB) approve the proposed information collection project ''*Patient Safety Organization Certification for Initial Listing and Related Forms, Patient Safety Confidentiality Complaint Form, and Common Formats*.''

DATES: Comments on this notice must be received by July 12, 2021

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov*.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Proposed Project

''*Patient Safety Organization Certification for Initial Listing and Related Forms, Patient Safety Confidentiality Complaint Form, and Common Formats*''

The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), signed into law on July 29, 2005, was enacted in response to growing concern about patient safety in the United States and the Institute of Medicine's 1999 report, *To Err is Human: Building a Safer Health System*. The goal of the statute is to create a national learning system. By providing incentives of nation-wide confidentiality and legal privilege, the Patient Safety Act learning system improves patient safety and quality by providing an incentive for health care providers to work voluntarily with experts in patient safety to reduce risks and hazards to the safety and quality of patient care. The Patient Safety Act signifies the Federal Government's commitment to fostering a culture of patient safety among health care providers; it offers a mechanism for creating an environment in which the causes of risks and hazards to patient safety can be thoroughly and honestly examined and discussed without fear of penalties and liabilities. It provides for the voluntary formation of Patient Safety Organizations (PSOs) that can collect, aggregate, and analyze confidential information reported voluntarily by health care providers. By analyzing substantial amounts of patient safety event information across multiple institutions, PSOs are able to identify patterns of failures and propose measures to eliminate or reduce risks and hazards.

In order to implement the Patient Safety Act, the Department of Health and Human Services (HHS) issued the Patient Safety and Quality Improvement Final Rule (Patient Safety Rule, 42 CFR part 3) which became effective on January 19, 2009. The Patient Safety Rule outlines the requirements that entities must meet to become and remain listed as PSOs, the process by which the Secretary of HHS (Secretary) will accept certifications and list PSOs, and provisions pertaining to the confidentiality and privilege protections for patient safety work product (PSWP).

When specific statutory requirements are met, the information collected and the analyses and deliberations regarding the information receive confidentiality and privilege protections under this legislation. The Secretary delegated authority to the Director of the Office for Civil Rights (OCR) to interpret and enforce the confidentiality protections of the Patient Safety Act (**Federal Register**, Vol. 71, No. 95, May 17, 2006, p. 28701–2). AHRQ implements and administers the rest of the statute's provisions.

Pursuant to the Patient Safety Rule (42 CFR 3.102), an entity that seeks to be listed as a PSO by the Secretary must certify that it meets certain requirements and, upon listing, would meet other criteria. To remain listed for renewable three-year periods, a PSO must re-certify that it meets these obligations and would continue to meet them while listed. The Patient Safety Act and Patient Safety Rule also impose other obligations discussed below that a PSO must meet to remain listed. In accordance with the requirements of the Patient Safety Rule (see, *e.g.,* 42 CFR 3.102(a)(1), 3.102(b)(2)(i)(E), 3.102(d)(1), and 3.112), the entities seeking to be listed and to remain listed must complete the proposed forms, in order to attest to compliance with statutory criteria and the corresponding regulatory requirements.

Method of Collection

With this submission, AHRQ is requesting approval of the following proposed administrative forms:

1. PSO Certification for Initial Listing Form. This form, containing certifications of eligibility and a capacity and intention to comply with statutory criteria and regulatory requirements, is to be completed, in accordance with 42 U.S.C. 299b–24(a)(1) and the above-cited regulatory certification provisions, by an entity seeking to be listed by the Secretary as a PSO for an initial three-year period.

2. PSO Certification for Continued Listing Form. In accordance with 42 U.S.C. 299b–24(a)(2) and the above-cited regulatory certification provisions, this form is to be completed by a listed PSO seeking continued listing by the Secretary as a PSO for each successive three-year period.

3. PSO Two Bona Fide Contracts Requirement Certification Form. To remain listed, a PSO must meet the requirement in 42 U.S.C. 299b–24(b)(1)(C) that it has contracts with more than one provider, within successive 24-month periods, beginning with the date of the PSO's initial listing. This form is to be used by a PSO to certify whether it has met this statutory requirement and the corresponding regulatory provision.

4. PSO Disclosure Statement Form. This form provides detailed instructions to a PSO regarding the disclosure statement it must submit and provides for the required certification by the PSO of the statement's accuracy in accordance with 42 U.S.C. 299b–24(b)(1)(E), when it (i) has a contract with a provider to carry out patient safety activities, and (ii) it has other financial, reporting, or contractual relationship(s) with that contracting provider, or it is not managed, controlled, and operated independently from that contracting provider. In accordance with the Patient Safety Act and the Patient Safety Rule, the Secretary is required to review each such report and make public findings as to whether a PSO can fairly and accurately carry out its responsibilities.

5. PSO Profile Form. This form is designed to collect voluntarily a minimum level of data necessary to develop aggregate statistics relating to PSOs, the types of providers they work with, and their general location in the US. The PSO Profile is intended to be completed annually by all PSOs that are ''AHRQ-listed'' during any part of the previous calendar year. This information is collected by AHRQ's PSO Privacy Protection Center (PSOPPC) and is used to populate the AHRQ PSO selection tool on the AHRQ PSO website, to generate slides presented at the PSO Annual Meeting, and to develop content for the AHRQ National Healthcare Quality and Disparities Report, an annual quality report required by 42 U.S.C. 299b–2(b)(2).

6. PSO Change of Listing Information Form. The Secretary is required under 42 U.S.C. 299b–24(d) to maintain a publicly available list of PSOs. Under the Patient Safety Rule, that list includes, among other information, each

PSO's current contact information. The Patient Safety Rule, at 42 CFR 3.102(a)(1)(vi), also requires that, during its period of listing, a PSO must promptly notify the Secretary of any changes in the accuracy of the information submitted for listing.

7. PSO Voluntary Relinquishment Form. A PSO may voluntarily relinquish its status as a PSO for any reason. Pursuant to 42 CFR 3.108(c)(2), in order for the Secretary to accept a PSO's notification of voluntary relinquishment, the notice must contain certain attestations and future contact information. This form provides an efficient manner for a PSO seeking voluntary relinquishment to provide all of the required information.

OCR is requesting approval of the following administrative form:

Patient Safety Confidentiality Complaint Form. The purpose of this collection is to allow OCR to collect the minimum information needed from individuals filing patient safety confidentiality complaints with OCR so that there is a basis for initial processing of those complaints.

In addition, AHRQ is requesting approval for a set of common definitions and reporting formats (Common Formats). As authorized by 42 U.S.C. 299b–23(b), AHRQ coordinates the development of the Common Formats that facilitate aggregation of comparable data at local, PSO, regional and national levels. The Common Formats allow PSOs and health care providers to voluntarily collect and submit standardized information regarding patient safety events to fulfill the national learning system envisioned by the Patient Safety Act.

OMB previously approved the Common Formats and forms described above in 2008, 2011, 2014, and 2018. AHRQ will use these forms, other than the Patient Safety Confidentiality Complaint Form, to obtain information necessary to carry out its authority to implement the Patient Safety Act and Patient Safety Rule. This includes obtaining initial and subsequent certifications from entities seeking to be or remain listed as PSOs and for making the statutorily required determinations prior to and during an entity's period of listing as a PSO. The PSO Division, housed in AHRQ's Center for Quality Improvement and Patient Safety, uses this information.

OCR will use the Patient Safety Confidentiality Complaint Form to collect information for the initial assessment of an incoming complaint. The form is modeled on OCR's form for complaints alleging violations of the privacy of protected health information. Use of the form is voluntary. It may help a complainant provide the essential information. Alternatively, a complainant may choose to submit a complaint in the form of a letter or electronically. An individual who needs help to submit a complaint in writing may call OCR for assistance.

Estimated Annual Respondent Burden

The PSO information collection forms described below will be implemented at different times and frequencies due to the voluntary nature of seeking listing and remaining listed as a PSO, filing an OCR Patient Safety Confidentiality Complaint Form, and using the Common Formats. The burden estimates are based on the average of the form submissions received over the past three years.

Exhibit 1 shows the estimated annualized burden hours for the respondent to provide the requested information, and Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to provide the requested information. The total burden hours are estimated to be 100,795.83 hours annually and the total cost burden is estimated to be $4,053,000.33 annually.

PSO Certification for Initial Listing Form: The average annual burden for the collection of information requested by the certification form for initial listing is based upon a total average estimate of 10 respondents per year and an estimated time of 18 hours per response. The estimated response number includes submissions by not only entities listed as PSOs, but also entities that submit initial listing forms that do not become PSOs. After submitting a PSO Certification for Initial Listing Form, an entity may withdraw its form or submit a revised form, particularly after receiving technical assistance from AHRQ. In addition, AHRQ, on behalf of the Secretary, may deny listing if an entity does not meet the requirements of the Patient Safety Act and Patient Safety Rule.

PSO Certification for Continued Listing Form: The average annual burden for the collection of information requested by the certification form for continued listing has an estimated time of eight hours per response and 42 responses annually. The PSO Certification for Continued Listing Form must be completed by any interested PSO at least 75 days before the end of its current three-year listing period.

PSO Two Bona Fide Contracts Requirement Certification Form: The average annual burden for the collection of information requested by the PSO Two Bona Fide Contract Certification Form is based upon an estimate of 51 respondents per year and an estimated one hour per response. This collection of information takes place once per 24-month period when the PSO notifies the Secretary that it has two contracts with providers that meet the requirements.

PSO Disclosure Statement Form: The average burden for the collection of information requested by the Disclosure Statement Form is based upon an estimate of two respondents per year and estimated three hours per response. This information collection takes place within 45 days of when a PSO begins having any of the specified types of additional relationships with a provider with which it has a contract to carry out patient safety activities.

PSO Profile Form. The overall annual burden for the collection of information requested by the PSO Profile Form is based upon an estimate of 72 respondents per year and an estimated three hours per response. The collection of information takes place annually; newly listed PSOs may first submit the form in the calendar year after their initial listing by the Secretary.

PSO Change of Listing Information Form: The average annual burden for the collection of information requested by the PSO Change of Listing Information Form is based upon an estimate of 54 respondents per year and an estimated time of five minutes per response. This collection of information takes place on an ongoing basis as needed when there are changes to the PSO's listing information.

PSO Voluntary Relinquishment Form: The average annual burden for the collection of information requested by the PSO Voluntary Relinquishment Form is based upon a total average estimate of four respondents per year and an estimated time of thirty minutes per response.

OCR Patient Safety Confidentiality Complaint Form: The overall annual burden estimate for the collection of information requested by the OCR Patient Safety Confidentiality Complaint Form is based on an estimate of one respondent per year and an estimated twenty minutes per response. The voluntary use of the form may occur when an allegation of a violation of the confidentiality protections of the Patient Safety Act is made.

Common Formats: AHRQ estimates that 5% full time equivalent (FTE) of a patient safety manager at a facility will be spent to administer the Common Formats, which is approximately 100 hours a year. The use of the formats by PSOs and other entities is voluntary and is on an ongoing basis. This estimate of

the 1,000 respondents is based on the feedback that AHRQ has received during meetings and technical assistance calls from PSOs and other entities that have been utilizing the formats.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
PSO Certification for Initial Listing Form	10	1	18	180
PSO Certification for Continued Listing Form	42	1	8	336
PSO Two Bona Fide Contracts Requirement Form	51	1	1	51
PSO Disclosure Statement Form	2	1	3	6
PSO Profile Form	72	1	3	216
PSO Change of Listing Information	54	1	05/60	4.50
PSO Voluntary Relinquishment Form	4	1	30/60	2
OCR Patient Safety Confidentiality Complaint Form	1	1	20/60	.33
Common Formats	1,000	1	100	100,000
Total		NA	NA	100,795.83

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost
PSO Certification for Initial Listing Form	10	180	$40.21	$7,237.80
PSO Certification for Continued Listing Form	42	336	40.21	13,510.56
PSO Two Bona Fide Contracts Requirement Form	51	51	40.21	2,050.71
PSO Disclosure Statement Form	2	6	40.21	241.26
PSO Profile Form	72	216	40.21	8,685.36
PSO Change of Listing Form	54	4.50	40.21	180.95
PSO Voluntary Relinquishment Form	4	2	40.21	80.42
OCR Patient Safety Confidentiality Complaint Form	1	.33	40.21	13.27
Common Formats	1,000	100,000	40.21	4,021,000.00
Total				4,053,000.33

* Based upon the mean of the hourly average wages for healthcare practitioner and technical occupations, 29–0000, National Compensation Survey, May 2019, ''U.S. Department of Labor, Bureau of Labor Statistics.'' *https://www.bls.gov/oes/current/oes290000.htm.*

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; and, for OCR's enforcement of confidentiality; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: May 6, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–09973 Filed 5–11–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–7062–N]

Request for Nominations and Announcement of the Advisory Panel on Outreach and Education (APOE) May 26, 2021 Virtual Meeting

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

ACTION: Notice.

SUMMARY: This notice invites all interested parties to submit nominations to fill vacancies on the Advisory Panel on Outreach and Education (APOE). This notice also announces the next meeting of the APOE (the Panel) in accordance with the Federal Advisory Committee Act. The Panel advises and makes recommendations to the Secretary of the U.S. Department of Health and Human Services (HHS) (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Health Insurance Marketplace®, Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). This meeting is open to the public.

DATES:

Meeting Date: Wednesday, May 26, 2021 from 12:00 p.m. to 5:00 p.m. eastern daylight time (e.d.t).

Deadline for Meeting Registration, Presentations, Special Accommodations, and Comments: Wednesday, May 19, 2021, 5:00 p.m. (e.d.t).

Deadline for Submitting Nominations: Nominations will be considered if we receive them at the appropriate address,

provided in the **ADDRESSES** section of this notice, no later than 5 p.m., (e.d.t.) on June 11, 2021.

ADDRESSES:

Meeting Location: Virtual. All those who RSVP will receive the link to attend.

Nominations, Presentations, and Written Comments: Nominations, presentations, and written comments should be submitted to: Lisa Carr, Designated Federal Official (DFO), Office of Communications, Centers for Medicare & Medicaid Services, 200 Independence Avenue SW, Mailstop 325G HHH, Washington, DC 20201, 202–690–5742, or via email at *APOE@cms.hhs.gov.*

Registration: The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register at the website *https://www.eventbrite.com/e/apoe-may-26-2021-virtual-meeting-tickets-150209828641* or by contacting the DFO listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, by the date listed in the **DATES** section of this notice. Individuals requiring sign language interpretation or other special accommodations should contact the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT: Lisa Carr, Designated Federal Official, Office of Communications, 200 Independence Avenue SW, Mailstop 325G HHH, Washington, DC 20201, 202–690–5742, or via email at *APOE@cms.hhs.gov.*

Additional information about the APOE is available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/APOE.* Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION:

I. Background and Charter Renewal Information

A. Background

The Advisory Panel for Outreach and Education (APOE) (the Panel) is governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of federal advisory committees. The Panel is authorized by section 1114(f) of the Social Security Act (the Act) (42 U.S.C. 1314(f)) and section 222 of the Public Health Service Act (42 U.S.C. 217a).

The Secretary of the U.S. Department of Health and Human Services (HHS) (the Secretary) signed the charter establishing the Citizen's Advisory Panel on Medicare Education [1] (the predecessor to the APOE) on January 21, 1999 (64 FR 7899) to advise and make recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on the effective implementation of national Medicare education programs, including with respect to the Medicare+Choice (M+C) program added by the Balanced Budget Act of 1997 (Pub. L. 105–33).

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) expanded the existing health plan options and benefits available under the M+C program and renamed it the Medicare Advantage (MA) program. CMS has had substantial responsibilities to provide information to Medicare beneficiaries about the range of health plan options available and better tools to evaluate these options. Successful MA program implementation required CMS to consider the views and policy input from a variety of private sector constituents and to develop a broad range of public-private partnerships.

In addition, Title I of the MMA authorized the Secretary and the Administrator of CMS (by delegation) to establish the Medicare prescription drug benefit. The drug benefit allows beneficiaries to obtain qualified prescription drug coverage. In order to effectively administer the MA program and the Medicare prescription drug benefit, we have substantial responsibilities to provide information to Medicare beneficiaries about the range of health plan options and benefits available, and to develop better tools to evaluate these plans and benefits.

The Patient Protection and Affordable Care Act (Pub. L. 111–148) and Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively referred to as the Affordable Care Act) expanded the availability of other options for health care coverage and enacted a number of changes to Medicare as well as to Medicaid and CHIP. Qualified individuals and qualified employers are now able to purchase private health insurance coverage through a competitive marketplace, called an Affordable Insurance Exchange (also called Health Insurance Marketplace®, or Marketplace® [2]). In order to effectively implement and administer these changes, we must provide information to consumers, providers, and other stakeholders through education and outreach programs regarding how existing programs will change and the expanded range of health coverage options available, including private health insurance coverage through the Marketplace®. The APOE allows us to consider a broad range of views and information from interested audiences in connection with this effort and to identify opportunities to enhance the effectiveness of education strategies concerning the Affordable Care Act. The scope of this Panel also includes advising on issues pertaining to the education of providers and stakeholders with respect to the Affordable Care Act and certain provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act enacted as part of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5).

On January 21, 2011, the Panel's charter was renewed and the Panel was renamed the Advisory Panel for Outreach and Education. The Panel's charter was most recently renewed on January 19, 2021, and will terminate on January 19, 2023 unless renewed by appropriate action.

B. Charter Renewal and Copies of the Charter

In accordance with the January 19, 2021, charter, the APOE will advise the HHS and CMS on developing and implementing education programs that support individuals who are enrolled in or eligible for Medicare, Medicaid, CHIP, or coverage available through the Health Insurance Marketplace® and other CMS programs. The scope of this FACA group also includes advising on education of providers and stakeholders with respect to health care reform and certain provisions of the HITECH Act enacted as part of the ARRA.

The charter will terminate on January 19, 2023, unless renewed by appropriate action. The APOE was chartered under 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended. The APOE is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

In accordance with the renewed charter, the APOE will advise the Secretary and the CMS Administrator concerning optimal strategies for the following:

- Developing and implementing education and outreach programs for individuals enrolled in, or eligible for,

[1] We note that the Citizen's Advisory Panel on Medicare Education is also referred to as the Advisory Panel on Medicare Education (65 FR 4617). The name was updated in the Second Amended Charter approved on July 24, 2000.

[2] Health Insurance Marketplace®SM and Marketplace®SM are service marks of the U.S. Department of Health and Human Services.

Medicare, Medicaid, the CHIP, and coverage available through the Health Insurance Marketplace® and other CMS programs.

- Enhancing the federal government's effectiveness in informing Medicare, Medicaid, CHIP, or the Health Insurance Marketplace® consumers, issuers, providers, and stakeholders, pursuant to education and outreach programs of issues regarding these programs, including the appropriate use of public-private partnerships to leverage the resources of the private sector in educating beneficiaries, providers, partners and stakeholders.
- Expanding outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of Medicare, Medicaid, the CHIP and the Health Insurance Marketplace® education programs, and other CMS programs as designated.
- Assembling and sharing an information base of ''best practices'' for helping consumers evaluate health coverage options.
- Building and leveraging existing community infrastructures for information, counseling, and assistance.
- Drawing the program link between outreach and education, promoting consumer understanding of health care coverage choices, and facilitating consumer selection/enrollment, which in turn support the overarching goal of improved access to quality care, including prevention services, envisioned under the Affordable Care Act.

The current members of the Panel as of April 9, 2021, are: E. Lorraine Bell, Chief Officer, Population Health, Catholic Charities USA; Nazleen Bharmal, Medical Director of Community Partnerships, Cleveland Clinic; Julie Carter, Senior Federal Policy Associate, Medicare Rights Center; Scott Ferguson, Director of Care Transitions and Population Health, Mount Sinai St. Luke's Hospital; Leslie Fried, Senior Director, Center for Benefits Access, National Council on Aging; Jean-Venable Robertson Goode, Professor, Department of Pharmacotherapy and Outcomes Science, School of Pharmacy, Virginia Commonwealth University; Ted Henson, Director of Health Center Performance and Innovation, National Association of Community Health Centers; Joan Ilardo, Director of Research Initiatives, Michigan State University, College of Human Medicine; Cheri Lattimer, Executive Director, National Transitions of Care Coalition; Cori McMahon, Vice President, Tridiuum; Alan Meade, Director of Rehab Services, Holston Medical group; Michael Minor, National Director, H.O.P.E. HHS Partnership, National Baptist Convention USA, Incorporated; Jina Ragland, Associate State Director of Advocacy and Outreach, AARP Nebraska; Morgan Reed, Executive Director, Association for Competitive Technology; Margot Savoy, Chair, Department of Family and Community Medicine, Temple University Physicians; Congresswoman Allyson Schwartz, President and CEO, Better Medicare Alliance; and; Tia Whitaker, Statewide Director, Outreach and Enrollment, Pennsylvania Association of Community Health Centers.

The Secretary's Charter for the APOE is available on the CMS website at: *https://www.facadatabase.gov/FACA/apex/FACAPublicCommittee?id=a10t0000001gzsCAAQ,* or you may obtain a copy of the charter by submitting a request to the contact listed in the **FOR FURTHER INFORMATION** section of this notice.

II. Request for Nominations

The APOE shall consist of no more than 20 members. The Chair shall either be appointed from among the 20 members, or a Federal official will be designated to serve as the Chair. The charter requires that meetings shall be held up to four times per year. Members will be expected to attend all meetings. The members and the Chair shall be selected from authorities knowledgeable in one or more of the following fields:

- Senior citizen advocacy
- Outreach to minority and underserved communities
- Health communications
- Disease-related advocacy
- Disability policy and access
- Health economics research
- Health insurers and plans
- Health IT
- Direct patient care
- Matters of labor and retirement

Representatives of the general public may also serve on the APOE.

This notice also requests nominations for three individuals to serve on the APOE to fill current vacancies and possible vacancies that may become available later in 2021. This notice is an invitation to interested organizations or individuals to submit their nominations for membership (no self-nominations will be accepted). The CMS Administrator will appoint new members to the APOE from among those candidates determined to have the expertise required to meet specific agency needs, and in a manner to ensure an appropriate balance of membership. We have an interest in ensuring that the interests of both women and men, members of all racial and ethnic groups, and disabled individuals are adequately represented on the APOE. Therefore, we encourage nominations of qualified candidates who can represent these interests. Any interested organization or person may nominate one or more qualified persons.

Each nomination must include a letter stating that the nominee has expressed a willingness to serve as a Panel member and must be accompanied by a curricula vitae and a brief biographical summary of the nominee's experience.

While we are looking for experts in a number of fields, our most specific needs are for experts in outreach to minority and underserved communities, health communications, disease-related advocacy, disability policy and access, health economics research, behavioral health, health insurers and plans, Health IT, social media, direct patient care, and matters of labor and retirement.

We are requesting that all submitted curricula vitae include the following:

- Date of birth
- Place of birth
- Title and current position
- Professional affiliation
- Home and business address
- Telephone and fax numbers
- Email address
- Areas of expertise

Phone interviews of nominees may also be requested after review of the nominations.

In order to permit an evaluation of possible sources of conflict of interest, potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts.

Members are invited to serve for 2-year terms, contingent upon the renewal of the APOE by appropriate action prior to its termination. A member may serve after the expiration of that member's term until a successor takes office. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term.

III. Meeting Format and Agenda

In accordance with section 10(a) of the FACA, this notice announces a meeting of the APOE. The agenda for the May 26, 2021 meeting will include the following:

- Welcome and listening session with CMS leadership
- Recap of the previous (March 31, 2021) meeting
- CMS programs, initiatives, and priorities
- An opportunity for public comment

- Meeting summary, review of recommendations, and next steps

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make an oral presentation may submit written comments to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

IV. Meeting Participation

The meeting is open to the public, but attendance is limited to registered participants. Persons wishing to attend this meeting must register at the website *https://www.eventbrite.com/e/apoe-may-26-2021-virtual-meeting-tickets-150209828641* or contact the DFO at the address or number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice. This meeting will be held virtually. Individuals who are not registered in advance will be unable to attend the meeting.

V. Collection of Information

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).

The Acting Administrator of the Centers for Medicare & Medicaid Services (CMS), Elizabeth Richter, 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 10, 2021.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2021–10118 Filed 5–11–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10398 #37]

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 [1] 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 May 26, 2021.

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 (#37)/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.html*.

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 Collection

1. *Title of Information Collection:* Medicaid Managed Care Rate Development Guide; *Type of Information Collection Request:* Revision of a currently approved collection; *Use:* States are required to submit rate certifications for all Medicaid managed care capitation rates per 42 CFR 438.7. Our collection of information request specifies our requirements for the rate certification and details what types of documentation we expect to be included. Elements include descriptions of data used, projected benefit and non-benefit costs, rate range development, risk and contract provisions, and other considerations in all rate setting packages. We also detail our expectations for states when they submit rate certifications.

[1] *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/inforeg/PRA_Gen_ICRs_5-28-2010.pdf.*

Section 1903(m) of the Social Security Act requires capitation rates paid to Medicaid managed care organizations (MCOs) to be actuarially sound. Regulations at § 438.4 require all capitation rates paid to an MCO, Prepaid Inpatient Health Plan (PIHP), or Prepaid Ambulatory Health Plans (PAHP) to be actuarially sound and require that each state submit a rate certification for each set of capitation rates developed. Regulations at § 438.7(e) also require that CMS annually publish this guidance; *Form Number:* CMS–10398 (#37) (OMB control number: 0938–1148); Frequency: Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 46; *Total Annual Responses:* 135; *Total Annual Hours:* 608. (For policy questions regarding this collection contact Amy Gentile at 410–786–3499.)

Dated: May 7, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–10050 Filed 5–11–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1609]

Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management; International Council for Harmonisation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management.'' The guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The guidance, which consists of a Guidance and Annexes, provides a framework to facilitate the management of postapproval chemistry, manufacturing, and controls changes for new and marketed pharmaceutical drug substances and drug products, including chemical and biotechnological/biological products. This guidance finalizes the draft guidance of the same title issued on May 31, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on May 12, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2018–D–1609 for ''Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–

800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Mahesh Ramanadham, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3272; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management.'' The guidance was prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the Membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the **Federal Register** of May 31, 2018 (83 FR 25018), FDA published a notice announcing the availability of a draft guidance entitled ''Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management.'' The notice gave interested persons an opportunity to submit comments by December 15, 2018.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in November 2019. Changes from the draft to the final guideline include: revision of the text regarding the compatibility of the guideline with regional legal frameworks, removal of the terms ''implicit'' and ''explicit'' as they referred to established conditions, removal of the term ''key process parameter,'' and revisions to the text to better explain the concept of critical process parameter and identification of established conditions for manufacturing processes. Other changes included revision of the description for identification of established conditions for analytical methods and development of an illustrative example, revisions to the recommended content of the product lifecycle management document and its location within the common technical document, and revisions to clarify the use of tools described in the guideline for master files. In addition, editorial changes were made to improve clarity.

The guidance provides guidance on postapproval chemistry, manufacturing, and controls changes for new and marketed pharmaceutical drug substances and drug products. The guidance describes regulatory tools and enablers, along with associated guiding principles, that are intended to enhance the management of postapproval changes and transparency between industry and regulatory authorities, encouraging innovation and continual improvement. The guidance is intended to demonstrate how increased product and process knowledge can contribute to a more precise and accurate understanding of which postapproval changes require a regulatory submission as well as the definition of the level of reporting categories for such changes (*i.e.,* a better understanding of risk to product quality). Increased knowledge and effective implementation of the tools and enablers described in this guidance should enhance industry's ability to manage many chemistry, manufacturing, and controls changes effectively under the company's Pharmaceutical Quality System (PQS) with less need for extensive regulatory oversight prior to implementation. This approach can incentivize continual improvement by providing an opportunity for greater flexibility in making postapproval changes. It could also result in fewer associated postapproval submissions to the Marketing Authorization Application and less associated regulatory burden. The extent of operational and regulatory flexibility and its adequate implementation is subject to the regulatory framework in place as well as product and process understanding (ICH Q8(R2) and Q11), application of risk management principles (ICH Q9), and an effective PQS (ICH Q10).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required.

However, this guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control

number 0910–0001 and in part 601 under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: May 6, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–09963 Filed 5–11–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–7001]

Qualified Infectious Disease Product Designation—Questions and Answers; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Qualified Infectious Disease Product Designation—Questions and Answers.'' The Food and Drug Administration Safety and Innovation Act (FDASIA) created incentives for the development of antibacterial and antifungal drug products that treat serious or life-threatening infections. The purpose of this final guidance is to provide a resource for information on FDA's policies and procedures related to the designation of a qualified infectious disease product (QIDP). This guidance finalizes the draft guidance of the same name issued on January 30, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on May 12, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2017–D–7001 for ''Qualified Infectious Disease Product Designation—Questions and Answers.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Katherine Schumann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993–0002, 301–796–1182, *Katherine.Schumann@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Qualified Infectious Disease Product Designation—Questions and Answers.'' Title VIII of FDASIA created the Generating Antibiotic Incentives Now (GAIN) provisions under section 505E of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355f). GAIN offers incentives for the development of

antibacterial and antifungal drugs for human use to treat serious or life-threatening infections. The primary incentive contained in GAIN is a 5-year extension of exclusivity for which a QIDP-designated application qualifies upon approval under the FD&C Act. QIDPs also receive fast-track designation at the sponsor's request (21 U.S.C. 356(b)(1)), and the first marketing application submitted for approval of a QIDP is granted priority review (21 U.S.C. 360n–1).

This guidance provides information about how FDA generally intends to implement GAIN and responses to common questions that might arise about QIDP designation and review of new drug applications for QIDPs.

This guidance finalizes the draft guidance of the same name issued on January 30, 2018 (83 FR 4216). Based on the comments submitted to the docket on the draft guidance, FDA made clarifying changes to this guidance, including further information on what drug products the Agency generally intends to consider to be an antibacterial or antifungal drug for the purposes of QIDP designation. The Agency also provided clarification about when a sponsor should submit a new request for QIDP designation and what information should be included in a QIDP designation request.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on QIDP designation. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: May 5, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–09986 Filed 5–11–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0074]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Enforcement Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by June 11, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0275. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

State Enforcement Notifications—21 CFR 100.2(d)

OMB Control Number 0910–0275—Extension

This information collection supports Agency regulations. Specifically, section 310(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 337(b)) authorizes a State to enforce certain sections of the FD&C Act in its own name and within its own jurisdiction. However, before doing so, a State must provide notice to FDA according to § 100.2 (21 CFR 100.2). The information required in a letter of notification under § 100.2(d) enables us to identify the food against which a State intends to take action and to advise that State whether Federal enforcement action against the food has been taken or is in process. With certain narrow exceptions, Federal enforcement action precludes State action under the FD&C Act.

In the **Federal Register** of December 17, 2020 (85 FR 81932), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
100.2(d)	1	1	1	10	10

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

The estimated reporting burden for § 100.2(d) is minimal because

enforcement notifications are seldom used by States. During the last 3 years, we have not received any new enforcement notifications; therefore, we estimate that one or fewer notifications will be submitted annually. Although we have not received any new enforcement notifications in the last 3 years, we believe these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing us when it intends to take enforcement action under the FD&C Act against a particular food located in the State.

Dated: May 5, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–09968 Filed 5–11–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6113]

E9(R1) Statistical Principles for Clinical Trials: Addendum: Estimands and Sensitivity Analysis in Clinical Trials; International Council for Harmonisation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''E9(R1) Statistical Principles for Clinical Trials: Addendum: Estimands and Sensitivity Analysis in Clinical Trials.'' The guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The guidance clarifies, updates, and extends the guidance for industry ''E9 Statistical Principles for Clinical Trials'' issued in September 1998 in two main areas. Concerning estimands, it provides a framework for discussion of how the aims of a trial relate to the proposed statistical analysis. Concerning sensitivity analysis, it discusses how to use additional analyses to address concerns about the validity of assumptions underlying the main analysis. The guidance is intended to better align the choice of statistical methods with questions of regulatory importance and so to improve the reliability of decisions about and representations of the effects of medical products. The guidance replaces the draft guidance issued on October 31, 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on May 12, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2017–D–6113 for ''E9(R1) Statistical Principles for Clinical Trials: Addendum: Estimands and Sensitivity Analysis in Clinical Trials.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive

label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Scott Goldie, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 21, Rm. 3557, Silver Spring, MD 20993–0002, 301–796–2055, *scott.goldie@fda.hhs.gov*; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''E9(R1) Statistical Principles for Clinical Trials: Addendum: Estimands and Sensitivity Analysis in Clinical Trials.'' The guidance was prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the Membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the **Federal Register** of October 31, 2017 (82 FR 50433), FDA published a notice announcing the availability of a draft guidance entitled ''E9(R1) Statistical Principles for Clinical Trials: Addendum: Estimands and Sensitivity Analysis in Clinical Trials.'' The notice gave interested persons an opportunity to submit comments by April 30, 2018.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in November 2019.

This guidance finalizes the draft guidance issued on October 31, 2017. The guidance provides clarification on statistical principles for clinical trials and an update on the choice of estimand to describe a framework for planning, conducting, and interpreting sensitivity analyses of clinical trial data. The focus of the guidance is on statistical principles related to estimands and sensitivity analysis for confirmatory clinical trials. The guidance provides recommendations for aligning the choice of statistical methods with the goals of a clinical trial; on communicating the rationale for such choices to FDA; and on using sensitivity analysis to characterize the robustness of the conclusions to plausible deviations from the assumptions of the main analysis. Revisions made following the public comment period are intended to clarify content within the guidance; however, no new concepts are presented in the revised version.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''E9(R1) Statistical Principles for Clinical Trials: Addendum: Estimands and Sensitivity Analysis in Clinical Trials.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances*.

Dated: May 7, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10066 Filed 5–11–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5138]

S5(R3) Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals; International Council for Harmonisation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''S5(R3) Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals.'' The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. The guidance provides key considerations for developing a testing strategy to identify hazard and characterize reproductive risk for human pharmaceuticals. The guidance is intended to align with other ICH guidances, elaborate on concepts to

consider when designing studies, and identify potential circumstances in which a risk assessment can be made based on preliminary studies. It also clarifies the qualification and potential use of alternative assays. This guidance finalizes the draft guidance issued on November 13, 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on May 12, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2017–D–5138 for ''S5(R3) Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Ronald Wange, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3342, Silver Spring, MD 20993–0002, 301–796–1304; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''S5(R3) Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals.'' The guidance was prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health

Canada and Swissmedic. Additionally, the Membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the **Federal Register** of November 13, 2017 (82 FR 52306), FDA published a notice announcing the availability of a draft guidance entitled ''S5(R3) Detection of Toxicity to Reproduction for Human Pharmaceuticals.'' The notice gave interested persons an opportunity to submit comments by February 12, 2018.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agency members in January 2020.

The guidance finalizes the guidance issued on November 13, 2017. The guidance has undergone revisions to align with other ICH guidances, elaborate on concepts to consider when designing studies, and identify potential circumstances in which a risk assessment can be made based on preliminary studies. It also clarifies the qualification and potential use of alternative assays.

The purpose of this guidance is to provide key considerations for developing a testing strategy to identify hazard and characterize reproductive risk for human pharmaceuticals. The guidance informs on the use of existing data and identifies potential study designs to supplement available data to identify, assess, and convey risk. General concepts and recommendations are provided that should be considered when interpreting study data and assessing reproductive risk in support of clinical development and marketing approval.

This guidance applies to pharmaceuticals, including biotechnology-derived pharmaceuticals; vaccines (and their novel constitutive ingredients) for infectious diseases; and novel excipients that are part of the final pharmaceutical product. It does not apply to cellular therapies, gene therapies, and tissue-engineered products. The methodological principles (*e.g.,* study design, dose selection, and species selection) outlined in this guidance can also apply to all compounds for which the conduct of reproductive and/or developmental toxicity studies is appropriate, including vaccines for other indications (*e.g.,* cancer). (see ICH guidance for industry ''S9 Nonclinical Evaluation for Anticancer Pharmaceuticals'' (March 2010), available at *https://www.fda.gov/media/73161/download*).

The guidance reflects revisions made in response to comments received on the draft guidance. These include reorganization of the guidance to improve readability and clarity, to introduce discussion of conventional assessment strategies earlier in the document, and to clarify which elements of the guidance are more appropriate for biotechnology-derived therapies. To accommodate the rapidly evolving nature of alternative assay development, the discussion of alternative assays was placed in an Annex, subject to a maintenance procedure, to allow for more frequent updating of this material.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''S5(R3) Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required.

However, this guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; and the content and format requirements for pregnancy and lactation labeling of human prescription drug and biological products have been approved under OMB control number 0910–0624.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: May 6, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10017 Filed 5–11–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1370]

COVID–19: Developing Drugs and Biological Products for Treatment or Prevention; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''COVID–19: Developing Drugs and Biological Products for Treatment or Prevention.'' This guidance describes FDA's current recommendations regarding phase 2 or phase 3 trials for drugs or biological products under development for the treatment or prevention of COVID–19. Given the public health emergency presented by COVID–19, this guidance document is being implemented without prior public comment because FDA has determined that prior public participation is not feasible or appropriate, but it remains subject to comment in accordance with the Agency's good guidance practices. This final guidance revises and replaces the final guidance of the same name issued

on May 11, 2020. Revisions were made to address the evolving landscape of COVID–19 drug development, including the emergence of SARS-CoV–2 variants and the availability of COVID–19 vaccines. The revision to this guidance was posted to the FDA website on February 22, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on May 12, 2021. The guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

ADDRESSES: You may submit electronic or written comments on Agency guidances at any time as follows:

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–2020–D–1370 for ''COVID–19: Developing Drugs and Biological Products for Treatment or Prevention.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Eithu Lwin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–0728; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''COVID–19: Developing Drugs and Biological Products for Treatment or Prevention.'' There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named SARS-CoV–2, and the disease it causes has been named Coronavirus Disease 2019 (COVID–19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID–19 and mobilized the Operating Divisions of HHS. The public health emergency declaration has been subsequently renewed. In addition, on March 13, 2020, the President declared a national emergency in response to COVID–19. The revision to this guidance was posted to the FDA website on February 22, 2021.

This guidance describes FDA's current recommendations regarding phase 2 or phase 3 trials for drugs under development to treat or prevent COVID–19. This guidance focuses on the patient population, trial design, efficacy endpoints, safety considerations, and statistical considerations for such trials. Drugs should have undergone sufficient development before their evaluation in phase 2 or phase 3.

This guidance focuses on the development of drugs with direct antiviral activity or immunomodulatory activity. However, the recommendations in this guidance may be applicable to development plans for drugs for COVID–19 with other mechanisms of action. The mechanism of action of the drug may impact key study design

elements (*e.g.,* population, endpoints, safety assessments, duration of followup, etc.).

Preventative vaccines are not within the scope of this guidance. Nor does this guidance provide general recommendations on early drug development in COVID–19, such as use of animal models.

In light of the public health emergency related to COVID–19 declared by the Secretary of HHS, FDA has determined that prior public participation for this guidance is not feasible or appropriate and is issuing this guidance without prior public comment (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

This guidance is intended to remain in effect for the duration of the public health emergency related to COVID–19 declared by HHS, including any renewals made by the Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)). However, the recommendations and processes described in the guidance are expected to assist the Agency more broadly in its continued efforts to assist sponsors in the clinical development of drugs for the treatment of COVID–19 beyond the termination of the COVID–19 public health emergency and reflect the Agency's current thinking on this issue. Therefore, within 60 days following the termination of the public health emergency, FDA intends to revise and replace this guidance with any appropriate changes based on comments received on this guidance and the Agency's experience with implementation.

This final guidance revises and replaces the final guidance with the same title issued on May 19, 2020 (85 FR 29949). The revision addresses the potential impact of the emergence of SARS-CoV–2 variants and the availability of COVID–19 vaccines. Additional updates reflecting the evolving landscape of COVID–19 drug development were made to the recommendations on patient population, trial design, efficacy endpoints, safety considerations, and statistical considerations. In addition, FDA considered comments received on the previous guidance, and editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''COVID–19: Developing Drugs and Biological Products for Treatment or Prevention.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR parts 312 and 320 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 58 regarding good laboratory practice for nonclinical laboratory studies have been approved under OMB control number 0910–0119; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 320 have been approved under OMB control number 0910–0291; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in FDA's draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of Prescription Drug User Fee Act Products'' have been approved under OMB control number 0910–0429; the collections of information in FDA's final guidance for clinical trial sponsors entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under OMB control number 0910–0581; and the collections of information in FDA's final guidance for industry entitled ''Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring'' have been approved under OMB control number 0910–0733.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders,* or *https://www.regulations.gov*.

Dated: May 7, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10061 Filed 5–11–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1156]

Q3D(R2)—Guideline for Elemental Impurities; International Council for Harmonisation; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Q3D(R2)—Guideline for Elemental Impurities.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The draft guidance provides Permissible Daily Exposures (PDEs) for the cutaneous and transcutaneous routes of administration and relevant risk assessment considerations to supplement previous guidance for the oral, parenteral, and inhalation routes of administration. In addition, error corrections to previously identified PDEs for gold (oral, parenteral, and inhalation routes), silver (parenteral route), and nickel (inhalation route) are provided. The draft guidance is intended to recommend acceptable amounts for the listed elemental impurities in pharmaceuticals for the safety of the patient and provide recommendations for conducting a risk assessment for pharmaceutical products.

DATES: Submit either electronic or written comments on the draft guidance by June 11, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2013–D–1156 for ''Q3D(R2)—Guideline for Elemental Impurities.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Timothy McGovern, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 22, Rm. 6426, Silver Spring, MD 20993–0002, 240–402–0477, *timothy.mcgovern@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Q3D(R2)—Guideline for Elemental Impurities.'' The draft guidance was prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the Membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In September 2020, the ICH Assembly endorsed the draft guidance entitled ''Q3D(R2)—Guideline for Elemental Impurities'' and agreed that the guidance should be made available for public comment. The draft guidance is the product of the Quality Expert Working Group of the ICH. Comments about this draft guidance will be considered by FDA and the Quality Expert Working Group.

The draft guidance provides guidance on PDEs for the cutaneous and transcutaneous routes of administration and relevant risk assessment considerations to supplement previous guidance for the oral, parenteral, and inhalation routes of administration. In addition, error corrections to previously identified PDEs for gold (oral, parenteral, and inhalation routes), silver (parenteral route), and nickel (inhalation route) are provided.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on ''Q3D(R2)—Guideline for Elemental Impurities.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: May 7, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10011 Filed 5–11–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3614]

M9 Biopharmaceutics Classification System-Based Biowaivers; International Council for Harmonisation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''M9 Biopharmaceutics Classification System-Based Biowaivers.'' The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. The guidance provides recommendations to support the biopharmaceutics classification of drug substances and the Biopharmaceutics Classification System (BCS)-based waiver of the in vivo bioequivalence (BE) study requirement for certain drug products. The guidance is intended to avoid or reduce the need for human BE trials based on extensive in vitro characterization of the drug substance and drug product properties. The guidance replaces the existing FDA guidance issued December 26, 2017, entitled ''Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System.'' The guidance also finalizes the draft ICH guidance, ''M9 Biopharmaceutics Classification System-Based Biowaivers,'' issued on October 26, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on May 12, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2018–D–3614 for ''M9 Biopharmaceutics Classification System-Based Biowaivers.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Mehul Mehta, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2178, Silver Spring, MD 20993–0002, 301–796–1573; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''M9 Biopharmaceutics Classification System-Based Biowaivers.'' The guidance was prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the Membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the **Federal Register** of October 26, 2018 (83 FR 54107), FDA published a notice announcing the availability of a draft guidance entitled ''M9 Biopharmaceutics Classification System-Based Biowaivers.'' The notice gave interested persons an opportunity to submit comments by January 24, 2019.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agency members in November 2019.

The guidance provides recommendations to support the biopharmaceutics classification of drug substances and the BCS-based waiver of the in vivo BE study requirement for drug products. The BCS-based biowaiver approach is intended to reduce the need for in vivo bioequivalence studies. In vivo bioequivalence studies may be waived if an assumption of equivalence in in vivo performance can be justified by satisfactory in vitro data. The BCS is a scientific approach based on the aqueous solubility and intestinal permeability characteristics of the drug substance or substances. The BCS categorizes drug substances into one of four BCS classes as follows:

- Class I: High solubility, high permeability
- Class II: Low solubility, high permeability
- Class III: High solubility, low permeability
- Class IV: Low solubility, low permeability

In vivo BE studies are needed to demonstrate lack of impact of significant formulation changes on a drug's bioavailability during its development, for post approval line extensions, and when developing a generic product. Utilizing the critical properties of the drug substance and the drug product, and applying the BCS framework, extensive in vitro studies

can support the waiver of the in vivo BE requirement for certain drug products.

Following the public consultation period, clarifications were made to the guidance based on the comments received.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''M9 Biopharmaceutics Classification System-Based Biowaivers.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required. However, this final guidance refers to previously approved FDA collections of information. The previously approved collections of information are subject to review by OMB under the PRA. The following collections of information have been approved under OMB control number 0910–0001:

- Submitting under 21 CFR 314.50 content and format of new drug applications, including the pharmacokinetics and bioavailability sections.
- Submitting under 21 CFR 314.70 postapproval changes.
- Submitting under 21 CFR 314.94 content and format of abbreviated new drug applications.

The collections of information for submitting under 21 CFR 312.23 information about pharmacokinetics and biological disposition of the drug has been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.regulations.gov, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Dated: May 6, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–09962 Filed 5–11–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4524]

S11 Nonclinical Safety Testing in Support of Development of Pediatric Pharmaceuticals; International Council for Harmonisation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''S11 Nonclinical Safety Testing in Support of Development of Pediatric Pharmaceuticals.'' The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. The guidance recommends international standards for the nonclinical safety studies recommended to support the development of pediatric medicines. The guidance provides a weight of evidence approach to determine when nonclinical toxicity studies may be recommended in juvenile animals. If such studies are recommended, the guidance provides appropriate study designs. The guidance is intended to promote harmonization of recommendations for such studies and should facilitate the timely conduct of pediatric clinical trials and reduce the use of animals in accordance with the 3R (replace/reduce/refine) principles. Tissue engineered products, gene and cellular therapies, and vaccines are excluded from the scope of this guidance. The guidance replaces the draft guidance issued on February 1, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on May 12, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2018–D–4524 for ''S11 Nonclinical Safety Testing in Support of Development of Pediatric Pharmaceuticals.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Karen Davis Bruno, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6428, Silver Spring, MD 20993–0002, 301–796–1199; or, Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''S11 Nonclinical Safety Testing in Support of Development of Pediatric Pharmaceuticals.'' The guidance was prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner. By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the Membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. In the **Federal Register** of February 1, 2019 (84 FR 1161), FDA published a notice announcing the availability of a draft guidance entitled ''S11 Nonclinical Safety Testing in Support of Development of Pediatric Medicines.'' The notice gave interested persons an opportunity to submit comments by April 2, 2019. After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in April 2020.

This guidance finalizes the draft guidance issued on February 1, 2019. The guidance describes a weight of evidence approach to determine when nonclinical toxicity studies may be recommended in juvenile animals to support development of medicines to be used in pediatric patients. If such studies are recommended, the guidance also provides appropriate study designs. The guidance describes study designs as consisting of a core set of endpoints that can be supplemented by additional endpoints depending on the concerns identified in the weight of evidence approach. The guidance also provides guidance on potential approaches for the nonclinical support of drugs that will be developed only for use in pediatric patients or that will be first tested in pediatric patients. The guidance is intended to promote harmonization of recommendations for such studies and should facilitate the timely conduct of pediatric clinical trials and reduce the use of animals in accordance with the 3R (replace/reduce/refine) principles.

The draft guidance was revised based on comments received. The revisions include refinement of the weight of evidence approach and in descriptions of the core and additional endpoints that can be incorporated into juvenile animal studies. The final guidance also includes a new section on data interpretation. The appendices on age-dependent development of organ systems by species and preweaning litter allocation in the rodent were also updated. Additionally, the title of the guidance was updated from ''Nonclinical Safety Testing in Support of Development of Pediatric Medicines'' to ''Nonclinical Safety Testing in Support of Development of Pediatric Pharmaceuticals.''

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''S11 Nonclinical Safety Testing in Support of Development of Pediatric Pharmaceuticals.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312, pertaining to the submission of nonclinical and preclinical data, including a pediatric clinical development plan, have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 58 pertaining to good laboratory practice for nonclinical laboratory studies have been approved under OMB control number 0910–0119; and the collections of information in FDA's guidance for industry on ''Expedited Programs for Serious Conditions—Drugs and Biologics'' has been approved under OMB control number 0910–0765.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: May 6, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–09964 Filed 5–11–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0390]

Lederle Laboratories et al.; Withdrawal of Approval of 12 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 12 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of June 11, 2021.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 060164	Nystatin Ointment	Lederle Laboratories, Division of American Cyanamid Co., P.O. Box 8299, Pearl River, NY 10965.
ANDA 060521	Humatin (paromomycin sulfate) Capsules, Equivalent to (EQ) 250 milligrams (mg)/base.	King Pharmaceuticals, 501 5th St., Bristol, TN 37620.
ANDA 061034	Lincomycin Hydrochloride (HCl)	The Upjohn Co. (formerly Pharmacia and Upjohn Co.), 7000 Portage Rd., Kalamazoo, MI 49001.
ANDA 061652	Oxytetracycline	Parke Davis, 201 Tabor Rd., Morris Plains, NJ 07950.
ANDA 061701	Tetracycline	Wyeth Pharmaceuticals, 1211 Sherwood Ave., Richmond, VA 23220.
ANDA 062032	Erypar (erythromycin stearate) Tablets, EQ 250 mg/base and EQ 500 mg/base.	Parke Davis.
ANDA 076490	Lithium Carbonate Extended-Release Tablets, 450 mg	Hikma Pharmaceuticals USA Inc., 1809 Wilson Rd., Columbus, OH 43228.
ANDA 083001	Triamcinolone Acetonide Foam	Lederle Laboratories.
ANDA 084803	Chlorpromazine HCl Tablets, 10 mg	Do.
ANDA 087635	Butalbital; Aspirin; Phenacetin; Caffeine, Tablets	Do.
ANDA 090102	Ranitidine HCl Syrup, EQ 15 mg base/milliliters	Torrent Pharma Inc., 150 Allen Rd., Suite 102, Basking Ridge, NJ 07920.
ANDA 206736	Rifampin for Injection, 600 mg/vial	Watson Pharmaceuticals, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of June 11, 2021. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on June 11, 2021 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: May 5, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–09980 Filed 5–11–21; 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 via WebEx and teleconference; 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 via WebEx/teleconference. Individuals who wish to send in their written public comment 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 June 25, 2021. Additional information about registering for the meeting and providing public comment can be obtained at *http://www.hhs.gov/paccarb* on the Meetings page.

DATES: The meeting is scheduled to be held on June 29, 2021, from 10:00 a.m. to 3:00 p.m. and June 30, 2021, from 10:00 a.m. to 3:00 p.m. ET (times are tentative and 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 is strongly suggested and should be completed no later than June 25, 2021.

ADDRESSES: Instructions regarding attending this meeting virtually will be posted one week prior to the meeting at: *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 20024. Phone: 202–746–1512; Email: *CARB@hhs.gov.*

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 June 29–30, 2021, public meeting will be dedicated to the council's deliberation and vote on two reports to transmit to the Secretary of Health and Human Services, the first from the Disparities in Antibiotics Access and Use Working Group, and the second from the Working Group on Antimicrobial Resistance (AMR) in Inter-Professional Education. The remainder of the two-day public meeting will include an update on the status of the antibiotic development pipeline and an open council discussion on provocative questions in AMR (no recommendations will be made), in addition to presentations from subject matter experts on Operationalizing One Health and the Environmental Dimensions of AMR. 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.

Instructions regarding attending this meeting virtually will be posted one week prior to the meeting at: *http://www.hhs.gov/paccarb.*

Members of the public will have the opportunity to provide comments live during the meeting via conference line by pre-registering online at *http://www.hhs.gov/paccarb.* There will be two separate sessions available for public comment: An Innovation Spotlight will be held on June 29th where companies and/or organizations involved in combating antibiotic resistance have an opportunity to present their work to members of the Advisory Council; and on June 30th, where all members of the general public are welcome to provide oral comment during this separate session. Pre-registration is required for participation in these sessions with limited spots available. Further information about these two sessions can be found online at *http://www.hhs.gov/paccarb.* Written public comments can also be emailed to *CARB@hhs.gov* by midnight June 25, 2021 and should be limited to no more than one page. All public comments received prior to June 25, 2021, will be provided to Advisory Council members.

Dated: April 30, 2021.

Jomana F. Musmar,

Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health.

[FR Doc. 2021–10014 Filed 5–11–21; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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: National Institute of Mental Health Special Emphasis Panel; Pilot Effectiveness Trials for Treatment, Prevention, and Services Interventions (R34).

Date: June 8, 2021.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Serena Chu, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Blvd., Room 6000, MSC 9606, Bethesda, MD 20852, 301–500–5829, *serena.chu@nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Device Development.

Date: June 9, 2021.

Time: 11:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Nicholas Gaiano, Ph.D., Review Branch Chief, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center/Room 6150/MSC 9606, 6001 Executive Boulevard, Bethesda, MD 20892–9606, 301–443–2742, *nick.gaiano@nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Mood Disorders in People Living with HIV: Mechanisms and Pathways (R01 & R21).

Date: June 9, 2021.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9608, Bethesda, MD 20892–9608, 301–443–4525, *steinerr@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: May 7, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–10026 Filed 5–11–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Center for Advancing Translational Sciences Advisory Council.

The meeting will be open to the public as indicated below. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*). Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Center for Advancing Translational Sciences Advisory Council.

Date: June 10–11, 2021.

Closed: June 10, 2021, 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Room 987/987, Bethesda, MD 20892 (Virtual Meeting).

Open: June 10, 2021, 1:00 p.m. to 4:00 p.m.

Agenda: Report from the Institute Director and other staff.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Room 987/987, Bethesda, MD 20892 (Virtual Meeting).

Open: June 11, 2021, 1:00 p.m. to 5:00 p.m.

Agenda: To view and discuss Clearance of Concepts.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Room 987/987, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Room 1072, Bethesda, MD 20892, 301–435–0809, *anna.ramseyewing@nih.gov*.

Attendees and interested parties may submit questions and comments through written Q&A during the meeting, and for 15 days after the meeting, to *NCATSCouncilInput@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice no later than 15 days after the meeting. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: May 7, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–10021 Filed 5–11–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*).

Name of Committee: National Cancer Institute Clinical Trials and Translational Research Advisory Committee (CTAC) Ad hoc Translational Research Strategy Subcommittee.

Date: June 17, 2021.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: Group Discussion of Opportunities and Gaps in Translational Research.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Virtual Meeting).

Contact Person: Peter Ujhazy, M.D., Ph.D., Deputy Associate Director, Translational Research Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health, 9609 Medical Center Drive, Room 3W106, Rockville, MD 20850, 240–276–5681, *ujhazyp@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://deainfo.nci.nih.gov/advisory/ctac/subcommittees/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 7, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–10027 Filed 5–11–21; 8:45 am]

BILLING CODE 4140–01–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: Risk, Prevention and Health Behavior Integrated Review Group; Social Psychology, Personality and Interpersonal Processes Study Section.

Date: June 10–11, 2021.

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: Shalanda A. Bynum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, Bethesda, MD 20892, 301–755–4355, *bynumsa@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neuroimmunology and Brain Tumors.

Date: June 10, 2021.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Samuel C. Edwards, Ph.D., Chief, Brain Disorders and Clinical Neuroscience, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Neurodevelopment, Synaptic Plasticity and Neurodegeneration.

Date: June 14–15, 2021.

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: Tina Tze-Tsang Tang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Suite 3030, Bethesda, MD 20817, (301) 435–4436, *tangt@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Membrane Biology and Protein Processing.

Date: June 14, 2021.

Time: 10:00 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: Maqsood A. Wani, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2114, MSC 7814, Bethesda, MD 20892, 301–435–2270, *wanimaqs@csr.nih.gov*.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function B Study Section.

Date: June 15–16, 2021.

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: C–L Albert Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7806, Bethesda, MD 20892, 301–435–1016, *wangca@csr.nih.gov*.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Surgery, Anesthesiology and Trauma Study Section.

Date: June 15–16, 2021.

Time: 9:30 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: Weihua Luo, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892, (301) 435–1170, *luow@csr.nih.gov*.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Kidney and Urological Systems Function and Dysfunction Study Section.

Date: June 17–18, 2021.

Time: 8:00 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: Ganesan Ramesh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, 301–827–5467, *ganesan.ramesh@nih.gov*.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Imaging Technology Development Study Section.

Date: June 17–18, 2021.

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: Ileana Hancu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, Bethesda, MD 20817, 301–402–3911, *ileana.hancu@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Lifestyle Change and Behavioral Health.

Date: June 17, 2021.

Time: 9:30 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: Weijia Ni, Ph.D., MA, BA, Chief/Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3100, MSC 7808, Bethesda, MD 20892, (301) 594–3292, *niw@csr.nih.gov*.

Name of Committee: Infectious Diseases and Immunology B Integrated Review Group;

Hypersensitivity, Autoimmune, and Immune-mediated Diseases Study Section.

Date: June 17–18, 2021.

Time: 10:00 a.m. to 9:00 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: Deborah Hodge, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4207, MSC 7812, Bethesda, MD 20892, (301) 435–1238, *hodged@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 7, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–10020 Filed 5–11–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R5–ES–2020–0098; FXES11130500000–212–FF05E00000]

Endangered and Threatened Wildlife and Plants; Draft Recovery Plan for the Rufa Red Knot

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability and request for public comment.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the availability of the draft recovery plan for rufa red knot, a bird subspecies listed as threatened under the Endangered Species Act. We request review and comment on this draft recovery plan from local, State, and Federal agencies, and the public.

DATES: We must receive comments by July 12, 2021.

ADDRESSES:

Document availability: The draft recovery plan, along with any comments and other materials that we receive, will be available for public inspection at *http://www.regulations.gov* in Docket No. FWS–R5–ES–2020–0098.

Submitting Comments: You may submit comments by one of the following methods:

- *Internet: http://www.regulations.gov.* Search for and submit comments on Docket No. FWS–R5–ES–2020–0098.
- *U.S. Mail:* Public Comments Processing, Attn: Docket No. FWS–R5–ES–2020–0098; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

For more information, see Availability of Public Comments under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Eric Schrading, Field Supervisor by phone at 609–382–5272, via email at *eric_schrading@fws.gov,* or via the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), announce the availability of the draft recovery plan for the threatened rufa red knot (*Calidris canutus rufa*) for public review and comment. The draft recovery plan includes objective, measurable criteria and management actions as may be necessary for removal of the species from the Federal List of Endangered and Threatened Wildlife. We request review and comment on this draft recovery plan from local, State, and Federal agencies, and the public.

Recovery Planning

Section 4(f) of the Endangered Species Act of 1973, as amended (Act; 16 U.S.C. 1531 *et seq.*), requires the development of recovery plans for listed species, unless such a plan would not promote the conservation of a particular species. Also pursuant to section 4(f) of the Act, a recovery plan must, to the maximum extent practicable, include (1) a description of site-specific management actions as may be necessary to achieve the plan's goals for the conservation and survival of the species; (2) objective, measurable criteria that, when met, would support a determination under section 4(a)(1) that the species should be removed from the List of Endangered and Threatened Species; and (3) estimates of the time and costs required to carry out those measures needed to achieve the plan's goal.

Species Background

The rufa red knot is a medium-sized, highly migratory shorebird that ranges across nearly the full latitude gradient of the Western Hemisphere. This subspecies is among the longest-distance migrants in the animal kingdom, and among the best-studied shorebirds in the world. Rufa red knots migrate annually between their breeding grounds on the central Canadian arctic tundra and four wintering regions that include the Atlantic coasts of Argentina and Chile, the northern coast of South America, the western Gulf of Mexico, and the southeast United States and the Caribbean. During migration, rufa red knots require a reliable network of coastal and inland staging areas and an ample supply of other coastal and inland stopover habitats distributed across the range. In the final listing rule published on December 12, 2014 (79 FR 73705), the Service determined that the rufa red knot is threatened under the ESA due to the following primary threats: Loss of breeding and nonbreeding habitat (including sea level rise, coastal engineering, coastal development, and arctic ecosystem change); likely effects related to disruption of natural predator cycles on the breeding grounds; reduced prey availability throughout the nonbreeding range; and increasing frequency and severity of asynchronies (mismatches) in the timing of the birds' annual migratory cycle relative to favorable food and weather conditions. Refer to the Species Status Assessment Report (USFWS 2020) for a full discussion of the species' biology and threats.

Recovery Strategy

The recovery strategy is to prevent loss of the rufa red knot's adaptive capacity by maintaining representation within and among four Recovery Units, and improving their resiliency and redundancy. Recovery efforts will focus on protecting, restoring, maintaining, and managing important nonbreeding habitats for adults and juveniles. Recovery actions will directly abate threats to red knots in their wintering and migration ranges, and will also increase resiliency of populations to withstand threats that stem from climate change in their Arctic breeding range and elsewhere. These actions include monitoring and safeguarding ample food supplies; preventing impacts from development and shoreline stabilization; managing human disturbance; and restoring key habitats. They may also include land acquisition, facilitated migration of certain beaches or tidal flats, and restoring natural coastal processes that create and maintain red knot habitat.

Availability of Public Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

The authority for this action is section 4(f) of the Endangered Species Act, 16 U.S.C. 1533(f).

Sharon Marino,

Assistant Regional Director, Ecological Services, North Atlantic—Appalachian Region.

[FR Doc. 2021–10064 Filed 5–11–21; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2020–N110; FXES11140800000–201–FF08EVEN00]

Endangered and Threatened Wildlife and Plants; Draft Habitat Conservation Plan and Draft Categorical Exclusion for the Santa Barbara County Distinct Population Segment of the California Tiger Salamander; Orcutt Hill Resource and Solar Project, Pacific Coast Energy Company, Santa Barbara County, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of a draft habitat conservation plan (HCP) and draft categorical exclusion (CatEx) for activities described in an application for an incidental take permit (ITP) under the Endangered Species Act of 1973, as amended. The ITP would authorize take of the Santa Barbara County distinct population segment of the California tiger salamander incidental to activities associated with oil production facilities and a solar photovoltaic system near the city of Orcutt in Santa Barbara County, California. The applicant developed the draft HCP as part of their application for an ITP. The Service prepared a draft CatEx in accordance with the National Environmental Policy Act to evaluate the potential effects to the natural and human environment resulting from issuing an ITP to the applicant. We invite public comment on these documents.

DATES: Written comments should be received on or before June 11, 2021.

ADDRESSES:

Obtaining Documents: You may download a copy of the draft HCP and draft CatEx at *http://www.fws.gov/ventura/,* or you may request copies of the documents by U.S. mail (below) or by email (see **FOR FURTHER INFORMATION CONTACT**).

Submitting Written Comments: Please send us your written comments using one of the following methods:

- *U.S. mail:* Stephen P. Henry, Field Supervisor, Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA 93003.
- *Email: rachel_henry@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Rachel Henry, Fish and Wildlife Biologist, by email, via the Federal Relay Service at 1–800–877–8339 for TTY assistance, or by mail at the Ventura address (see **ADDRESSES**).

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), announce the availability of a draft habitat conservation plan (HCP) and draft categorical exclusion (CatEx) with an application for an incidental take permit (ITP) by Pacific Coast Energy Company, LLC (applicant). The ITP would authorize take of the federally endangered Santa Barbara County distinct population segment (DPS) of the California tiger salamander (*Ambystoma californiense*) incidental to activities described in the HCP for activities associated with the operation and maintenance of existing ongoing oil production facilities and operations; the maintenance and management of 101 seep cans; the installation, maintenance, and management of future seep cans; and the installation, operation, and maintenance of a solar photovoltaic system near the City of Orcutt in Santa Barbara County, California. The applicant developed a draft HCP as part of the application for an ITP under section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The Service prepared a draft CatEx in accordance with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) to evaluate the potential effects to the natural and human environment resulting from issuing an ITP to the applicant. We invite public comment on these documents.

Background

The Service listed the Santa Barbara County DPS of the California tiger salamander as endangered on September 21, 2000 (65 FR 57242). Section 9 of the ESA prohibits take of fish and wildlife species listed as endangered (16 U.S.C. 1538). Under the ESA, ''take'' is defined to include the following activities: ''to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct'' (16 U.S.C. 1532). Under section 10(a)(1)(B) of the ESA (16 U.S.C. 1539(a)(1)(B)), we may issue permits to authorize take of listed fish and wildlife species that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Regulations governing incidental take permits for endangered species are in the Code of Federal Regulations (CFR) at 50 CFR 17.22. Issuance of an ITP also must not jeopardize the existence of federally listed fish, wildlife, or plant species, pursuant to section 7 of the ESA and 50 CFR 402.02. The permittee would receive assurances under our ''No Surprises'' regulations (50 CFR 17.22(b)(5)).

Proposed Activities

The applicant has applied for a permit for incidental take of the Santa Barbara County DPS of the California tiger salamander. The take would occur in association with the operation and maintenance of existing ongoing oil production facilities and installation, operation, and maintenance of a solar photovoltaic system.

The HCP includes avoidance and minimization measures for the Santa Barbara County DPS of the California tiger salamander and mitigation for unavoidable loss of habitat. As mitigation for habitat loss, the applicant proposes to establish a conservation easement within an area that is known to support the Santa Barbara County DPS of the California tiger salamander or purchase credits from a Service-approved mitigation bank.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public view, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.22) and NEPA (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1506.6).

Stephen Henry,

Field Supervisor, Ventura Fish and Wildlife Office, Ventura, California.

[FR Doc. 2021–10045 Filed 5–11–21; 8:45 am]

BILLING CODE 4333–15–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–585]

Foreign Censorship Part 1: Policies and Practices Affecting U.S. Businesses and Investigation No. 332–586: Foreign Censorship Part 2: Trade and Economic Effects on U.S. Businesses

AGENCY: United States International Trade Commission.

ACTION: Change in title, scope, and schedule of Investigation No. 332–585 and institution of Investigation No. 332–586 to address trade and economic effects of foreign censorship on U.S. businesses.

SUMMARY: Following receipt of a letter from the U.S. Senate Committee on Finance (Committee) on April 8, 2021, under section 332(g) of the Tariff Act of 1930, the Commission has changed the title, scope, and schedule, including the hearing date, for Investigation No. 332–585, with the investigation to be retitled *Foreign Censorship Part 1: Policies and Practices Affecting U.S. Businesses.* The Commission has also instituted a second Investigation in response to the letter, Investigation No. 332–586, *Foreign Censorship Part 2: Trade and Economic Effects on U.S. Businesses.* The public hearing has been rescheduled to July 1, 2021 and will be in conjunction with both investigations. The hearing will be conducted via an online videoconferencing platform. Dates relating to written submissions have been adjusted accordingly.

DATES:

June 17, 2021: Deadline for filing requests to appear at the public hearing.

June 18, 2021: Deadline for filing prehearing briefs and statements.

June 24, 2021: Deadline for filing electronic copies of oral hearing statements.

July 1, 2021: Public hearing.

July 12, 2021: Deadline for filing posthearing briefs and statements.

July 22, 2021: Deadline for filing all other written submissions for Investigation No. 332–585.

December 30, 2021: Transmittal of Commission's Part 1 report to the Committee.

January 14, 2022: Deadline for filing all other written submissions for Investigation No. 332–586.

July 5, 2022: Transmittal of Commission's Part 2 report to the Committee.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC. All written submissions should be submitted electronically and addressed to the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Project Leader Isaac Wohl (202–205–3356 or *isaac.wohl@usitc.gov*), or Deputy Project Leader Jean Yuan (202–205–2383 or *wen.yuan@usitc.gov*) for information specific to Investigation No. 332–585. Project Leader Ricky Ubee (202–205–3493 or *ravinder.ubee@usitc.gov*), Deputy Project Leader Shova KC (202–205–2234 or *shova.kc@usitc.gov*), or Deputy Project Leader George Serletis (202–205–3315 or *george.serletis@usitc.gov*) for information specific to Investigation No. 332–586. For information on the legal aspects of these investigations, contact William Gearhart of the Commission's Office of the General Counsel (202–205–3091 or *william.gearhart@usitc.gov*). The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819 or *margaret.olaughlin@usitc.gov*). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its website (*https://www.usitc.gov*).

SUPPLEMENTARY INFORMATION: The Committee's new letter received on April 8, 2021 modified its earlier letter of January 4, 2021 in three principal ways: (1) It calls for two reports instead of one, with the first report to focus on policies and practices affecting U.S. businesses, and a second to focus on trade and economic effects on U.S. businesses, based in part on a Commission survey; (2) it defines the scope of the investigations by indicating which elements of the original request letter should be addressed in the first and second reports, respectively; and (3) it provides a new delivery date for the first report (December 30, 2021) and sets a later delivery date for the second report (July 5, 2022). As in the January 4, 2021, letter, the Committee requested the investigations and reports pursuant to section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)). The Commission published the initial notice of Investigation No. 332–585 in the **Federal Register** of January 29, 2021 (86 FR 7559).

As in the original letter, the Committee defined censorship as ''the prohibition or suppression of speech or other forms of communication,'' and stated that foreign governments use many tools to carry out censorship, including technological measures that restrict digital trade. The Committee said that these tools, and the policies that enable them, allow authorities in foreign markets to limit speech by controlling the flow of information and services.

In response to the Committee's letter received on April 8, 2021, the Commission has changed the title of the report in Investigation No. 332–585, to *Foreign Censorship Part 1: Policies and Practices Affecting U.S. Businesses,* and it has changed the delivery date for this first report to December 30, 2021. The first report will contain detailed information on the following:

1. Identification and descriptions of various foreign censorship practices, in particular any examples that U.S. businesses consider to impede trade or investment in key foreign markets. The description should include to the extent practicable:

a. The evolution of censorship policies and practices over the past 5 years in key foreign markets;

b. any elements that entail extraterritorial censorship; and

c. the roles of governmental and non-governmental actors in implementation and enforcement of the practices.

In response to the request for the second report, the Commission has instituted Investigation No. 332–586, *Foreign Censorship Part 2: Trade and Economic Effects on U.S. Businesses.* The Commission will deliver the second report by July 5, 2022. The second report will provide:

2. To the extent practicable, including through the use of survey data, an analysis of the trade and economic effects of such policies and practices on affected businesses in the United States and their global operations. The analysis should include to the extent practicable, quantitative and qualitative impacts of the identified policies, including by reference, where identifiable, to:

a. Impact on employment;

b. direct costs (*e.g.,* compliance and entry costs);

c. foregone revenue and sales;

d. self-censorship; and

e. other effects the Commission considers relevant for the Committee to know.

In view of the fact the Committee intends to make these reports available to the public in their entirety, the Commission will not include any confidential business information in its reports.

Public Hearing: A public hearing in connection with both investigations will be held via an online videoconferencing platform, beginning at 9:30 a.m. on July 1, 2021. This hearing replaces the previously announced hearing in connection with Investigation No. 332–585, scheduled for September 14, 2021. Information about how to participate in or view the hearing will be posted on the Commission's website at (*https://usitc.gov/research_and_analysis/what_we_are_working_on.htm*). Once on that web page, scroll down to either entry for Investigation No. 332–585, *Foreign Censorship Part 1: Policies and Practices Affecting U.S. Businesses* or Investigation No. 332–586, *Foreign Censorship Part 2: Trade and Economic Effects on U.S. Businesses* and click on the link to ''Hearing Instructions.'' Interested parties should check the Commission's website periodically for updates.

Requests to appear at the public hearing should be filed electronically with the Secretary no later than 5:15 p.m., June 17, 2021, in accordance with the requirements in the ''Written Submissions'' section below. All prehearing briefs and statements should be filed electronically not later than 5:15 p.m., June 18, 2021. To facilitate the hearing, including the preparation of an accurate written transcript of the hearing, oral testimony to be presented at the hearing must be submitted to the Commission electronically no later than noon, June 24, 2021. All posthearing briefs and statements should be filed electronically not later than 5:15 p.m., July 12, 2021. Posthearing briefs and statements should address matters raised at the hearing. For a description of the different types of written briefs and statements, see the ''Definitions'' section below.

In the event that, as of the close of business on June 17, 2021, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or nonparticipant should contact the Office of the Secretary at 202–205–2000 after June 17, 2021, for information concerning whether the hearing will be held.

Written Submissions: In lieu of or in addition to participating in the hearing, interested parties are invited to file, electronically, written submissions concerning these investigations. All written submissions should be addressed to the Secretary. Written submissions specific to Investigation No. 332–585, *Foreign Censorship Part 1: Policies and Practices Affecting U.S. Businesses,* should be received not later than 5:15 p.m., July 22, 2021. Written submissions specific to Investigation No. 332–586, *Foreign Censorship Part 2: Trade and Economic Effects on U.S. Businesses,* should be received not later than 5:15 p.m., January 14, 2022. All written submissions must conform to the provisions of section 201.8 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.8), as temporarily amended by 85 FR 15798 (March 19, 2020). Under that rule waiver, the Office of the Secretary will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding electronic filing should contact the Office of the Secretary, Docket Services Division (202–205–1802), or consult the Commission's Handbook on Filing Procedures.

Definitions of Types of Documents That May Be Filed; Requirements: In addition to requests to appear at the hearing, this notice provides for the possible filing of four types of documents: Prehearing briefs, oral hearing statements, posthearing briefs, and other written submissions.

(1) *Prehearing briefs* refers to written materials relevant to the investigation and submitted in advance of the hearing, and includes written views on matters that are the subject of the investigation, supporting materials, and any other written materials that you consider will help the Commission in understanding your views. You should file a prehearing brief particularly if you plan to testify at the hearing on behalf of an industry group, company, or other organization, and wish to provide detailed views or information that will support or supplement your testimony.

(2) *Oral hearing statements (testimony)* refers to the actual oral statement that you intend to present at the public hearing. *Do not* include any confidential business information in that statement. If you plan to testify, you must file a copy of your oral statement by the date specified in this notice. This statement will allow Commissioners to understand your position in advance of the hearing and will also assist the court reporter in preparing an accurate transcript of the hearing (*e.g.,* names spelled correctly).

(3) *Posthearing briefs* refers to submissions filed after the hearing by persons who appeared at the hearing. Such briefs: (a) Should be limited to matters that arose during the hearing, (b) should respond to any Commissioner and staff questions addressed to you at the hearing, (c) should clarify, amplify, or correct any statements you made at the hearing, and (d) may, at your option, address or rebut statements made by other participants in the hearing.

(4) *Other written submissions* refers to any other written submissions that interested persons wish to make, regardless of whether they appeared at the hearing, and may include new information or updates of information previously provided.

There is no standard format that briefs or other written submissions must follow. However, each such document must identify on its cover (1) the investigation number and title and the type of document filed (*i.e.,* prehearing brief, oral statement of (name), posthearing brief, or written submission), (2) the name of the person or organization filing it, and (3) whether it contains confidential business information (CBI). If it contains CBI, it must comply with the marking and other requirements set out below in this notice relating to CBI. Submitters of written documents (other than oral hearing statements) are encouraged to include a short summary of their position or interest at the beginning of the document, and a table of contents when the document addresses multiple issues.

Confidential Business Information: Any submissions that contain confidential business information must also conform to the requirements of section 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the ''confidential'' or ''non-confidential'' version, and that the confidential business information is clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties.

As requested by the Committee on Finance, the Commission will not include any confidential business information in its report. However, all information, including confidential business information, submitted in this investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government

employees and contract personnel for cybersecurity purposes. The Commission will not otherwise disclose any confidential business information in a way that would reveal the operations of the firm supplying the information.

Summaries of Written Submissions: Persons wishing to have a summary of their position included in the first report should include a summary with their written submission on or before July 22, 2021 and should mark the summary as having been provided for that purpose. The summary should be clearly marked as ''summary for inclusion in the part 1 report'' at the top of the page. Persons wishing to have a summary of their position included in the second report should include a summary with their written submission on or before January 14, 2022 and should mark the summary as having been provided for that purpose. The summary should be clearly marked as ''summary for inclusion in the part 2 report'' at the top of the page.

The summary may not exceed 500 words, should be in MS Word format or a format that can be easily converted to MS Word, and should not include any confidential business information. The summary will be published as provided if it meets these requirements and is germane to the subject matter of the investigation. The Commission will list the name of the organization furnishing the summary and will include a link to the Commission's Electronic Document Information System (EDIS) where the written submission can be found.

By order of the Commission.

Issued: May 6, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–09991 Filed 5–11–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Electrolyte Containing Beverages and Labeling and Packaging Thereof, DN 3547*; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov*. For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of CAB Enterprises, Inc. and Sueros y Bebidas Rehidratantes S.A. de C.V. on May 6, 2021. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain electrolyte containing beverages and labeling and packaging thereof. The complainant names as respondents: Flexicompuestos S.A. de C.V. of Mexico; Grupo Comercial Lux del Norte S.A. de C.V. of Mexico; Carbonera Los Asadores S.A. de C.V. of Mexico; Caribe Agencia Express, S.A. de C.V. of Mexico; Comercializadora Degu S.A. de C.V. of Mexico; Comercial Treviño de Reynosa, S.A. de C.V. of Mexico; H & F Tech International S.A. de C.V. of Mexico; MPC Foods S.A. de C.V. of Mexico; Myrna Guadalupe Perez Martinez of Mexico; Leticia Angélica Saenz Fernandez of Mexico; Yoselen Susana Martinez Tirado of Mexico; Distribuidora Mercatto S.A. de C.V. of Mexico; Comercializadora Embers S.A. de C.V. of Mexico; and Manuel Bautista Nogales of Mexico. The complainant requests that the Commission issue a general exclusion order, cease and desist orders, and impose a bond upon respondent alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer

to the docket number (''Docket No. 3547'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*.) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel [2], solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: May 7, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–10003 Filed 5–11–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–753, 754, and 756 (Fourth Review)]

Cut-to-Length Carbon Steel Plate From China, Russia, and Ukraine; Scheduling of Expedited Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty order on cut-to-length carbon steel plate from China and the termination of the suspended investigations on cut-to-length carbon steel plate from Russia and Ukraine would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: February 5, 2021.

FOR FURTHER INFORMATION CONTACT: Celia Feldpausch (202–205–2387), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*.

SUPPLEMENTARY INFORMATION:

Background.—On February 5, 2021, the Commission determined that the domestic interested party group response to its notice of institution (85 FR 69362, November 2, 2020) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.[1] Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Staff report.—A staff report containing information concerning the subject matter of the reviews will be placed in the nonpublic record on May 13, 2021, and made available to persons on the Administrative Protective Order service list for these reviews. A public version will be issued thereafter, pursuant to § 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in § 207.62(d) of the Commission's rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,[2] and any party other than an interested party to the reviews may file written comments with the Secretary on what determination the Commission should reach in the reviews. Comments are due on or before May 20, 2021 and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by May 20, 2021. However, should the Department of Commerce (''Commerce'') extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov*.

[1] A record of the Commissioners' votes is available from the Office of the Secretary and at the Commission's website.

[2] The Commission has found a joint response to its notice of institution filed on behalf of ArcelorMittal USA LLC, Nucor Corporation, and SSAB Enterprises, LLC, domestic producers of cut-to-length carbon steel plate, to each be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: May 7, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–10004 Filed 5–11–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1145 (Bond Return)]

Certain Botulinum Toxin Products, Processes for Manufacturing or Relating to Same and Certain Products Containing Same; Notice of Commission Decision Not To Review an Initial Determination Granting an Unopposed Motion for Return of Bond; Return of Bond

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') of the presiding Administrative Law Judge (''ALJ'') granting an unopposed motion of respondent Evolus, Inc. (''Evolus'') for the return of the bond it paid under the cease and desist order (''CDO'') during the period of Presidential review. The bond is returned to Evolus.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–4716. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On March 6, 2019, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based on a complaint filed by Medytox Inc. (''Medytox'') of Seoul, South Korea; Allergan plc of Dublin, Ireland; and Allergan, Inc. of Irvine, California (collectively, ''Complainants''). *See* 84 FR 8112–13 (Mar. 6, 2019). The complaint, as supplemented, alleges a violation of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain botulinum toxin products, processes for manufacturing or relating to same and certain products containing same by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure a domestic industry in the United States. *See id.* The notice of investigation names as respondents Daewoong Pharmaceuticals Co., Ltd. (''Daewoong'') of Seoul, Republic of Korea and Evolus of Irvine, California (collectively, ''Respondents''). *See id.* The Office of Unfair Import Investigations (''OUII'') was also a party to the investigation. *See id.*

On July 6, 2020, the ALJ issued a final initial determination (''FID'') finding a violation of section 337 based on the misappropriation of Complainants' asserted trade secrets (including the Medytox bacterial strain and Medytox manufacturing processes), the threat or effect of which is to destroy or substantially injure an industry in the United States. On September 21, 2020, the Commission issued a notice determining to review the FID in part. *See* 85 FR 60489–90 (Sept. 25, 2020).

On December 16, 2020, the Commission found a violation of section 337 based on the misappropriation of Complainants' trade secrets (including the Medytox manufacturing processes but not the Medytox bacterial strain). *See* 85 FR 83610–11 (Dec. 22, 2020). The Commission issued a limited exclusion order against certain botulinum neurotoxin products that are imported and/or sold by Respondents Daewoong and Evolus and a CDO against Evolus. *See id.* The Commission also set a bond during the period of Presidential review in an amount of $441 per 100U vial of Respondents' accused products. *See id.*

On February 12, 2021, Complainants filed an appeal from the Commission's final determination with the Federal Circuit. On the same day, Respondents also filed an appeal from the Commission's final determination of a violation of section 337. On February 18, 2021, Complainants and Evolus (''Settling Parties'') announced that they reached a settlement agreement to resolve all pending issues between them.

On March 3, 2021, the Settling Parties filed a joint petition to rescind the LEO and CDO based on the settlement agreements between Complainants and Evolus. No party opposed the joint petition. On May 3, 2021, the Commission rescinded the remedial orders issued in this investigation based on the settlement agreements. Comm'n Notice (May 3, 2021).

On February 25, 2021, Evolus filed an unopposed motion, pursuant to Commission Rule 210.50(d) (19 CFR 210.50(d)), for the return of the bond it paid under the CDO during the period of Presidential review. On February 26, 2021, the motion was amended to reflect Daewoong's consent to the motion. On March 4, 2021, OUII filed a response in support of the motion.

On March 31, 2021, the ALJ issued the subject ID granting the motion. The ID notes that the motion was filed within 90 days of the expiration of the period of Presidential review, in compliance with Commission Rule 210.50(d)(1)(ii) (19 CFR 210.50(d)(1)(ii)). *See* ID at 2. The ID also finds no substantive or procedural reason to deny the return of the bond to Evolus. *See id.* No petition for review of the subject ID was filed.

The Commission has determined not to review the subject ID. The bond is returned to Evolus.

The Commission's vote on this determination took place on May 6, 2021.

The authority for the Commission's determination is contained in section

337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: May 6, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–09990 Filed 5–11–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1178]

Certain Collapsible and Portable Furniture; Notice of a Commission Determination To Review in Part a Final Initial Determination and To Affirm With Modifications the Finding of No Violation of Section 337; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined to review in part the Administrative Law Judge's (''ALJ'') final initial determination (''FID''), issued on February 18, 2021, and to affirm with modifications the FID's finding of no violation of section 337 in the above-referenced investigation. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Benjamin S. Richards, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–5453. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on October 3, 2019. 84 FR 52896 (Oct. 3, 2019). The complaint, as amended, filed by GCI Outdoor, Inc., of Higganum, Connecticut (''GCI''), alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain collapsible and portable furniture by reason of infringement of certain claims of U.S. Patent No. 9,282,824 (''the '824 patent'') and U.S. Patent No. 9,060,611 (''the '611 patent''). *Id.* at 52896–97. The complaint further alleges that a domestic industry exists. *Id.* at 52897. The Commission's notice of investigation named the following respondents: Denovo Brands, LLC of Bentonville, Akansas; Zhenli (Zhangzhou) Industrial Co., Ltd. of Zhangzhou, Fujian, China; Fujian Zenithen Consumer Products Co., Ltd. of Fuzhou, Fujian, China; Zenithen Hong Kong Ltd. of Hong Kong; Zenithen USA LLC of Upland, California; Westfield Outdoor, Inc., d/b/a Westfield Outdoors of Indianapolis, Indiana; MacSports Inc. of La Verne, California; Meike (Qingdao) Leisure Products Co., Ltd of Qing Dao, China. *Id.* The Office of Unfair Import Investigations is not participating in the investigation. *Id.*

During the course of the investigation, respondents Fujian Zenithen Consumer Products Co., Ltd., Zenithen Hong Kong Ltd., and Zenithen USA LLC were terminated from the investigation. The remaining respondents are Denovo Brands, LLC and Zhenli (Zhangzhou) Industrial Co., Ltd. (the ''Denovo'' respondents); Westfield Outdoor, Inc. (''Westfield''); and MacSports Inc. and Meike (Qingdao) Leisure Products Co., Ltd (the ''MacSports'' respondents) (collectively, ''Respondents'').

On February 18, 2021, the ALJ issued his FID in this investigation. The FID found no violation of section 337. For the '824 patent, the FID found that GCI established infringement by Denovo's products but failed to establish that GCI satisfied the technical prong of the domestic industry requirement. The FID also found that Denovo did not establish that any of the asserted claims of the '824 patent is invalid. For the '611 patent, the FID found that GCI failed to establish infringement by Westfield's and MacSports' products but did establish that GCI satisfied the technical prong of the domestic industry requirement. The FID also found that Westfield and MacSports did not establish that any of the asserted claims of the '611 patent is invalid. The FID additionally found that GCI established that it satisfied the economic prong of the domestic industry requirement for both asserted patents.

On March 2, 2021 the parties submitted petitions seeking review of the FID. On March 10, 2021, the parties submitted responses to the others' petitions.

Having examined the record of this investigation, including the FID, the petitions for review, and the responses thereto, the Commission has determined to review the FID with respect to (1) all of the FID's findings concerning the '824 patent; (2) infringement and validity of the '611 patent; and (3) the FID's findings concerning the economic prong of the domestic industry requirement. The Commission has determined not to review the remainder of the FID.

On review, the Commission has determined to affirm the FID's finding of no violation of section 337 with regard to the '824 patent and the '611 patent. In connection with that determination the Commission has also determined to modify and supplement certain of the FID's subsidiary findings. The Commission has also determined to take no position on certain portions of the FID. The Commission opinion is issued concurrently herewith.

The investigation is hereby terminated.

The Commission vote for this determination took place on May 6, 2021.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: May 6, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–09989 Filed 5–11–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0072]

Agency Information Collection Activities; Proposed eCollection of eComments Requested; Revision of a Currently Approved Collection; Explosives Employee Possessor Questionnaire—ATF Form 5400.28

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Department of Justice (DOJ), will submit 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. The proposed collection OMB 1140–0072 (Explosives Employee Possessor Questionnaire—ATF Form 5400.28) is being revised to include additional questions, and a new format and layout to improve user experience. This collection is also being published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for 60 days until July 12, 2021.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact: Shawn Stevens, Federal Explosives Licensing Center either by mail at 44 Needy Road, Martinsburg, WV 25405, by email at *Shawn.Stevens@atf.gov,* or by telephone at 304–616–4400.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the 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;

—Evaluate whether and if so, how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection (check justification or form 83):* Revision of a currently approved collection.

2. *The Title of the Form/Collection:* Explosives Employee Possessor Questionnaire.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): ATF Form 5400.28.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individuals or households.

Other (if applicable): Business or other for-profit.

Abstract: The Explosives Employee Possessor Questionnaire—ATF Form 5400.28 will be used to determine if an individual is qualified to serve as an employee possessor, who can ship, transport, receive, and/or possess materials for an explosives business or operation.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 10,000 respondents will use the form annually, and it will take each respondent approximately 20 minutes to complete their responses.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 3,334 hours, which is equal to 10,000 (# of respondents) * .3333 (20 minutes).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: May 7, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–10005 Filed 5–11–21; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–826]

Bulk Manufacturer of Controlled Substances Application: Patheon API Manufacturing, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Patheon API Manufacturing, Inc., has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before July 12, 2021. Such persons may also file a written request for a hearing on the application on or before July 12, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on March 18, 2021, Patheon API Manufacturing, Inc., 309 Delaware Street, Greenville, South Carolina 29605–5420, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid	2010	I
Tetrahydrocannabinols	7370	I
5-Methoxy-N-N-Dimethyltryptamine	7431	I
a-Methyltryptamine	7432	I
Psilocybin	7437	I
Thebaine	9333	II
Oxymorphone	9652	II
Noroxymorphone	9668	II

The company plans to bulk manufacture the listed controlled substances as an Active Pharmaceutical Ingredient (API) for distribution to its customers. In reference to dug code 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture this drug as synthetic. No other activities for these drug codes are authorized for this registration.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2021–09988 Filed 5–11–21; 8:45 am]

BILLING CODE P

OFFICE OF MANAGEMENT AND BUDGET

Designation of Databases for Treasury's Working System Under the Do Not Pay Initiative

AGENCY: Office of Management and Budget.

ACTION: Notice of designation.

SUMMARY: The Payment Integrity Information Act of 2019 (PIIA) authorizes the Office of Management and Budget (OMB) to designate databases for inclusion in Treasury's Working System under the Do Not Pay (DNP) Initiative. PIIA further requires OMB to provide public notice and opportunity for comment prior to designating additional databases. In fulfillment of this requirement, on January 22, 2021, OMB published a Notice of Proposed Designation for 12 additional databases. OMB received one comment during the 30-day comment period for this notice; however, the suggestions found therein did not preclude further action for the formal designation of the databases into Treasury's Working System. Effective immediately, OMB designates the following 12 databases: The United States Postal Service (USPS) Delivery Sequence File, the Census Bureau Federal Audit Clearinghouse, the Do Not Pay (DNP) Agency Adjudication Data, Fiscal Service's Payments, Claims, and Enhanced Reconciliation (PACER) database, Bureau of Prisons (BOP) Incarceration Data, Digital Accountability and Transparency Act (DATA Act) data, Census Bureau's American Communities Survey (ACS) Annual State and County Data Profiles, Veterans Affairs' (VA) Beneficiary Identification Records Locator Service (BIRLS), Department of Agriculture's National Disqualified List (NDL), Center for Medicare and Medicaid Services (CMS) National Plan and Provider Enumeration System (NPPES), Internal Revenue Service's (IRS) Statistics of Income (SOI) Annual Individual Income Tax ZIP Code Data, and the U.S. Securities and Exchange Commission's (SEC) Electronic Data Gathering, Analysis, and Retrieval (EDGAR) System.

FOR FURTHER INFORMATION CONTACT: Regina Kearney at the OMB Office of Federal Financial Management at (202) 395–3993.

Shalanda Young,

Acting Director.

[FR Doc. 2021–10025 Filed 5–11–21; 8:45 am]

BILLING CODE 3110–01–P

NATIONAL SCIENCE FOUNDATION

Committee on Equal Opportunities in Science and Engineering; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Committee on Equal Opportunities in Science and Engineering (CEOSE) Virtual Meeting (1173).

Date and Time: June 10, 2021; 1:00 p.m.–5:30 p.m.; June 11, 2021; 10:00 a.m.–3:30 p.m.

Place: National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314 (Virtual). Meeting Registration: Virtual attendance information will be forthcoming on the CEOSE website at *http://www.nsf.gov/od/oia/activities/ceose/index.jsp.*

Type of Meeting: Open.

Contact Person: Dr. Bernice Anderson, Senior Advisor and CEOSE Executive Secretary, Office of Integrative Activities (OIA), National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314. Contact Information: 703–292–8040/*banderso@nsf.gov.*

Minutes: Meeting minutes and other information may be obtained from the CEOSE Executive Secretary at the above address or the website at *http://www.nsf.gov/od/oia/activities/ceose/index.jsp.*

Purpose of Meeting: To study data, programs, policies, and other information pertinent to the National Science Foundation and to provide advice and recommendations concerning broadening participation in science and engineering.

Agenda

Day 1: June 10, 2021

- Welcome, Introductions, Opening Remarks
- Report of the CEOSE Executive Liaison
- Presentation: Missing Millions and NSF Efforts
- Joint Session with NSB [Focus on STEM Technical Careers]
- Discussion with NSF Director and Chief Operating Officer
- CEOSE Liaison Reports
- Working Session: DCL and Flyer for the 2019–2020 CEOSE Report

Day 2: June 11, 2021

- Welcome and Remarks about Subcommittee: The Future of EPSCoR
- BP Accountability Data
- Presentation: Broadening Participation Research
- Reports of the Federal Liaisons
- Presentation: NSF's Racial Equity Task Force
- Reports of the CEOSE Liaisons
- Announcements, Closing Remarks, and Adjournment

Dated: May 7, 2021.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2021–10033 Filed 5–11–21; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of May 17, 24, 31, June 7, 14, 21, 2021.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

MATTERS TO BE CONSIDERED:

Week of May 17, 2021

Monday, May 17, 2021

3:00 p.m.—Affirmation Session (Public Meeting) (Tentative), Direct Final Rule: Advanced Boiling Water Reactor Design Certification Renewal (RIN 3150–AK04; NRC–2017–0090) (Tentative) (Contact: Wesley Held: 301–287–3591)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live; via teleconference. Details for joining the teleconference in listen only mode may be found at *https://www.nrc.gov/pmns/mtg.*

Week of May 24, 2021—Tentative

Tuesday, May 25, 2021

9:00 a.m.—Strategic Programmatic Overview of the Fuel Facilities and the Spent Fuel Storage and Transportation Business Lines (Public Meeting) (Contact: Damaris Marcano: 301–415–7328)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/.*

Week of May 31, 2021—Tentative

There are no meetings scheduled for the week of May 31, 2021.

Week of June 7, 2021—Tentative

Tuesday, June 8, 2021

10:00 a.m.—Briefing on Human Capital and Equal Employment Opportunity (Public Meeting) (Contact: Anne DeFrancisco: 610–337–5078)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/.*

Thursday, June 10, 2021

10:00 a.m.—Briefing on Results of the Agency Action Review Meeting (Public Meeting) (Contact: Nicole Fields: 630–829–9570)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/.*

Week of June 14, 2021—Tentative

There are no meetings scheduled for the week of June 14, 2021.

Week of June 21, 2021—Tentative

Tuesday, June 22, 2021

9:00 a.m.—Briefing on Transformation at the NRC—Midyear Review (Public Meeting) (Contact: Maria Arribas-Colon: 301–415–6026)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/.*

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 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.*

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.

Members of the public may request to receive this information 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 *Tyesha.Bush@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 10, 2021.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2021–10136 Filed 5–10–21; 4:15 pm]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2021–88 and CP2021–91]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 14, 2021.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2021–88 and CP2021–91; Filing Title: USPS Request

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

to Add Priority Mail Contract 698 to Competitive Product List and Notice of Filing Materials Under Seal; Filing Acceptance Date: May 6, 2021; Filing Authority: 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; Public Representative: Kenneth R. Moeller; Comments Due: May 14, 2021.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2021–10001 Filed 5–11–21; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91771; File No. SR–NYSEArca–2021–31]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of a Proposed Rule Change To List and Trade Shares of the Valkyrie Bitcoin Fund Under NYSE Arca Rule 8.201–E

May 6, 2021.

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 April 23, 2021, NYSE Arca, Inc. (''NYSE Arca'' 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 list and trade the shares of the Valkyrie Bitcoin Fund under NYSE Arca Rule 8.201–E. The proposed 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 to list and trade shares (''Shares'') of the Valkyrie Bitcoin Fund (the ''Trust'') under NYSE Arca Rule 8.201–E, which governs the listing and trading of Commodity-Based Trust Shares.

Description of the Trust

The Shares will be issued by the Trust, a Delaware statutory trust. The Trust will operate pursuant to a trust agreement (the ''Trust Agreement'') between Valkyrie Digital Assets LLC (the ''Sponsor'') and Delaware Trust Company, as the Trust's trustee (the ''Trustee''). The Shares will be registered with the Commission by means of the Trust's registrations statement on Form S–1 (the ''Registration Statement'').[4] Pursuant to the Trust Agreement, the Sponsor has entered into a custodian agreement (the ''Custodian Agreement'') with Coinbase Custody Trust Company, LLC (the ''Custodian'') to act as custodian for the Trust's bitcoins. Pursuant to the Custodian Agreement, the Custodian will establish accounts that hold the bitcoins deposited with the Custodian on behalf of the Trust. U.S. Bancorp Fund Services, LLC will act as the transfer agent for the Trust (the ''Transfer Agent'') and as the administrator of the Trust (the ''Administrator'') to perform various administrative, accounting and recordkeeping functions on behalf of the Trust.

Description of the Trust

According to the Registration Statement, the investment objective of the Trust is for the Shares to reflect the performance of the value of a bitcoin as represented by the CF Bitcoin US Settlement Price (the ''Index''), less the Trust's liabilities and expenses. The purpose of the Trust is to provide investors with a cost-effective and convenient way to invest in bitcoin in a manner that is more efficient and convenient than the purchase of a stand-alone bitcoin, while also mitigating some of the risk by reducing the volatility typically associated with the purchase of stand-alone bitcoin and without the uncertain and often complex requirements relating to acquiring and/or holding bitcoin.

According to the Registration Statement, the Trust will only hold bitcoin, and will, from time to time, issue Baskets [5] in exchange for deposits of bitcoins and to distribute bitcoins in connection with redemptions of Baskets. The Shares of the Trust represent units of fractional undivided beneficial interest in, and ownership of, the Trust. The bitcoins held by the Custodian on behalf of the Trust will be transferred out of the Bitcoin Account only in the following circumstances: Transferred to pay the Sponsor's Fee, distributed to Authorized Participants or Liquidity Providers, as applicable, in connection with the redemption of Baskets, transferred to be sold on an as-needed basis to pay Additional Trust Expenses, sold on behalf of the Trust in the event the Trust terminates and liquidates its assets or as otherwise required by law or regulation.

Custody of the Trust's Bitcoins

According to the Registration Statement, the Custodian is a New York-state chartered trust company operating under the direct supervision of the New York State Department of Financial Services and is subject to the anti-money laundering requirements of the Financial Crimes Enforcement Network (''FinCEN''). In addition, the Custodian is a qualified custodian under the Investment Advisers Act of 1940. Under the Custodian Agreement, the Custodian will be responsible for the safety and security of the Trust's Bitcoins as well as overseeing the process of deposit, withdrawal, sale and purchase of the Trust's bitcoins. The Custodian will custody the bitcoin in accordance with the terms of the Custodian Agreement.

According to the Registration Statement, all bitcoins exist and are stored on the Blockchain, the decentralized transaction ledger of the Bitcoin Network. The Blockchain records most transactions (including mining of new bitcoins) for all bitcoins in existence, and in doing so verifies the

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Registration Statement on Form S–1, dated January 22, 2021 filed with the Commission by the Sponsor on behalf of the Trust (File No. 333–252344). The descriptions of the Trust contained herein are based, in part, on information in the Registration Statement. The Registration Statement in not yet effective and the Shares will not trade on the Exchange until such time that the Registration Statement is effective.

[5] According to the Registration Statement, a Basket equals a block of 50,000 Shares.

location of each bitcoin (or fraction thereof) in a particular digital wallet. The Bitcoin Account will be maintained by the Custodian and cold storage [6] mechanisms will be used for the Vault Account by the Custodian. Each digital wallet of the Trust may be accessed using its corresponding private key. The Custodian's custodial operations will maintain custody of the private keys that have been deposited in cold storage at its various vaulting premises which are located in geographically dispersed locations across the world, including but not limited to the United States, Europe, including Switzerland, and South America. The locations of the vaulting premises may change regularly and are kept confidential by the Custodian for security purposes.

According to the Registration Statement, the Custodian is the custodian of the Trust's private keys in accordance with the terms and provisions of the Custodian Agreement and will utilize the certain security procedures such as algorithms, codes, passwords, encryption or telephone call-backs (together, the ''Security Procedures'') in the administration and operation of the Trust and the safekeeping of its bitcoins and private keys. The Custodian will create a Vault Account for the Trust assets in which private keys are placed in cold storage. The Custodian will segregate the private keys stored with it from any other assets it holds or holds for others. Further, multiple distinct private keys must sign any transaction in order to transfer the Trust's bitcoins from a multi-signature address to any other address on the Bitcoin blockchain. Distinct private keys required for multi-signature address transfers reside in geographically dispersed vault locations, known as ''signing vaults.'' In addition to multiple signing vaults, the Custodian maintains multiple ''back-up vaults'' in which backup private keys are stored. In the event that one or more of the ''signing vaults'' is compromised, the back-up vaults would be activated and used as signing vaults to complete a transaction within 72 hours. As such, if any one signing vault is compromised, it would have no impact on the ability of the Trust to access its bitcoins, other than a possible delay in operations of 72 hours, while one or more of the ''backup vaults'' is transitioned to a signing vault. These Security Procedures ensure that there is no single point of failure in the protection of the Trust's assets.

Overview of the Bitcoin Industry and Market [7]

Bitcoin

According to the Registration Statement, bitcoin is the digital asset that is native to, and created and transmitted through the operations of, the peer-to-peer Bitcoin network, a decentralized network of computers that operates on cryptographic protocols. No single entity owns or operates the Bitcoin network, the infrastructure of which is collectively maintained by a decentralized user base. The Bitcoin network allows people to exchange tokens of value, called bitcoin, which are recorded on a public transaction ledger known as the Blockchain. Bitcoin can be used to pay for goods and services, or it can be converted to fiat currencies, such as the U.S. dollar, at rates determined on bitcoin trading platforms or in individual end-user-to-end-user transactions under a barter system.

The value of bitcoin is determined by the supply of and demand for bitcoin. New bitcoins are created and rewarded to the parties providing the Bitcoin network's infrastructure (''miners'') in exchange for their expending computational power to verifying transactions and add them to the Blockchain. The Blockchain is effectively a decentralized database that includes all blocks that have been solved by miners and it is updated to include new blocks as they are solved. Each bitcoin transaction is broadcast to the Bitcoin network and, when included in a block, recorded in the Blockchain. As each new block records outstanding bitcoin transactions, and outstanding transactions are settled and validated through such recording, the Blockchain represents a complete, transparent and unbroken history of all transactions of the Bitcoin network.

Bitcoin Network

According to the Registration Statement, bitcoin was first described in a white paper released in 2008 and published under the pseudonym ''Satoshi Nakamoto.'' The protocol underlying Bitcoin was subsequently released in 2009 as open source software and currently operates on a worldwide network of computers.

The first step in directly using the Bitcoin network for transactions is to download specialized software referred to as a ''bitcoin wallet.'' A user's bitcoin wallet can run on a computer or smartphone, and can be used both to send and to receive bitcoin. Within a bitcoin wallet, a user can generate one or more unique ''bitcoin addresses,'' which are conceptually similar to bank account numbers. After establishing a bitcoin address, a user can send or receive bitcoin from his or her bitcoin address to another user's address. Sending bitcoin from one bitcoin address to another is similar in concept to sending a bank wire from one person's bank account to another person's bank account; provided, however, that such transactions are not managed by an intermediary and erroneous transactions generally may not be reversed or remedied once sent.

The amount of bitcoin associated with each bitcoin address, as well as each bitcoin transaction to or from such address, is transparently reflected in the Blockchain and can be viewed by websites that operate as ''blockchain explorers.'' Copies of the Blockchain exist on thousands of computers on the Bitcoin network. A user's bitcoin wallet will either contain a copy of the blockchain or be able to connect with another computer that holds a copy of the blockchain. The innovative design of the Bitcoin network protocol allows each Bitcoin user to trust that their copy of the Blockchain will generally be updated consistent with each other user's copy.

Bitcoin Protocol

According to the Registration Statement, the Bitcoin protocol is open source software, meaning any developer can review the underlying code and suggest changes. There is no official company or group that is responsible for making modifications to Bitcoin. There are, however, a number of individual developers that regularly contribute to a specific distribution of Bitcoin software known as the ''Bitcoin Core,'' which is maintained in an open-source repository on the website Github. There are many other compatible versions of Bitcoin software, but Bitcoin Core provides the de-facto standard for the Bitcoin protocol, also known as the ''reference software.'' The core developers for Bitcoin Core operate under a volunteer basis and without strict hierarchical administration.

[6] According to the Registration Statement, the term ''cold storage'' refers to a safeguarding method by which the private keys corresponding to bitcoins stored on a digital wallet are removed from any computers actively connected to the internet. Cold storage of private keys may involve keeping such wallet on a non-networked computer or electronic device or storing the public key and private keys relating to the digital wallet on a storage device (for example, a USB thumb drive) or printed medium (for example, papyrus or paper) and deleting the digital wallet from all computers.

[7] For the purpose of this section, Bitcoin with an upper case ''B'' is used to describe the system as a whole that is involved in maintaining the ledger of bitcoin ownership and facilitating the transfer of bitcoin among parties. When referring to the digital asset within the bitcoin network, bitcoin is written with a lower case ''b'' (except, at the beginning of sentences or paragraph sections).

Significant changes to the Bitcoin protocol are typically accomplished through a so-called ''Bitcoin Improvement Proposal'' or BIP. Such proposals are generally posted on websites, and the proposals explain technical requirements for the protocol change as well as reasons why the change should be accepted. Upon its inclusion in the most recent version of Bitcoin Core, a new BIP becomes part of the reference software's Bitcoin protocol. Several BIPs have been implemented since 2011 and have provided various new features and scaling improvements.

Because Bitcoin has no central authority, updating the reference software's Bitcoin protocol will not immediately change the Bitcoin network's operations. Instead, the implementation of a change is achieved by users and miners downloading and running updated versions of Bitcoin Core or other Bitcoin software that abides by the new Bitcoin protocol. Users and miners must accept any changes made to the Bitcoin source code by downloading a version of their Bitcoin software that incorporates the proposed modification of the Bitcoin network's source code. A modification of the Bitcoin network's source code is only effective with respect to the Bitcoin users and miners that download it. If an incompatible modification is accepted only by a percentage of users and miners, a division in the Bitcoin network will occur such that one network will run the pre-modification source code and the other network will run the modified source code. Such a division is known as a ''fork'' in the Bitcoin network.

Such a fork in the Bitcoin network occurred on August 1, 2017, when a group of developers and miners accepted certain changes to the Bitcoin network software intended to increase transaction capacity. Blocks mined on this network now diverge from blocks mined on the Bitcoin network, which has resulted in the creation of a new blockchain whose digital asset is referred to as ''bitcoin cash.'' Bitcoin and bitcoin cash now operate as separate, independent networks, and have distinct related assets (bitcoin and bitcoin cash). Additional forks have followed the Bitcoin Cash fork, including those for Bitcoin Gold and Bitcoin SegWit2X, in the months after the creation of Bitcoin Cash.

Bitcoin Transactions

According to the Registration Statement, a bitcoin transaction contains the sender's bitcoin address, the recipient's bitcoin address, the amount of bitcoin to be sent, a transaction fee and the sender's digital signature. Bitcoin transactions are secured by cryptography known as public-private key cryptography, represented by the bitcoin addresses and digital signature in a transaction's data file. Each Bitcoin network address, or wallet, is associated with a unique ''public key'' and ''private key'' pair, both of which are lengthy alphanumeric codes, derived together and possessing a unique relationship. The public key is visible to the public and analogous to the Bitcoin network address. The private key is a secret and may be used to digitally sign a transaction in a way that proves the transaction has been signed by the holder of the public-private key pair, without having to reveal the private key.

The Bitcoin network incorporates a system to prevent double-spending of a single bitcoin. To prevent the possibility of double-spending a single bitcoin, each validated transaction is recorded, time stamped and publicly displayed in a ''block'' in the Blockchain, which is publicly available. Any user may validate, through their Bitcoin wallet or a blockchain explorer, that each transaction in the Bitcoin network was authorized by the holder of the applicable private key, and Bitcoin network mining software consistent with reference software requirements typically validates each such transaction before including it in the Blockchain.

Bitcoin Mining—Creation of New Bitcoins

According to the Registration Statement, the process by which bitcoins are created and bitcoin transactions are verified is called mining. To begin mining, a user, or ''miner,'' can download and run a mining client, which, like regular Bitcoin network software, turns the user's computer into a ''node'' on the Bitcoin network that validates blocks. Each time transactions are validated and bundled into new blocks added to the Blockchain, the Bitcoin network awards the miner solving such blocks with newly issued bitcoin and any transaction fees paid by bitcoin transaction senders. This reward system is the method by which new bitcoins enter into circulation to the public.

Mathematically Controlled Supply

According to the Registration Statement, the method for creating new bitcoin is mathematically controlled in a manner so that the supply of bitcoin grows at a limited rate pursuant to a pre-set schedule. The number of bitcoin awarded for solving a new block is automatically halved every 210,000 blocks. Thus, the current fixed reward for solving a new block is 6.25 bitcoin per block; the reward decreased from twenty-five (25) bitcoin in July 2016 and 12.5 in May 2020. It is estimated to halve again at the start of 2024. This deliberately controlled rate of bitcoin creation means that the number of bitcoin in existence will never exceed twenty-one (21) million and that bitcoin cannot be devalued through excessive production unless the Bitcoin network's source code (and the underlying protocol for bitcoin issuance) is altered. As of January 1, 2021, approximately 18,587,000 bitcoin have been mined. It is estimated that more than ninety (90) percent of the twenty-one (21) million bitcoin will have been produced by 2022.

Bitcoin Value

According to the Registration Statement, the value of Bitcoin is determined by the value that various market participants place on Bitcoin through their transactions. The most common means of determining the value of a Bitcoin is by surveying one or more Bitcoin Exchanges where Bitcoin is traded publicly and transparently (*e.g.,* Bitstamp, Coinbase, Kraken, itBit, and Gemini). Additionally, in parallel to the open bitcoin exchanges, informal ''over-the-counter'' or ''OTC markets'' for bitcoin trading also exist as a result of the peer-to-peer nature of the Bitcoin Network, which allows direct transactions between any seller and buyer.

On each exchange, bitcoin is traded with publicly disclosed valuations for each executed trade, measured by one or more fiat currencies such as the U.S. dollar or Euro. OTC markets do not typically disclose their trade data.

Currently, there are many exchanges operating worldwide, and each such exchange represents a substantial percentage of bitcoin buying and selling activity. These exchanges provide the most data with respect to prevailing valuations of bitcoins. The below table reflects the trading volume (in thousands of USD) of each of the bitcoin exchanges included in the Index as of January 1, 2021 using data reported by the Index Provider from January 1, 2020 to January 1, 2021:

Bitcoin exchanges in the index as of January 1, 2021	Total volume (in thousands of USD)
Bitstamp	$33,291,537
Coinbase	63,462,664
Gemini	8,317,528
itBit	2,775,916

Bitcoin exchanges in the index as of January 1, 2021	Total volume (in thousands of USD)
Kraken	25,445,906
	133,293,551

Bitcoin futures contracts are traded on the Chicago Mercantile Exchange (the ''CME'') and other exchanges. However, the Trust will not hold or trade in commodity futures contracts or other derivative contracts regulated by the Commodities Exchange Act,[8] as administered by the Commodity Futures Trading Commission (the ''CFTC'').

The Index

As described in the Registration Statement, the Fund will use the Index to calculate the Trust's NAV. The Index is not affiliated with the Sponsor and was created and is administered by CF Benchmarks Ltd. (the ''Benchmark Administrator''), an independent entity, to facilitate financial products based on bitcoin. The Index is designed based on the IOSCO Principals for Financial Benchmarks and serves as a once-a-day benchmark rate of the U.S. dollar price of bitcoin (USD/BTC), calculated as of 4 p.m. Eastern time. The Index is based on materially the same methodology (except calculation time) [9] as the Benchmark Administrator's CME CF Bitcoin Reference Rate (the ''BRR''), which was first introduced on November 14, 2016 and is the rate on which bitcoin futures contracts are cash-settled in U.S. dollars at the CME. The Index aggregates the trade flow of several bitcoin exchanges, during an observation window between 3:00 p.m. and 4:00 p.m. Eastern time into the U.S. dollar price of one bitcoin at 4:00 p.m. Eastern time. The current constituent bitcoin exchanges of the Index are Bitstamp, Coinbase, Gemini, itBit and Kraken (the ''Constituent Bitcoin Exchanges'').

The Index is calculated based on the ''Relevant Transactions'' [10] of all of its Constituent Bitcoin Exchanges, as follows:

- All Relevant Transactions are added to a joint list, recording the time of execution, trade price and size for each transaction.
- The list is partitioned by timestamp into 12 equally-sized time intervals of 5 (five) minute length.
- For each partition separately, the volume-weighted median trade price is calculated from the trade prices and sizes of all Relevant Transactions, *i.e.,* across all Constituent Bitcoin Exchanges. A volume-weighted median differs from a standard median in that a weighting factor, in this case trade size, is factored into the calculation.
- The Index is then determined by the arithmetic mean of the volume-weighted medians of all partitions.

By employing the foregoing steps, the Index thereby seeks to ensure that transactions in bitcoin conducted at outlying prices do not have an undue effect on the value of a specific partition, large trades or clusters of trades transacted over a short period of time will not have an undue influence on the index level, and the effect of large trades at prices that deviate from the prevailing price are mitigated from having an undue influence on the benchmark level. In addition, the Sponsor notes that an oversight function is implemented by the Benchmark Administrator in seeking to ensure that the Index is administered through codified policies for Index integrity.

According to the Registration Statement, the Index provides an accurate reference to the average spot price of Bitcoin and the methodology employed in constructing the Index, specifically its use of medians in filtering out small trades, makes the Index more resistant to manipulation than other measurements that employ different methodologies. In addition, the Index included over $133,293,551,000 billion in bitcoin trades (approximately 16,304,168 bitcoins) during the one-year period ended December 31, 2020. Finally, an oversight committee is responsible for regularly reviewing and overseeing the methodology, practice, standards and scope of the Index to ensure that it continues to accurately track the spot prices of Bitcoin.

Calculation of Net Asset Value

The Trust's net asset value (''NAV'') is calculated by taking the current market value of its total assets, less any liabilities of the Trust, and dividing that total by the total number of outstanding Shares. The bitcoin held by the Trust will be valued based on the price set by the Index. The Administrator will calculate the NAV of the Trust once each Exchange trading day. The Exchange's Core Trading Session closes at 4:00 p.m. EST. The NAV for a normal trading day will be released after the end of the Core Trading Session. However, NAVs are not officially struck until later in the day (often by 5:30 p.m. EST and almost always by 8:00 p.m. EST). The pause between 4:00 p.m. EST and 5:30 p.m. EST provides an opportunity to algorithmically detect, flag, investigate, and correct unusual pricing should it occur. The NAV for the Trust's Shares will be disseminated daily to all market participants at the same time. The Sponsor anticipates that the Index will be reflective of a reasonable valuation of the average spot price of bitcoin. However, in the event the Index is not available or determined by the Sponsor to not be reliable, the Sponsor would ''fair value'' the Trust's bitcoin holdings. The Sponsor does not anticipate that the need to ''fair value'' bitcoin will be a common occurrence. The Sponsor will publish the NAV and NAV per Share at *www.valkyriefunds.io* as soon as practicable after their determination and availability.

Intraday Indicative Value

In order to provide updated information relating to the Trust for use by Shareholders and market professionals, the Trust will disseminate an updated intraday indicative value (''IIV'') per Share updated every 15 seconds by one of more major market data vendors during the Exchange's Core Trading Session.[11] The IIV will be calculated by a third-party financial data provider during the Exchange's Core Trading Session. The IIV will be calculated by using the prior day's closing NAV per Share of the Trust as a base and updating that value throughout the trading day to reflect changes in the most recently reported price level of the CME CF Bitcoin Real-Time Index (''BRTI''), as reported by CME Group, Inc., Bloomberg, L.P. or another reporting service. The BRTI is calculated in real time based on the Relevant Order Books of all Constituent Bitcoin Exchanges. A ''Relevant Order Book'' is the universe of the currently unmatched limit orders to buy or sell in the BTC/USD pair that is reported and disseminated by CF Benchmarks Ltd., as the BRTI calculation agent.

Creation and Redemption of Shares

According to the Registration Statement, the Trust will issue Shares on an ongoing basis, but only in one or more Baskets. The creation and redemption of a Basket requires the delivery to the Trust, or the distribution by the Trust, of the number of whole and fractional bitcoins represented by

[8] 7 U.S.C. 1.

[9] The Index is calculated as of 4 p.m. Eastern Time, whereas the BRR is calculated as of 4 p.m. London Time.

[10] A ''Relevant Transaction'' is any cryptocurrency versus U.S. dollar spot trade that occurs during the observation window between 3:00 p.m. and 4:00 p.m. Eastern time on a Constituent Bitcoin Exchange in the BTC/USD pair that is reported and disseminated by a Constituent Bitcoin Exchange through its publicly available API and observed by the Benchmark Administrator, CF Benchmarks Ltd.

[11] Several major market data vendors display and/or make widely available IIVs taken from the Consolidated Tape Association (''CTA'') or other data feeds. In addition, the indicative fund value will be available through on-line information services such as Bloomberg and Reuters.

each Basket being created or redeemed, the number of which is determined by dividing the number of bitcoins owned by the Trust at 4:00 p.m., New York time, on the trade date of a creation or redemption order, as adjusted for the number of whole and fractional bitcoins constituting accrued but unpaid fees and expenses of the Trust, by the number of Shares outstanding at such time (the quotient so obtained calculated to one-hundred-millionth of one bitcoin), and multiplying such quotient by 50,000 (the ''Basket Bitcoin Amount''). The Basket Bitcoin Amount multiplied by the number of Baskets being created or redeemed is the ''Total Basket Bitcoin Amount.''

According to the Registration Statement, Authorized Participants are the only persons that may place orders to crate or redeem Baskets. Each Authorized Participant must (i) be a registered broker-dealer, (ii) enter into a Participant Agreement with the Sponsor, the Administrator, the Marketing Agent and the Liquidity Providers and (iii) in the case of the creation or redemption of Baskets that do not use the Conversion Procedures, own a bitcoin wallet address that is recognized by the Custodian as belonging to the Authorized Participant (an ''Authorized Participant Self-Administered Account''). Authorized Participants may act for their own accounts or as agents for broker-dealers, custodians and other securities market participants that wish to create or redeem Baskets. Shareholders who are not Authorized Participants will only be able to redeem their Shares through an Authorized Participant.

Although the Trust will create Baskets only upon the receipt of bitcoins, and will redeem Baskets only by distributing bitcoins, an Authorized Participant may deposit cash with the Administrator, which will facilitate the purchase or sale of bitcoins through a Liquidity Provider on behalf of an Authorized Participant (the ''Conversion Procedures''). Liquidity Providers must (i) enter into a Participant Agreement with the Sponsor, the Administrator, the Marketing Agent and each Authorized Participant and (ii) own a Liquidity Provider Account.

The Conversion Procedures will be facilitated by a single Liquidity Provider. On an order-by-order basis, the Sponsor will select the Liquidity Provider that it believes will provide the best execution of the Conversion Procedures, and will base its decision on factors such as the Liquidity Provider's creditworthiness, financial stability, the timing and speed of execution, liquidity and the likelihood of, and capabilities in, execution, clearance and settlement. In the event that an order cannot be filled in its entirety by a single Liquidity Provider, additional Liquidity Provider(s) will be selected by the Sponsor to fill the remaining amount based on the criteria above.

Creation Procedures

According to the Registration Statement, on any Business Day, an Authorized Participant may order one or more Creation Baskets from the Trust by placing a creation order with the Administrator. Creation orders may be placed either ''in-kind'' or ''in-cash.'' Creation orders must be placed no later than 3:59:59 p.m., New York time, for in-kind creations, and 4:59:59 p.m., New York time, for in-cash creations, on each Business Day. Authorized Participants may only create Baskets and cannot create any Shares in an amount less than a Basket.

In-Kind Creations

In-kind creations will take place as follows, where ''T'' is the trade date and each day in the sequence is a Business Day:

T

- The Authorized Participant places a creation order with the Administrator.
- The Marketing Agent accepts (or rejects) the creation order, which is communicated to the Authorized Participant by the Administrator.
- The Total Basket Bitcoin Amount is determined as soon as practicable after 4:00 p.m., New York time.

T+1

- The Authorized Participant transfers the Total Basket Bitcoin Amount from its Authorized Participant Self-Administered Account to the Custodian.
- Once the Total Basket Bitcoin Amount is received by the Custodian, the Administrator directs the Transfer Agent to credit the Creation Baskets to the Authorized Participant's DTC account.

In-Cash Creations

Upon receiving instruction from the Administrator that a creation order has been accepted by the Marketing Agent, the Authorized Participant will send 110% of the U.S. Dollar value of the Total Basket Bitcoin Amount, as calculated using the most recently published Bitcoin Index Price (the ''Cash Collateral Amount''). Once the Cash Collateral Amount is received by the Administrator, the Sponsor will notify the Liquidity Provider of the creation order. The Liquidity Provider will then (i) determine the Cash Exchange Rate, which, in the case of a creation order, is the Index spot price at the time at which the Cash Collateral Amount is received by the Administrator, plus the 1% Liquidity Provider Fee, and (ii) provide a firm quote to the Authorized Participant for the Total Basket Bitcoin Amount, determined by using the Cash Exchange Rate. If the Liquidity Provider's quote is greater than the Cash Collateral Amount received, the Authorized Participant will be required to pay the difference on the same day. Under the Conversion Procedures, the Authorized Participant does not pay more than the firm quote provided by the Liquidity Provider. The Liquidity Provider bears the risk of any change in the Total Basket Bitcoin Amount and of any change in the price of bitcoin once the Cash Exchange Rate has been determined. Provided that payment for the Total Basket Bitcoin Amount is received by the Administrator, the Liquidity Provider will deliver the bitcoins to the Custodian on the settlement date on behalf of the Authorized Participant. After the Custodian receives the Total Basket Bitcoin Amount, the Administrator will instruct the Transfer Agent to deliver the Creation Baskets to the Authorized Participant. The Administrator will then send the Liquidity Provider the cash equal to the Cash Exchange Rate times the Total Basket Bitcoin Amount, plus the 1% Liquidity Provider Fee. The Administrator will return any remaining amount of the Cash Collateral Amount to the Authorized Participant.

Redemption Procedures

According to the Registration Statement, the procedures by which an Authorized Participant can redeem one or more Baskets mirror the procedures for the creation of Baskets. On any Business Day, an Authorized Participant may place a redemption order specifying the number of Redemption Baskets to be redeemed. Redemption orders may be placed either ''in-kind'' or ''in-cash.'' Redemption orders must be placed no later than 3:59:59 p.m., New York time, for in-kind redemptions, and 4:59:59 p.m., New York time, for in-cash redemption, on each Business Day. Authorized Participants may only redeem Baskets and cannot redeem any Shares in an amount less than a Basket.

In-Kind Redemptions

In-kind redemptions will take place as follows, where ''T'' is the trade date and

each day in the sequence is a Business Day:

T

- The Authorized Participant places a redemption order with the Administrator.
- The Marketing Agent accepts (or rejects) the redemption order.
- The Total Basket Bitcoin Amount is determined as soon as practicable after 4:00 p.m., New York time.

T+1

- The Authorized Participant delivers to the Transfer Agent Redemption Baskets from its DTC account.
- Once the Redemption Baskets are received by the Transfer Agent, the Custodian transfers the Total Basket Bitcoin Amount to the Authorized Participant and the Transfer Agent cancels the Shares.

In-Cash Redemptions

To redeem Baskets using the Conversion Procedures, Authorized Participants will send the Administrator a redemption order. The Marketing Agent will accept or reject the redemption order on that same date. A Liquidity Provider will then (i) determine the Cash Exchange Rate, which, in the case of a redemption order, is the Index spot price minus the 1% Liquidity Provider Fee at the time at which the Administrator notifies the Authorized Participant that an order has been accepted and (ii) provide a firm quote to an Authorized Participant for the Total Basket Bitcoin Amount, determined by using the Cash Exchange Rate. Under the Conversion Procedures, the Authorized Participant does not receive less than the firm quote provided by the Liquidity Provider. The Liquidity Provider bears the risk of any change in the Total Basket Bitcoin Amount and of any change in the price of bitcoin once the Cash Exchange Rate has been determined. The Liquidity Provider will send the Administrator the cash proceeds equal to the Cash Exchange Rate times the Total Basket Bitcoin Amount, minus the 1% Liquidity Provider Fee. Once the Authorized Participant delivers the Redemption Baskets to the Transfer Agent, the Administrator will send the cash proceeds to the Authorized Participant and the Transfer Agent will cancel the Shares. At the instruction of the Administrator, the Custodian will then send the Liquidity Provider the Total Basket Bitcoin Amount.

Potential Manipulation in the Bitcoin Market

In prior orders relating to the listing of products on U.S. exchanges, the Commission Staff expressed its concern that the global market for bitcoin may be subject to potential manipulation.[12] In order for any proposed rule change from an exchange to be approved, the Commission must determine that, among other things, the proposal is consistent with the requirements of Section 6(b)(5) of the Act. The Exchange believes that this proposal is consistent with the requirements of Section 6(b)(5) of the Act and that the Sponsor's representations below sufficiently demonstrate that the manipulation concerns previously articulated by the Commission are mitigated by investor protection issues.

According to the Sponsor, the bitcoin marketplace has matured rapidly in recent years regarding user growth, market capitalization, volume, market participants, and liquidity shifts. The Sponsor notes that Coinbase alone enables access to cryptocurrency exchange or professional custodial solutions to over 43 million retail users as well as 7,000 institutions. The Sponsor further notes that the bitcoin market has seen a dramatic shift from retail-driven growth to institutional involvement. Large, publicly-traded companies such as Tesla and MicroStrategy have purchased bitcoin to hold on corporate balance sheets. The Sponsor additionally notes that, typically, in a thinly traded asset, it would not be feasible to trade in as large of quantities without causing corresponding spikes in price action. According to the Sponsor, asset managers alongside numerous corporations around the world have been able to obtain bitcoin, at times surpassing billion-dollar notional values, without significantly distorting the marketplace. As provided below, the bitcoin ecosystem has matured considerably since the last time the Commission reviewed a proposal for a bitcoin ETF. The Sponsor notes below the advancement of the application of the Index (as described below) over that same period of time, including how the Index articulates the potential remedy that it can be to sufficiently mitigate the pricing issues and various risks surrounding market manipulation.

Price Manipulation and Market Integrity

According to the Sponsor, the bitcoin market has experienced significant maturity as adoption pressure has broadened from both retail and institutional clients on a global perspective. There has been concern over whether cryptocurrency exchanges have mechanisms in place to report and remediate price and overall, ensure market integrity. As the industry has grown exponentially and the number of marketplaces expands, it follows that the quality of several factors of these marketplaces will vary. This notion is amplified for exchanges in some jurisdictions that are unregulated or decentralized. Therefore, the Sponsor believes that there must be sufficiency of data inputs for the calculation of the spot price of bitcoin. In turn the data must be provided under licensing arrangements with each exchange, who in turn meet strict entry criteria. The design choices within the methodology and framework of the Index are sufficiently resistant to market manipulation while providing oversight managed by an independent committee.

According to the Sponsor, the Index is the aggregation of executed trade data for major bitcoin spot exchanges. To be eligible for inclusion in the Index, a Constituent Bitcoin Exchange must facilitate spot trading of bitcoin against the U.S. Dollar and make trade data and order data available through an API with sufficient reliability, relevant data, and appropriate speed. The volume for spot trading must meet a minimum threshold when compared to the total volume of all Constituent Bitcoin Exchanges included in the Index. To be considered, an exchange must also enforce policies to ensure fair and transparent market conditions and have processes in place to impede illegal, or manipulative trading practices. Additionally, to be included as a constituent in the Index, each Constituent Bitcoin Exchange must comply with applicable law and regulation, including proper AML/KYC procedures. According to the Sponsor, the BRR, which uses an identical methodology as the Index except with respect to is calculation times, is the

[12] *See* Securities Exchange Act Release Nos. 80206 (Mar. 10, 2017), 82 FR 14076 (Mar. 16, 2017) (SR–BatsBZX–2016–30) (Order Disapproving a Proposed Rule Change, as Modified by Amendments No. 1 and 2, to BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, To List and Trade Shares Issued by the Winklevoss Bitcoin Trust) (''*Winklevoss I*''); and 83723 (July 26, 2018), 83 FR 37579 (August 1, 2018) (SR–BatsBZX–2016–30) (Order Setting Aside Action by Delegated Authority and Disapproving a Proposed Rule Change, as Modified by Amendments No. 1 and 2, To List and Trade Shares of the Winklevoss Bitcoin Trust) (''*Winklevoss II*''); *see also* Securities Exchange Act Release No. 88284 (February 26, 2020), 85 FR 12595 (March 3, 2020) (SR–NYSEArca–2019–39) (Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, To Amend NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares) and To List and Trade Shares of the United States Bitcoin and Treasury Investment Trust Under NYSE Arca Rule 8.201–E).

settlement index for the regulated futures contracts listed by CME Group, Kraken Futures, as well as being the pricing source for various NAV determinations for investment products offered by major financial institutions. According to the Sponsor, the Calculation Agent of the Index further ascertains the presence of fair and transparent market conditions and processes to identify and impede illegal, unfair, or manipulative practices by conducting a thorough review of any spot bitcoin exchange under consideration for inclusion as a Constituent Bitcoin Exchange. According to the Sponsor, the arrangements of all Constituent Bitcoin Exchanges are reviewed regularly to ensure that they continue to meet all criteria.

The Sponsor notes that, currently, the Constituent Bitcoin Exchanges currently included in the Index are Bitstamp, Coinbase, Gemini, itBit and Kraken. The Sponsor further notes that after ascertaining API data from these exchanges, the information is aggregated from actual trade data in a manner designed to resist manipulation. Partitions are utilized to ensure large individual trades have a limited effect on the price of the Index by only influencing the volume-weighted median for a particular partition. Use of volume-weighted medians, as opposed to volume-weighted means, verifies that transactions conducted at outlying prices do not have an excessive effect on the value of a partition. The Index weights each partition equally as well as equal weighting of each exchange that is a part of the Index. In the event of an instance of index calculation in which a Constituent Bitcoin Exchange's volume-weighted median transaction price exhibits an absolute percentage deviation from the volume-weighted median price of other Constituent Bitcoin Exchange transactions greater than the potentially erroneous data parameter (10%), then transactions from that Constituent Bitcoin Exchange are deemed potentially erroneous and excluded from the index calculation.

Index Price Manipulation

According to the Sponsor, to date, there has been no evidence that the Index has been subject to manipulation. The Sponsor notes that, in order for the Index to be manipulated, one or both of the following must be true: (a) The Index provider is manipulating the Index, or (b) the prices being fed to the Index provider are being manipulated by their sources. The Sponsor notes that the CME participates in the oversight committee of the Index, and no evidence has been presented of the provider failing to maintain processes and controls to prevent manipulation by its organization.[13] If such a manipulation were to occur, it would be quickly detected by the CME, and hundreds of sophisticated market participants, as the Index formula and the data sources are both publicly available.[14] Finally, according to the Sponsor, the CFTC has been successfully exercising its enforcement authority related to fraud and manipulation on the Constituent Bitcoin Exchanges.[15] In addition, any platform that is accepted by the CME to become part of the constituent trading platforms that are used to calculate the Index or the CME CF BRR, including the Constituent Platforms, (1) must enter into a data sharing agreement with the CME, (2) must cooperate with inquiries and investigations of regulators and the Benchmark Administrator and (3) must submit each of its clients to its Know-Your-Customer (''KYC'') procedures; therefore, the CME would be able, in the case of any suspicious trades, to discover all material trade information including the identities of the customers placing the trades.

Availability of Information

The website for the Trust (*www.valkyriefunds.io*) will contain the following information, on a per Share basis, for the Trust: (a) The current NAV per Share daily and the prior business day's NAV and the reported closing price; (b) the Official Closing Price;[16] (c) midpoint of the national best bid and the national best offer (''NBBO'') as of the time the NAV is calculated (''Bid-Ask Price''); (d) calculation of the premium or discount of the Official Closing Price against such NAV expressed as a percentage of such NAV; (e) a table showing the number of days the Shares of the Trust traded at a premium or discount during the most recently complete calendar year and the most recently completed calendar quarters since that year; (f) a line graph showing the Shares' premiums or discounts for the most recently completed calendar year and the most recently completed calendar quarters since that year (or the life of the exchange-traded fund, if shorter); (g) the prospectus; and (h) other applicable quantitative information.

The Trust's website will be publicly available prior to the public offering of Shares and accessible at no charge.

The Index value is available on the CF Benchmarks website and from major market data vendors. The spot price of bitcoin also is available on a 24-hour basis from major market data vendors.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Trust.[17] Trading in Shares of the Trust will be halted if the circuit breaker parameters in NYSE Arca Rule 7.12–E have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable.

The Exchange may halt trading during the day in which an interruption to the dissemination of the IIV or the value of the Index occurs. If the interruption to the dissemination of the IIV or the value of the Index persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption. In addition, if the Exchange becomes aware that the NAV with respect to the Shares is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the NYSE Arca Marketplace from 4:00 a.m. to 8:00 p.m. E.T. in accordance with NYSE Arca Rule 7.34–E (Early, Core, and Late Trading Sessions). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Rule 7.6–E, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is

[13] *See* CME CF Cryptocurrency Pricing Products Oversight Committee (July 31, 2020), *available at: https://docs-cfbenchmarks.s3.amazonaws.com/CME+CF+Oversight+Committee+Charter.pdf.*

[14] *See* CME CF Cryptocurrency Reference Rates Methodology Guide (July 31, 2020), *available at: https://docs-cfbenchmarks.s3.amazonaws.com/CME+CF+Reference+Rates+Methodology.pdf.*

[15] *See e.g.,* CFTC Rel. No. 8369–21, ''CFTC Orders Coinbase Inc. to Pay $6.5 Million for False, Misleading, or Inaccurate Reporting and Wash Trading'' (March 19, 2021); and ''Remarks of Commissioner Dawn D. Stump Before Texas A&M's Bitcoin Conference'' (April 16, 2021), *available at: https://cftc.gov/PressRoom/SpeechesTestimony/opastump7.*

[16] The term ''Official Closing Price'' is defined in NYSE Arca Rule 1.1(ll) as the reference price to determine the closing price in a security for purposes of Rule 7–E Equities Trading, and the procedures for determining the Official Closing Price are set forth in that rule.

[17] *See* NYSE Arca Rule 7.12–E.

$0.01, with the exception of securities that are priced less than $1.00 for which the MPV for order entry is $0.0001.

The Shares will conform to the initial and continued listing criteria under NYSE Arca Rule 8.201–E. The trading of the Shares will be subject to NYSE Arca Rule 8.201–E(g), which sets forth certain restrictions on Equity Trading Permit (''ETP'') Holders acting as registered Market Makers in Commodity-Based Trust Shares to facilitate surveillance. The Exchange represents that, for initial and continued listing, the Trust will be in compliance with Rule 10A–3 [18] under the Act, as provided by NYSE Arca Rule 5.3–E. A minimum of 100,000 Shares of the Trust will be outstanding at the commencement of trading on the Exchange.

Surveillance

The Exchange represents that trading in the Shares of the Trust will be subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances administered by FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[19] The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares and bitcoin futures with other markets and other entities that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares and bitcoin futures from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and bitcoin futures from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement (''CSSA'').[20] The Exchange is also able to obtain information regarding trading in the Shares in connection with ETP Holders' proprietary or customer trades which they effect through ETP Holders on any relevant market.

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

All statements and representations made in this filing regarding (a) the description of the portfolio of the Trust, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange listing rules specified in this rule filing shall constitute continued listing requirements for listing the Shares on the Exchange.

The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Trust to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If the Trust is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Rule 5.5–E(m).

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5) [21] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Rule 8.201–E. Investing in the Trust will provide investors with exposure to bitcoin in a manner that is more efficient and convenient than the purchase of stand-alone bitcoin, while also mitigating some of the risk by reducing the volatility typically associated with the purchase of stand-alone bitcoin. The proposed rule change is designed to prevent fraudulent and manipulative acts and practices because, although the global Bitcoin market is not inherently resistant to fraud and manipulation, the Index used by the Trust to determine the value of its bitcoin assets and its NAV, serves as a benchmark mechanism sufficient to mitigate the impact of instances of fraud and manipulation on a reference price for Bitcoin. As discussed above, while bitcoin is listed and traded on a number of markets and platforms, the Index exclusively utilizes its Constituent Bitcoin Exchanges to determine the value of the Index. Therefore, use of the Index would mitigate the effects of potential manipulation of the bitcoin market. Bitcoin trades in a well-arbitraged and distributed market. The linkage between the bitcoin markets and the presence of arbitrageurs in those markets means that the manipulation of the price of bitcoin on any Constituent Platform would likely require overcoming the liquidity supply of such arbitrageurs who are potentially eliminating any cross-market pricing differences.

In addition, the Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares with other markets that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares and bitcoin futures with other markets and other entities that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares and bitcoin futures from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares from markets that are members of ISG or with which the Exchange has in place a CSSA. Also, pursuant to NYSE Arca Rule 8.201–E(g), the Exchange is able to obtain information regarding trading in the Shares and the underlying bitcoin or any bitcoin derivative through ETP Holders acting as registered Market Makers, in connection with such ETP Holders' proprietary or customer trades through ETP Holders which they effect on any relevant market.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the

[18] 17 CFR 240.10A–3.

[19] FINRA conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

[20] For a list of the current members of ISG, *see www.isgportal.org.* The Exchange notes that not all components of the Trust may trade on markets that are members of ISG or with which the Exchange has in place a CSSA.

[21] 15 U.S.C. 78f(b)(5).

public interest in that there is a considerable amount of bitcoin price and market information available on public websites and through professional and subscription services. Investors may obtain, on a 24-hour basis, bitcoin pricing information based on the spot price for bitcoin from various financial information service providers. The closing price and settlement prices of bitcoin are readily available from the Bitcoin exchanges and other publicly available websites. In addition, such prices are published in public sources, or on-line information services such as Bloomberg. The Trust will provide website disclosure of its bitcoin holdings daily. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the CTA. The IIV will be widely disseminated on a per Share basis every 15 seconds during the NYSE Arca Core Trading Session (normally 9:30 a.m., E.T., to 4:00 p.m., E.T.) by one or more major market data vendors. In addition, the IIV will be available through on-line information services. The Exchange represents that the Exchange may halt trading during the day in which an interruption to the dissemination of the IIV or the Index value occurs. If the interruption to the dissemination of the IIV or the Index value persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption. In addition, if the Exchange becomes aware that the NAV with respect to the Shares is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a CSSA. In addition, as noted above, investors will have ready access to information regarding the Trust's bitcoin holdings, the IIV, and quotation and last sale information for the Shares.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change will facilitate the listing and trading of an exchange-traded product based on the price of bitcoin, which will enhance competition among market participants, to the benefit of investors and the marketplace.

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

Within 45 days of the date of publication of this notice in the **Federal Register** or *up to 90 days* (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be 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–NYSEArca–2021–31 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–NYSEArca-2021–31. 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–NYSEArca–2021–31 and should be submitted on or before June 2, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09969 Filed 5–11–21; 8:45 am]

BILLING CODE 8011–01–P

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91785; File Nos. SR–NYSE–2021–05, SR–NYSEAMER–2021–04, SR–NYSEArca–2021–07, SR–NYSECHX–2021–01, SR–NYSENAT–2021–01]

Self-Regulatory Organizations; New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove Proposed Rule Changes To Amend the Exchange's Price List Related to Co-Location To Establish Two Additional Partial Cabinet Solution Bundles

May 6, 2021.

I. Introduction

On January 19, 2021, New York Stock Exchange LLC (''NYSE''), NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), NYSE Chicago, Inc. (''NYSE Chicago''), and NYSE National, Inc. (''NYSE National'') (collectively, the ''Exchanges'') each filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend the Exchanges' fee schedules related to co-location to add two Partial Cabinet Solution bundles. The proposed rule changes were published for comment in the **Federal Register** on February 5, 2021 or February 8, 2021, as applicable.[3] On March 18, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to either approve the proposed rule changes, disapprove the proposed rule changes, or institute proceedings to determine whether to disapprove the proposed rule changes.[5] The Commission received no comments on the proposed rule changes.

This order institutes proceedings under Section 19(b)(2)(B) of the Exchange Act [6] to determine whether to approve or disapprove the proposed rule changes.

II. Description of the Proposed Rule Changes

The Exchanges, as part of their co-location services, currently offer Users [7] four Partial Cabinet Solutions bundles, labeled Options A, B, C, and D. Options A and B include a partial cabinet powered to either one or two kilowatts (''kW''); a 1 Gb connection to the liquidity center network (''LCN'') and a 1 Gb connection to the internet protocol (''IP'') network, two fiber cross connections, and connectivity to one of two time feeds.[8] Options C and D include a 10 Gb connection to the LCN Network and a 10 GB connection to the IP network and are otherwise the same as Options A and B.[9] The Exchanges state that the Partial Cabinet Solution bundles are designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs of having a dedicated cabinet are too burdensome.[10] To purchase a bundle, Users must pay an initial charge and a monthly charge per bundle.[11]

The Exchanges recently amended Options C and D, which offer 10 Gb connections to the LCN and IP networks, to also offer, at no additional cost, two 10 Gb connections to the NMS Network, an alternate dedicated network connection that Users could use to access the NMS feeds for which the Securities Industry Automation Corporation is engaged as the securities information processor.[12] The Exchanges now propose to add two new Partial Cabinet Solution bundles: Proposed Options E and F would offer a 40 Gb connection to the LCN network and a 40 Gb connection to the IP network, and two 40 Gb connections to the NMS Network. Otherwise, proposed Options E and F would be the same as the Options C and D bundles, offering a 1 kW (Option E) or 2 kW (Option F) partial cabinet, two fiber cross connects, and either the Network Time Protocol Feed or the Precision Timing Protocol.[13] The Exchanges state that, currently, Users who are interested in Partial Cabinet Solution bundles, either because they have minimal power and cabinet space demands or because the costs attendant with having a dedicated cabinet are too burdensome, cannot access 40 Gb connections and are limited to the 10 Gb connections offered as part of the Option C and D bundles.[14] According to the Exchanges, Users and potential customers requested that the Exchange offer Partial Cabinet Solution bundles that include 40 Gb connections, enabling them to connect to more of the Included Data Products and Third Party Data Feeds or have the same size connection in co-location that they have everywhere.[15]

The Exchanges propose to offer each new bundle for an initial charge of $10,000, and, following an initial promotional period, a charge of $18,000 per month for Option E, and $19,000 per month for Option F.[16] In support of the proposed fees, the Exchanges state that the proposed $10,000 initial charge for a new Option E or F bundle is reasonable because it is the same as that assessed for Users choosing the currently available Options C or D, and

---

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release Nos. 91034 (February 1, 2021), 86 FR 8443 (February 5, 2021) (SR–NYSE–2021–05); 91035 (February 1, 2021), 86 FR 8449 (February 5, 2021) (SR–NYSEAMER–2021–04); 91036 (February 1, 2021), 86 FR 8440 (February 5, 2021) (SR–NYSECHX–2021–01); and 91037 (February 1, 2021), 86 FR 8424 (February 5, 2021) (SR–NYSENAT–2021–01); 91044 (February 2, 2021), 86 FR 8662 (February 8, 2021) (SR–NYSEArca–2020–08) (each, a ''Notice''). For ease of reference, page citations are to the Notice for NYSE–2021–05.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release Nos. 91357 (March 18, 2021), 86 FR 15732 (March 24, 2021) (SR–NYSE–2021–05); 91358 (March 18, 2021), 86 FR 15732 (March 24, 2021) (SR–NYSEAMER–2021–04); 91362 (March 18, 2021), 86 FR 15765 (March 24, 2021) (SR–NYSECHX–2021–01); and 91363 (March 18, 2021), 86 FR 15763 (March 24, 2021) (SR–NYSENAT–2021–01). The Commission designated May 6, 2021, as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule changes.

See Securities Exchange Act Release No. 91360 (March 18, 2021), 86 FR 15764 (March 24, 2021) (SR–NYSEArca-2020–08). The Commission designated May 9, 2021, as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

[6] 15 U.S.C. 78s(b)(2)(B).

[7] For purposes of the Exchanges' co-location services, a ''User'' means any market participant that requests to receive co-location services directly from one or more of the Exchanges.

[8] See Notice, *supra* note 3, at 8444. *See* Securities Exchange Act Release Nos. 77072 (February 5, 2016), 81 FR 7394 (February 11, 2016) (SR–NYSE–2015–53); 77070 (February 5, 2016), 81 FR 7401 (February 11, 2016) (SR–NYSEArca-2015–102); 77072 (February 5, 2016), 81 FR 7382 (February 11, 2016) (SR–NYSEMKT–2015–89); 83351 (May 31, 2018), 83 FR 26314, 26315 (June 6, 2018) (SR–NYSENAT–2018–07); 87408 (October 28, 2019), 84 FR 58778, 58779–80 (November 1, 2019) (SR–NYSECHX–2019–12).

[9] *Id.*

[10] *See id.* at 8444.

[11] *Id.* In addition, Users must satisfy the following conditions to qualify for a Partial Cabinet Solution bundle: (1) A User and its Affiliates are limited to one Partial Cabinet Solution bundle at a time, and (2) after the purchase of the Partial Cabinet Solution bundle, the User, together with its Affiliates, must have an aggregate cabinet footprint of no more than 2 kW. *See* General Note 2 of the Price List. The Exchanges also propose that General Note 2 apply to the Option E and F bundles, without alteration. *Id.*

[12] *See* Securities Exchange Act Release Nos. 88837 (May 7, 2020), 85 FR 28671 (May 13, 2020) (SR–NYSE–2019–46, SR–NYSEAMER–2019–34, SR–NYSEArca–2019–61, SR–NYSENAT–2019–19) and 88972 (May 29, 2020), 85 FR 34472 (June 4, 2020) (SR–NYSECHX–2020–18).

[13] *See* Notice, *supra* note 3, at 8444.

[14] *Id.*

[15] *Id.* The list of Included Data Products and Third Party Data Feeds are set forth in the Exchanges' fee schedules.

[16] Users who order before December 31, 2021 would be charged $9,000 per month for Option E or $9,500 per month for Option F for the first 12 months of service.

setting up each of the four options involves a similar amount of work for the Exchanges. The Exchanges also state that proposed monthly charges of $18,000 and $19,000 for Options E and F, respectively, each of which reflects a $4,000 increase over Options C and D, respectively, are reasonable because the Exchanges will have to supply multiple 40 Gb connections to offer the proposed new options.[17]

The Exchanges state that the proposed fees are equitably allocated and not unfairly discriminatory, and will not impose any burden on competition that is not necessary or appropriate because they would apply to all Users equally, the purchases would be completely voluntary, and the Exchanges are subject to significant competitive forces.[18] Regarding the competitive environment, the Exchanges state that offering Options E and F to potential Users would expand the range of options available, possibly making the proposed bundles more attractive to potential Users who might otherwise seek similar services from Hosting Users.[19] According to the Exchanges, the proposal would enhance the competitive environment for potential Users while also allowing the Exchanges to attempt to maintain a more level playing field with Hosting Users.[20] The Exchanges further state that the fees charged for co-location services are constrained by the active competition for the order flow and other business from market participants who believe that co-location enhances the efficiency of their operations.[21]

III. Proceedings To Determine Whether To Approve or Disapprove the Proposed Rule Changes

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act to determine whether the Exchanges' proposed rule changes should be approved or disapproved.[22] Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, the Commission seeks and encourages interested persons to provide additional comment on the proposed rule changes to inform the Commission's analysis of whether to approve or disapprove the proposed rule changes.

Pursuant to Section 19(b)(2)(B) of the Act,[23] the Commission is providing notice of the grounds for possible disapproval under consideration:

- Whether the Exchanges have demonstrated how the proposals are consistent with Section 6(b)(4) of the Act, which requires that the rules of a national securities exchange ''provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities;'' [24]
- Whether the Exchanges have demonstrated how the proposals are consistent with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be ''designed to perfect the operation of a free and open market and a national market system'' and ''protect investors and the public interest,'' and not be ''designed to permit unfair discrimination between customers, issuers, brokers, or dealers;'' [25] and
- Whether the Exchanges have demonstrated how the proposals are consistent with Section 6(b)(8) of the Act, which requires that the rules of a national securities exchange ''not impose any burden on competition not necessary or appropriate in furtherance of the purposes of [the Act].'' [26]

As discussed in Section II above, the Exchanges make various arguments in support of the proposals, including that the proposed initial charge and proposed monthly charge of $18,000 for Option E and $19,000 for Option F are reasonable in relation to the fees charged for Options C and D, based on the work entailed to provide the services and supply the 40 Gb connections, and that the Exchanges are subject to significant competitive forces. The Commission believes that there are questions as to whether the Exchanges have provided sufficient information to demonstrate that the proposals, including the proposed fees, are consistent with the Act.

Under the Commission's Rules of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization ['SRO'] that proposed the rule change.'' [27] The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding.[28] Any failure of an SRO to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Act and the applicable rules and regulations.[29]

The Commission is instituting proceedings to allow for additional consideration and comment on the issues raised herein, including as to whether the proposals are consistent with the Act, specifically, with its requirements that the rules of a national securities exchange provide for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers, and other persons using its facilities; are designed to perfect the operation of a free and open market and a national market system, and to protect investors and the public interest; are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers; and do not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act; [30] as well as any other provision of the Act, or the rules and regulations thereunder.

IV. Commission's Solicitation of Comments

The Commission requests written views, data, and arguments with respect to the concerns identified above as well as any other relevant concerns. Such comments should be submitted by June 2, 2021. Rebuttal comments should be submitted by June 16, 2021. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any

[17] *Id.*

[18] *See* Notice, *supra* note 3, at 8446.

[19] *Id.* As the Exchanges acknowledge, a Hosting User is itself a co-location User, allowed by the Exchanges to host other entities in the data center for monthly fees charged by the Exchanges. *See* Notice, *supra* note 3, at 8445 and n. 10. The Exchanges state that they believe Hosting Users offer similar services to those proposed, and that because Hosting Users' services are not regulated, they may offer differentiated pricing and are not required to make their pricing public. *See* Notice, *supra* note 3, at 8445 and n. 11.

[20] *See* Notice, *supra* note 3, at 8446.

[21] *See id.*

[22] 15 U.S.C. 78s(b)(2)(B).

[23] *Id.* Section 19(b)(2)(B) of the Act also provides that proceedings to determine whether to disapprove a proposed rule change must be concluded within 180 days of the date of publication of notice of the filing of the proposed rule change. *See id.* The time for conclusion of the proceedings may be extended for up to 60 days if the Commission finds good cause for such extension and publishes its reasons for so finding, or if the exchange consents to the longer period. *See id.*

[24] 15 U.S.C. 78f(b)(4).

[25] 15 U.S.C. 78f(b)(5).

[26] 15 U.S.C. 78f(b)(8).

[27] 17 CFR 201.700(b)(3).

[28] *See id.*

[29] *See id.*

[30] *See* 15 U.S.C. 78f(b)(4), (5), and (8).

request for an opportunity to make an oral presentation.[31]

The Commission asks that commenters address the sufficiency and merit of the Exchanges' statements in support of the proposal, in addition to any other comments they may wish to submit about the proposed rule change.

Interested persons are invited to submit written data, views, and arguments concerning the proposed rule changes, including whether the proposed rule changes are 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 Nos. SR–NYSE–2021–05, SR–NYSEAMER–2021–04, SR–NYSEArca–2021–07, SR–NYSECHX–2021–01, and SR–NYSENAT–2021–01 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 Nos. SR–NYSE–2021–05, SR–NYSEAMER–2021–04, SR–NYSEArca–2021–07, SR–NYSECHX–2021–01, and SR–NYSENAT–2021–01. The file numbers should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the 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 such filing also will be available for inspection and copying at the principal office of the Exchanges. 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 publicly available. All submissions should refer to File Nos. SR–NYSE–2021–05, SR–NYSEAMER–2021–04, SR–NYSEArca–2021–07, SR–NYSECHX–2021–01, and SR–NYSENAT–2021–01and should be submitted on or before June 2, 2021. Rebuttal comments should be submitted by June 16, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09971 Filed 5–11–21; 8:45 am]

BILLING CODE 8011–01–P

[31] 15 U.S.C. 78s(b)(2). Section 19(b)(2) of the Act grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by an SRO. *See* Securities Acts Amendments of 1975, Report of the Senate Committee on Banking, Housing and Urban Affairs to Accompany S. 249, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[32] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91789; File No. SR–FINRA–2021–008]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change Relating to Security-Based Swaps

May 7, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 26, 2021, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. 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

FINRA is proposing to amend FINRA Rules 0180, 4120, 4210, 4220, 4240 and 9610 to clarify the application of its rules to security-based swaps (''SBS'') following the SEC's completion of its rulemaking regarding SBS dealers (''SBSDs'') and major SBS participants (''MSBSPs'') (collectively, ''SBS Entities'').

The text of the proposed rule change is available on FINRA's website at *http://www.finra.org,* at the principal office of FINRA 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, FINRA 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. FINRA 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

Background

On July 21, 2010, President Obama signed into law the Dodd-Frank Wall Street Reform and Consumer Protection Act (the ''Dodd-Frank Act'').[3] Title VII of the Dodd-Frank Act, entitled the ''Wall Street Transparency and Accountability Act of 2010,''[4] established a comprehensive new regulatory framework for over-the-counter (''OTC'') derivatives known in the industry as ''swaps,'' which were generally unregulated in the United States prior to passage of the Dodd-Frank Act. Among other things, Title VII of the Dodd-Frank Act was intended to implement in the United States the mandate agreed by the G20 in September 2009 for its members to improve the OTC derivatives markets by improving transparency, mitigating systemic risk and protecting against market abuse.[5]

Generally, Title VII of the Dodd-Frank Act divided regulatory jurisdiction over swap products between the Commodity Futures Trading Commission (''CFTC'') and the SEC, with the CFTC regulating ''swaps'' and the SEC regulating SBS.[6]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Public Law 111–203, 124 Stat. 1376 (2010).

[4] *See* Dodd-Frank Act Section 701.

[5] *See* G20 Leaders' Statement from The Pittsburgh Summit (Sept. 24–25, 2009), *https://www.treasury.gov/resource-center/international/g7-g20/Documents/pittsburgh_summit_leaders_statement_250909.pdf.*

[6] The terms ''swap'' and ''security-based swap'' are defined in Sections 721 and 761 of the Dodd-

The Dodd-Frank Act directed the SEC to promulgate rulemakings implementing the new regulatory framework for SBS, including rules requiring SBS Entities to register with the SEC; business conduct and supervision requirements, risk mitigation techniques and other rules specifically applicable to SBS Entities; recordkeeping and financial reporting rules for SBS Entities; capital, margin and segregation requirements for SBS Entities; rules requiring regulatory reporting and public dissemination of SBS information; and processes to require SBS to become subject to mandatory clearing and execution on a registered or exempt execution facility or exchange.[7] The Commission has now finalized a majority of its rulemakings pursuant to Title VII of the Dodd-Frank Act (the ''Title VII rulemakings'').[8] The Commission has also established the compliance date for registration of SBS Entities, which will be October 6, 2021 (the ''Registration Compliance Date''), and has broadly coordinated the compliance date for a number of other Title VII rulemakings with the Registration Compliance Date.[9] Accordingly, beginning on October 6, 2021, registered SBS Entities will become subject to the Title VII rulemakings, and the deadline for the initial wave of SBS Entity registrations is November 1, 2021.[10]

Title VII of the Dodd–Frank Act also amended the definition of ''security'' under the Act to expressly encompass SBS.[11] Therefore, in addition to the comprehensive new SBS-specific regulatory framework discussed above, SBS are now also defined as securities under the Act and the rules thereunder. This amendment to the Act was effective as of July 16, 2011, the effective date of Title VII of the Dodd-Frank Act. However, to allow sufficient time to consider the potentially complex interpretive issues that may arise by defining SBS as securities, the SEC issued a series of temporary exemptive orders beginning in July 2011.[12] With limited exceptions, the SEC's temporary exemptive orders relating to the regulation of SBS as securities have now expired or will expire on the Registration Compliance Date.[13]

The addition of SBS to the definition of ''security'' under the Act had similar implications for FINRA rules. In particular, under the amended definition, any FINRA rule that applies to FINRA members' activities involving a security, securities business, a transaction involving a security or a securities position applies by its terms to those activities involving SBS. Therefore, consistent with the SEC's actions in this area, on July 8, 2011, FINRA filed for immediate effectiveness FINRA Rule 0180, which, with certain exceptions noted below, temporarily limits the application of FINRA rules with respect to SBS, thereby avoiding undue market disruptions resulting from the change to the definition of ''security'' under the Act.[14] Pending the SEC's final implementation of the Title

Frank Act. The Commission and the CFTC have jointly promulgated rules further defining these terms. *See* Securities Exchange Act Release No. 67453 (July 18, 2012), 77 FR 48208 (August 13, 2012) (Further Definition of ''Swap,'' ''Security-Based Swap,'' and ''Security-Based Swap Agreement''; Mixed Swaps; Security-Based Swap Agreement Recordkeeping) (''Product Definitions''). Very generally, SBS are swaps referencing a single security or loan, or a narrow-based security index. Certain products sharing characteristics of both swaps and SBS are regulated as ''mixed swaps'' subject to both CFTC and SEC jurisdiction.

[7] *See* Dodd-Frank Act Section 763.

[8] *See* Securities Exchange Act Release No. 74244 (February 11, 2015), 80 FR 14564 (March 19, 2015) (Regulation SBSR—Reporting and Dissemination of Security-Based Swap Information) (''Regulation SBSR Release''); Securities Exchange Act Release No. 75611 (August 5, 2015), 80 FR 48964 (August 14, 2015) (Final Rule: Registration Process for Security-Based Swap Dealers and Major Security-Based Swap Participants) (''Registration Process Release''); Securities Exchange Act Release No. 77617 (April 14, 2016), 81 FR 29960 (May 13, 2016) (Final Rule: Business Conduct Standards for Security-Based Swap Dealers and Major Security-Based Swap Participants) (''Business Conduct Standards Release''); Securities Exchange Act Release No. 78011 (June 8, 2016), 81 FR 39808 (June 17, 2016) (Final Rule: Trade Acknowledgment and Verification of Security-Based Swap Transactions) (''Trade Acknowledgment and Verification Release''); Securities Exchange Act Release No. 86175 (June 21, 2019), 84 FR 43872 (August 22, 2019) (Final Rule: Capital, Margin, and Segregation Requirements for Security-Based Swap Dealers and Major Security-Based Swap Participants and Capital and Segregation Requirements for Broker-Dealers) (''Capital, Margin, and Segregation Release''); Securities Exchange Act Release No. 87005 (September 19, 2019), 84 FR 68550 (December 16, 2019) (Final Rule: Recordkeeping and Reporting Requirements for Security-Based Swap Dealers, Major Security-Based Swap Participants, and Broker-Dealers) (''Recordkeeping Release''); Securities Exchange Act Release No. 87780 (December 18, 2019), 85 FR 6270 (February 4, 2020) (Final Rules; Guidance: Rule Amendments and Guidance Addressing Cross-Border Application of Certain Security-Based Swap Requirements) (''Cross-Border Release''); Securities Exchange Act Release No. 87782 (December 18, 2019), 85 FR 6359 (February 4, 2020) (Final Rule: Risk Mitigation Techniques for Uncleared Security-Based Swaps) (''Risk Mitigation Release''). The SEC has also proposed, but not yet finalized, rules governing SBS execution facilities (''SBSEFs'') and rules regarding fraud in the SBS market. *See* Securities Exchange Act Release No. 63236 (November 3, 2010), 75 FR 68560 (November 8, 2010) (Prohibition Against Fraud, Manipulation, and Deception in Connection with Security-Based Swaps; Proposed Rule); Securities Exchange Act Release No. 63825 (February 2, 2011), 76 FR 10948 (February 28, 2011) (Registration and Regulation of Security-Based Swap Execution Facilities; Proposed Rule; Proposed Interpretation).

[9] *See* Cross-Border Release *supra* note 8, at 6345. The Commission stated that the Registration Compliance Date for SBS Entities will be 18 months after the effective date of the rules adopted pursuant to the Cross-Border Release, which was April 6, 2020. *See* Cross-Border Release at 6270. Generally, the other Title VII rulemakings will apply to SBS Entities upon registration with the SEC. The first compliance date for SBS reporting under Regulation SBSR will be the first Monday that is the later of (1) six months after the date on which the first SBS data repository (''SBSDR'') that can accept reports in a given asset class registers with the SEC and (2) one month after the Registration Compliance Date. *See* Cross-Border Release at 6346. No SBSDRs are currently registered with the SEC.

[10] The Registration Compliance Date is October 6, 2021. The SEC has also clarified that the transitional period before a person that is deemed to be an SBSD must register with the SEC runs until two months after the end of the month in which the person is no longer able to satisfy the *de minimis* exception from the SBSD definition. Therefore, entities exceeding the *de minimis* threshold on the first counting date of August 6, 2021 or later in August 2021 must register no later than November 1, 2021. *See* SEC, Key Dates for Registration of Security-Based Swap Dealers and Major Security-Based Swap Participants, *https://www.sec.gov/page/key-dates-registration-security-based-swap-dealers-and-major-security-based-swap-participants* (''SEC Transitional Period Guidance'').

[11] *See* Dodd–Frank Act Section 761(a)(2) (inserting ''security–based swap'' in the definition of ''security'' in Section 3(a)(10) of the Act); *see also* 15 U.S.C. 78c(a)(10).

[12] *See, e.g.,* Securities Exchange Act Release No. 64795 (July 1, 2011), 76 FR 39927 (July 7, 2011) (Order Granting Temporary Exemptions Under the Securities Exchange Act of 1934 in Connection With the Pending Revision of the Definition of ''Security'' To Encompass Security-Based Swaps, and Request for Comment) (''2011 Exemptive Order''); Securities Exchange Act Release No. 71485 (February 5, 2014), 79 FR 7731 (February 10, 2014) (Order Extending Temporary Exemptions Under the Securities Exchange Act of 1934 in Connection With the Revision of the Definition of ''Security'' to Encompass Security-Based Swaps, and Request for Comment).

[13] *See* Securities Exchange Act Release No. 84991 (January 25, 2019), 84 FR 863 (January 31, 2019) (Order Granting a Limited Exemption from the Exchange Act Definition of ''Penny Stock'' for Security-Based Swap Transactions between Eligible Contract Participants; Granting a Limited Exemption from the Exchange Act Definition of ''Municipal Securities'' for Security-Based Swaps; and Extending Certain Temporary Exemptions under the Exchange Act in Connection with the Revision of the Definition of ''Security'' to Encompass Security-Based Swaps) (''2019 Exemptive Order''); Securities Exchange Act Release No. 90308 (November 2, 2020), 85 FR 70667 (November 5, 2020) (Order Granting Exemptions from Sections 8 and 15(a)(1) of the Securities Exchange Act of 1934 and Rules 3b–13(b)(2), 8c–1, 10b–10, 15a–1(c), 15a–1(d) and 15c2–1 Thereunder in Connection with the Revision of the Definition of ''Security'' to Encompass Security-Based Swaps and Determining the Expiration Date for a Temporary Exemption from Section 29(b) of the Securities Exchange Act of 1934 in Connection with Registration of Security-Based Swap Dealers and Major Security-Based Swap Participants). Generally, the SEC has extended the expiration date for the temporary exemptions directly related to pending SBS rulemakings until the compliance date for the related SBS rulemakings. Temporary exemptions not directly linked to SBS rulemakings have either expired or, in certain limited circumstances, been extended or made permanent.

[14] *See* Securities Exchange Act Release No. 64884 (July 14, 2011), 76 FR 42755 (July 19, 2011) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2011–033).

VII rulemakings, FINRA has extended the expiration date of FINRA Rule 0180 a number of times, mostly recently in January 2020.[15] FINRA Rule 0180 is currently set to expire on September 1, 2021.

FINRA Rule 0180 broadly excepts SBS activities from most FINRA requirements. Specifically, FINRA Rule 0180(a) provides that FINRA rules shall not apply to members' activities and positions with respect to SBS, except for FINRA Rule 2010 (Standards of Commercial Honor and Principles of Trade), FINRA Rule 2020 (Use of Manipulative, Deceptive or Other Fraudulent Devices), FINRA Rule 3310 (Anti-Money Laundering Compliance Program) and FINRA Rule 4240 (Margin Requirements for Credit Default Swaps).[16] In addition, FINRA Rule 0180(b) provides that the following rules apply to members' activities and positions with respect to SBS only to the extent they would have applied as of July 15, 2011 (*i.e.,* the day before the effective date of Title VII of the Dodd-Frank Act): (i) NASD Rule 3110 and all successor FINRA Rules to such NASD Rule, (ii) the FINRA Rule 4500 Series and (iii) the FINRA Rule 4100 Series.[17] Finally, FINRA Rule 0180(c) provides that certain other rules apply as necessary to effectuate members' compliance with the rules applicable to SBS as noted above, including, for example, supervision requirements and rules relating to FINRA investigations and sanctions.

In light of the expiration of the SEC's temporary exemptive orders, the finalization of the SEC's regulatory framework for SBS, and the upcoming Registration Compliance Date, FINRA believes it is appropriate and in the public interest for current FINRA Rule 0180 to expire and for FINRA to clarify the treatment of SBS under FINRA rules going forward.[18] Accordingly, FINRA is proposing to amend FINRA Rules 0180, 4120, 4210, 4220, 4240 and 9610 to take into account members' SBS activities once SBS Entities begin registering with the SEC on October 6, 2021. These proposed amendments generally fall into three categories. First, the proposed rule change would adopt a new FINRA Rule 0180, to replace expiring current FINRA Rule 0180, that would generally apply FINRA rules to members' activities and positions with respect to SBS, while providing limited exceptions for SBS in circumstances where FINRA believes such exceptions are appropriate. Second, the proposed rule change would amend FINRA's financial responsibility and operational rules to conform to the SEC's amendments to its capital, margin and segregation requirements for SBSDs and broker-dealers, and to otherwise take into account members' SBS activities. Finally, the proposed rule change would adopt a new margin rule specifically applicable to SBS, which would replace the expiring interim pilot program establishing margin requirements for CDS. Each aspect of the proposed rule change is discussed in greater detail below.

General Presumption of Applicability

As described above, FINRA Rule 0180 currently provides a broad, temporary exception from the application of FINRA requirements to SBS by providing that FINRA rules shall not apply to members' activities and positions with respect to SBS, with limited exceptions. Under the proposed rule change, current FINRA Rule 0180 would be replaced by a new FINRA Rule 0180 on October 6, 2021, which would effectively flip the existing presumption that FINRA rules do not apply to SBS, with certain exceptions, and instead provide that, going forward, FINRA rules do apply to SBS, with certain exceptions.[19] Specifically, proposed FINRA Rule 0180(a) would provide that, except as otherwise provided in FINRA Rule 0180, FINRA rules shall apply to members' activities and positions with respect to SBS.[20] As discussed in greater detail below, proposed FINRA Rules 0180(b) through (g) would specify the exceptions from this general presumption of applicability that FINRA believes it should provide to members engaged in SBS activity. Proposed FINRA Rule 0180(i) also would provide FINRA with exemptive authority to consider exemptive relief from the application of specific FINRA rules to SBS on a case-by-case basis.

As discussed above, Title VII of the Dodd-Frank Act amended the definition of ''security'' under the Act to specifically encompass SBS.[21] As the Commission has noted, in ''making this change, Congress intended for [SBS] to be treated as securities under the Exchange Act and the underlying rules and regulations.'' [22] FINRA is a registered national securities association under Section 15A of the Act, which requires, among other things, that FINRA rules 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.[23] FINRA adopted existing Rule 0180 to avoid undue market disruption while the SEC completed its Title VII rulemaking, but this broad exception was always intended to be temporary. Now that the SEC has largely finalized its regulatory framework for SBS and set the Registration Compliance Date for SBS Entities, FINRA believes it would be consistent with Congress's intent and FINRA's regulatory responsibility to generally apply FINRA rules to members' activities and positions with respect to SBS, subject to specified exceptions.

Under proposed Rule 0180(a), FINRA rules would generally apply to SBS in the same manner that such rules apply to securities generally.[24] FINRA notes that while the proposed rule change would therefore regulate SBS activities similarly to any other securities

[15] *See* Securities Exchange Act Release No. 88023 (January 23, 2020), 85 FR 5261 (January 29, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2020–001).

[16] FINRA Rule 4240 establishes an interim pilot program with respect to margin requirements for any transactions in credit default swaps (''CDS'') held in an account at a FINRA member. Like FINRA Rule 0180, the interim pilot program under FINRA Rule 4240 will automatically expire on September 1, 2021. *See* FINRA Rule 4240(a); *see also* Securities Exchange Act Release No. 89036 (June 10, 2020), 85 FR 36458 (June 16, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2020–016).

[17] These FINRA rules relate to books and records requirements and financial responsibility standards.

[18] FINRA intends to extend the expiration dates of existing FINRA Rules 0180 and 4240 to October 6, 2021 to align with the Registration Compliance Date and implementation of the proposed rule change.

[19] Supplementary Material .01 to FINRA Rule 0180 provides that for purposes of FINRA Rule 0180, ''security-based swap'' has the same meaning as defined in Section 3(a)(68) of the Act and the rules and guidance of the SEC or its staff. FINRA is not proposing to modify the definition of ''security-based swap'' in Supplementary Material .01.

[20] FINRA notes that since the definition of ''security'' now includes SBS, once current FINRA Rule 0180 expires all FINRA rules applicable to securities will apply by their terms to SBS, regardless of whether a FINRA rule specifically states that FINRA rules apply to SBS. However, FINRA believes that including an affirmative statement regarding the application of FINRA rules to SBS in proposed FINRA Rule 0180(a) will promote legal certainty and provide greater clarity for its members.

[21] *See supra* note 11.

[22] *See* 2011 Exemptive Order, *supra* note 12, at 39929.

[23] 15 U.S.C. 78*o*–3(b)(6).

[24] As for any other activity or product, members are responsible for determining the regulatory characterization of SBS and the applicability of specific rules to such products.

activities of its members, it expects that the practical impact of the proposed rule change will be limited. As an initial matter, in developing the proposed rule change, FINRA solicited input from its members regarding their anticipated SBS activities, including through direct conversations with a number of members that currently engage or have affiliates that engage in SBS activity, an invitation for submission of views and information on SBS activities on the FINRA website,[25] and issuance of *Regulatory Notice* 20–36 soliciting comment on a concept proposal relating to SBS.[26] Based on feedback received, FINRA understands that only a small number of its members will register as SBSDs or otherwise directly engage in SBS activities. In addition, FINRA notes that many of its rules relate to specific activities or lines of business that are unlikely to be relevant to SBS given the unique and limited characteristics of SBS. For example, FINRA's rules relating to securities offerings and underwriting are unlikely to implicate SBS.[27] Moreover, at present SBS generally may only be entered into with persons who qualify as ''eligible contract participants'' (''ECPs''),[28] such that FINRA rules specific to activities involving retail customers are unlikely to apply to SBS at this time.

FINRA notes that current FINRA Rule 0180(a) provides: ''The Rules shall not apply to members' activities and positions with respect to security-based swaps, except for'' certain rules noted above. Article I of the FINRA By-Laws defines the ''Rules'' as used in FINRA Rule 0180(a) to mean ''the numbered rules set forth in the [FINRA manual] beginning with the Rule 0100 Series, as adopted by the Board pursuant to these By-Laws, as hereafter amended or supplemented.'' Current FINRA Rule 0180 does not provide an exception from other parts of the FINRA manual, including the FINRA By-Laws and related governance documents, the Capital Acquisition Broker (CAB) rulebook, the Funding Portal rulebook or the Temporary Dual FINRA–NYSE Member Rules Series. Therefore, to the extent any of FINRA's governance documents or other rule sets apply to securities activities, they already apply to SBS by their terms. However, FINRA believes that these other parts of the FINRA manual likely have little direct relevance to SBS activities, since they relate primarily to governance or, as is the case for the CAB and Funding Portal rulebooks, are likely generally inapplicable due to the restricted nature of activities covered. FINRA also notes that Schedule A to the FINRA By-laws lists various fees that FINRA may assess, including two types of transaction fees. First, Section 1 of Schedule A provides for assessment of Member Regulatory Fees, including the Trading Activity Fee or ''TAF.'' The TAF applies only to sales of ''covered securities'' as defined in paragraph (b) of Section 1 of Schedule A. FINRA does not currently consider SBS to be ''covered securities'' as currently defined in paragraph (b), and therefore has not assessed the TAF with respect to SBS transactions entered into by its members. Second, Section 3 of Schedule A provides that each member shall be assessed a Regulatory Transaction Fee, which shall be determined periodically in accordance with Section 31 of the Act.[29] The SEC has addressed whether SBS are subject to Section 31 fees, stating that SBS are not currently subject to Section 31 fees and will not become subject to Section 31 fees until such time as the SEC implements real-time public reporting of SBS transactions.[30] FINRA will monitor developments with respect to the applicability of Section 31 fees to SBS and apply its Regulatory Transaction Fee coextensively with Section 31 fees. Therefore, FINRA expects that its Regulatory Transaction Fee will apply to SBS if real-time reporting for SBS comes into effect without the SEC providing an exemption for SBS from Section 31 fees. However, if the SEC grants an exemption from Section 31 for SBS, the Regulatory Transaction Fee would likewise not apply to SBS.

FINRA believes that applying the general presumption of applicability of FINRA rules to SBS under proposed

[25] *See* FINRA, Views and Information on Activity Related to Security-Based Swaps, *https://www.finra.org/rules-guidance/requests-for-comments/security-based-swaps.*

[26] *See* FINRA *Regulatory Notice* 20–36 (October 2020).

[27] FINRA notes that certain rules in the FINRA Rule 5200 Series (Quotation and Trading Obligations and Practices) and 5300 Series (Handling of Customer Orders) apply by their terms to ''securities'' generally, and therefore would apply to SBS under the proposed rule change. FINRA believes such rules are likely to have limited impact on SBS at present because SBS are generally bilateral OTC derivatives transactions negotiated and entered into between two counterparties. However, these trading and quoting rules may become more relevant to SBS in the future, particularly if trading or execution of SBS on exchanges or SBSEFs becomes prevalent. FINRA will monitor developments in the SBS market and evaluate the appropriateness of applying these rules to SBS transactions if quoting and trading activity develops.

[28] ''Eligible contract participant'' is defined under the Act to have the same meaning as under the Commodity Exchange Act (''CEA''). *See* 15 U.S.C. 78c(a)(65). Under the CEA, ECPs are defined to include certain regulated entities, such as broker-dealers, futures commission merchants (''FCMs''), financial institutions and insurance companies, as well as government entities and certain qualifying individuals and entities meeting net worth or total assets thresholds. *See* 7 U.S.C. 1a(18). Generally, an individual qualifying as an ECP must have amounts invested on a discretionary basis in excess of $10,000,000, or $5,000,000 if hedging. *See* 7 U.S.C. 1a(18)(A)(xi). The Dodd-Frank Act amended the Securities Act of 1933 (''Securities Act'') and the Act to require that SBS transactions involving a person that is not an ECP must be registered under the Securities Act and effected on a national securities exchange. *See* Product Definitions, *supra* note 6, at 48246 n.429. FINRA understands that no SBS are currently registered or available for execution on an exchange, and therefore all SBS at present must be entered into with ECPs.

FINRA's retail customer-focused rules generally apply to accounts of customers that do not meet the definition of an ''institutional account'' under FINRA Rule 4512(c). In addition to certain types of regulated entities, an ''institutional account'' under FINRA Rule 4512(c) includes any person with total assets of at least $50 million. *See* FINRA Rule 4512(c)(3). Certain FINRA rules also exclude other specified types of entities or persons from the coverage of retail customer-focused provisions. *See, e.g.,* FINRA Rule 2210(a)(4) (defining ''institutional investor'' for purposes of the communications with the public requirements as an institutional account under FINRA Rule 4512(c) or certain other specified entities, plans or persons). Given the differences between the ECP definition and the definition of ''institutional account'' (or other variations used to define non-retail customers in the FINRA rulebook), it is possible that FINRA members may engage in SBS with customers that qualify as ECPs but that do not qualify as ''institutional accounts,'' and therefore would be covered by FINRA retail customer-focused rules. For example, an individual may have more than $10 million invested on a discretionary basis, but not total assets of at least $50 million. Given the nature of the SBS market, FINRA believes that this scenario is likely to occur infrequently, but believes it would be appropriate to apply FINRA rules applicable to activities involving retail customers in such situations. FINRA notes that its retail customer-focused rules would also apply to SBS if non-ECP markets develop.

[29] *See* 15 U.S.C. 78ee.

[30] Specifically, the SEC has stated:

A sale of a security is subject to Section 31 fees only if (1) the sale occurs on a national securities exchange, or (2) the sale is transacted by or through a member of a national securities association otherwise than on a national securities exchange and the security is registered on a national securities exchange or subject to prompt last-sale reporting pursuant to the rules of the Commission or a registered national securities association. Although security-based swaps are securities, they do not meet any of the conditions noted above. Thus, security-based swaps are currently not subject to Section 31 fees and would not become subject to Section 31 fees due to the expiration of the Unlinked Temporary Exemptions or the full implementation of Regulation SBSR as it currently exists.

The Dodd-Frank Act created a new Section 13(m) of the Exchange Act that requires ''real-time public reporting'' of security-based swap transactions. Once real-time public reporting is fully-implemented, security-based swaps will be subject to prompt last-sale reporting pursuant to the rules of the Commission, which will subject them to Section 31 fees. Thus, when the Commission proposes to implement prompt last-sale reporting for security-based swap transactions, it may also revisit the appropriateness of exempting security-based swaps from Section 31 fees at such time.

See 2019 Exemptive Order, *supra* note 13, at 866 (citations omitted).

FINRA Rule 0180(a) as described above is appropriate and in the public interest. In formulating the proposed rule change, however, FINRA reviewed its rulebook to evaluate whether it would be appropriate to provide exceptions for SBS from particular FINRA rules or rule series and, if so, under what circumstances such exceptions should apply. Based on this review and feedback from its members and others, FINRA is proposing to provide three categories of exceptions: (1) General exceptions based on impracticability or operational burdens; (2) limited exceptions for SBS Entities and associated persons of SBS Entities; and (3) limited exceptions in connection with the conditions to the SEC's cross-border SBS counting exception. In addition, FINRA is proposing to provide exemptive authority to exempt a person from the application of specific FINRA rules to the person's SBS activities in circumstances not already covered by the proposed rule change. Each of these aspects of the proposed rule change is discussed in greater detail below.

General Exceptions From Presumption of Applicability

Proposed FINRA Rule 0180(b) would provide that the following FINRA rules shall not apply to members' activities and positions with respect to SBS: (1) The FINRA Rule 6000 Series; (2) the FINRA Rule 7000 Series; and (3) the FINRA Rule 11000 Series. While some of these rules could potentially be interpreted as applying to SBS activities by their terms, FINRA believes that these rules were intended for other types of securities and could create operational difficulties if so applied. Therefore, FINRA believes the proposed rule change would provide legal certainty and clarity for its members by specifically excepting these rules from applying to members' activities and positions with respect to SBS.

The FINRA Rule 6000 Series (Quotation, Order, and Transaction Reporting Facilities) and 7000 Series (Clearing, Transaction and Order Data Requirements, and Facility Charges) include various rules relating to trading, quoting, clearing and reporting for different types of securities. These rule series includes rules relating to quoting and trading in NMS stocks, quoting and trading in OTC Equity Securities, the Alternative Display Facility (the ADF, a facility for display of quotations in, and reporting OTC transactions in, NMS stocks), the Trade Reporting Facilities (the TRFs, facilities for reporting OTC transactions in NMS stocks), the OTC Reporting Facility (the ORF, a facility for reporting transactions in OTC Equity Securities), the OTC Bulletin Board Service (the OTCBB, an interdealer quotation system for OTC Equity Securities), the Trade Reporting and Compliance Engine (TRACE, a facility for reporting transactions in eligible debt securities), the Order Audit Trail system (OATS, a system to capture order information in NMS stocks and OTC Equity Securities), compliance with the Consolidated Audit Trail (CAT), and fees and charges associated with various FINRA facilities. Many of these rules would clearly not apply to SBS by their terms. For example, SBS are not NMS stocks, nor are SBS subject to the CAT. However, FINRA understands that the characterization of SBS may be unclear in some circumstances, which could raise the possibility that certain of these rules could be interpreted as applying to SBS. FINRA does not intend for the FINRA Rule 6000 or 7000 Series to apply to SBS, as these rules were specifically designed for other types of securities and would be operationally burdensome if applied to SBS. In addition, reporting to FINRA's various trade reporting facilities would be unnecessarily duplicative with the SEC's Title VII rulemakings related to regulatory reporting and public dissemination of SBS information.[31] Therefore, the proposed rule change would provide clarity in this area by specifically providing exceptions for SBS from the FINRA Rule 6000 and 7000 Series.[32]

In addition, the FINRA Rule 11000 Series sets forth the Uniform Practice Code (''UPC''). The UPC is a series of rules, interpretations and explanations designed to make uniform, where practicable, custom, practice, usage, and trading technique in the investment banking and securities business, particularly with regards to operational and settlement issues. These can include such matters as trade terms, deliveries, payments, dividends, rights, interest, reclamations, exchange of confirmations, stamp taxes, claims, assignments, powers of substitution, computation of interest and basis prices, due-bills, transfer fees, ''when, as and if issued'' trading, ''when, as and if distributed'' trading, marking to the market, and close-out procedures. The UPC was created so that the transaction of day-to-day business by members may be simplified and facilitated, that business disputes and misunderstandings, which arise from uncertainty and lack of uniformity in such matters, may be eliminated, and that the mechanisms of a free and open market may be improved and impediments thereto removed. For example, FINRA Rules 11310 through 11365 address matters relating to the delivery of securities, FINRA Rules 11510 through 11581 address certificated security matters, FINRA Rules 11610 through 11650 address the delivery of bonds and other evidence of indebtedness and FINRA Rules 11810 through 11894 address close-out procedures.

By its terms, the UPC applies to all OTC secondary market transactions in securities between members, with enumerated exceptions.[33] Therefore, the UPC could be interpreted as applying to SBS transactions in some circumstances. However, FINRA notes that the UPC is limited to transactions between members. It would therefore apply only in the very limited circumstances involving SBS transacted between FINRA members. As discussed above, FINRA understands that only a small number of its members will register as SBSDs or otherwise directly engage in SBS activities. The UPC would therefore only potentially be invoked for a small portion of the SBS market, which FINRA believes has the potential to create confusion and uncertainty. In addition, while FINRA recognizes the importance of operational and settlement risks in SBS transactions, FINRA believes these risks are more appropriately addressed through other means, including through the contractual provisions utilized by SBS counterparties under industry-standard SBS documentation and, where applicable, the SEC's risk mitigation requirements.[34] By contrast,

[31] *See* Regulation SBSR Release, *supra* note 8.

[32] FINRA notes that the FINRA Rule 6400 Series (Quoting and Trading in OTC Equity Securities) includes certain rules governing quoting and trading practices for OTC Equity Securities. FINRA believes these rules are not relevant to SBS at present because SBS are generally OTC derivatives transactions negotiated and entered into between two counterparties. However, these type of trading and quoting rules may become more relevant to SBS in the future, particularly if market centers begin quoting or trading SBS. FINRA will monitor developments in the SBS market and evaluate the appropriateness of applying these or similar rules to SBS transactions at such time.

[33] *See* FINRA Rule 11100(a). Under FINRA Rule 11100(a)(1), transactions in securities between members which are compared, cleared or settled through the facilities of a registered clearing agency are not subject to the UPC, except to the extent that the rules of the clearing agency provide that rules of other organizations shall apply. Paragraphs (a)(2) through (a)(5) of FINRA Rule 11100 also provide exceptions for specific types of securities, including exempted securities, municipal securities, redeemable securities issued by investment companies and Direct Participation Program Securities.

[34] For example, the SEC's SBS trading relationship documentation rules require SBS Entities to have in place trading relationship documentation including all terms governing the

the UPC was designed to facilitate and make uniform the operational aspects of cash securities transactions. These operational provisions were not designed for, and are not well-suited to, the particular characteristics of SBS transactions involving bilateral contractual negotiations between counterparties. FINRA therefore believes it is appropriate to except the FINRA Rule 11000 Series from applying to members' activities and positions with respect to SBS.

Exceptions for SBS Entities and Associated Persons

As discussed above, the SEC has now completed the majority of its Title VII rulemakings, including business conduct standards, trade acknowledgement and verification requirements, risk mitigation techniques and recordkeeping rules for SBS Entities.[35] These rules will apply to SBS Entities once they register with the SEC on or after the Registration Compliance Date. As described below, certain of these new SBS-specific rules are similar to existing FINRA rules that apply to members' securities activities generally. FINRA believes that applying both the SEC's rules for SBS Entities and FINRA's parallel rules for its members to the same SBS activity would result in unnecessary regulatory duplication. Therefore, to promote regulatory clarity and avoid unnecessary regulatory duplication, the proposed rule change would provide exceptions from specific FINRA rules in circumstances where the SEC's SBS Entity rules will apply to the SBS activity. As described in further detail below, proposed FINRA Rules 0180(c), (d), (f) and (g) would specify the FINRA rules subject to these exceptions and the conditions to such exceptions.

Proposed FINRA Rules 0180(c) and (d) would provide that certain specified FINRA rules shall not apply to members' activities and positions with respect to SBS, to the extent that the member is acting in its capacity as an SBS Entity or the associated person of the member is acting in his or her capacity as an associated person of an SBS Entity, as applicable, and that such activities or positions relate to the business of the SBS Entity within the meaning of the Exchange Act Rule 15Fh–3(h)(1).[36] As described below, each rule listed in proposed FINRA Rules 0180(c) and (d) is similar to a particular SEC rule or set of rules applicable to SBS Entities (or specifically applicable to SBSDs, but not MSBSPs, in the case of proposed FINRA Rule 0180(d)). FINRA believes it is appropriate to provide exceptions from these specific FINRA rules, but only to the extent that the SEC's parallel SBS Entity rules will apply to the SBS activity.[37] The exceptions are therefore limited to circumstances where the member engaged in the SBS activity is acting in its capacity as an SBS Entity, or where the associated person engaged in the SBS activity is acting in his or her capacity as an associated person of an SBS Entity.[38] To ensure that the exceptions apply only where the SBS activity is covered by the SEC's rules and subject to the oversight and supervision of an SBS Entity (which itself is subject to oversight by the Commission and, if a FINRA member, FINRA), proposed FINRA Rules 0180(c) and (d) include a further condition that the SBS activities or positions relate to the business of the SBS Entity within the meaning of the SEC's SBS Entity supervision rule.[39]

Under proposed FINRA Rules 0180(c) and (d), these proposed exceptions would be available for eight FINRA rules, subject to the conditions described above. Specifically, proposed FINRA Rule 0180(c) would provide exceptions for the following FINRA rules:

- FINRA Rule 2210(d) (Communications with the Public—Content Standards) requires members to adhere to content standards with respect to all of their communications, whether correspondence, retail communications or institutional communications. Among other things, FINRA Rule 2210(d) requires that member communications be based on principles

trading relationship between the SBS Entity and its counterparty, including, without limitation, terms addressing payment obligations, netting of payments, events of default or other termination events, calculation and netting of obligations upon termination, transfer of rights and obligations, governing law, valuation, and dispute resolution. *See* 17 CFR 240.15Fi–5(b)(1).

[35] *See* Business Conduct Standards Release; Trade Acknowledgment and Verification Release; Risk Mitigation Release; Recordkeeping Release, *supra* note 8.

[36] *See* 17 CFR 240.15Fh–3(h)(1). These exceptions are split between paragraphs (c) and (d) of proposed FINRA Rule 0180 to account for certain SEC rules that apply only to SBSDs, but not MSBSPs. Specifically, the exceptions in proposed FINRA Rule 0180(c) would apply for all Swap Entities, while the exceptions in proposed FINRA Rule 0180(d) would apply only for SBSDs.

[37] Conversely, the proposed exceptions would not apply in circumstances where the SEC's SBS Entity rules do not apply. For example, the exceptions in proposed FINRA Rules 0180(c) and (d) would not apply to a member engaged in SBS brokerage activity. FINRA notes that the SEC has contemplated that a registered broker-dealer engaged in SBS brokerage activity would be subject to applicable self-regulatory organization rules. *See, e.g.,* Cross-Border Release at 6284, Business Conduct Standards Release at 29966–68, *supra* note 8. The exceptions would also not apply to a member entering into SBS below the *de minimis* threshold for SBSD registration or engaging in other SBS activity not requiring SBS Entity registration (*e.g.,* SBS hedging activity). In these circumstances, the FINRA rules would apply to the SBS activity.

[38] FINRA's business conduct rules apply both to the FINRA member and persons associated with the member. Similarly, the SEC's SBS Entity rules apply to activity undertaken by an SBS Entity or its associated persons. Therefore, proposed Rule 0180(c) applies to the SBS activities engaged in by a member that is also registered as an SBS Entity as well as SBS activities engaged in by an associated person of a member where the associated person is acting in their capacity as an associated person of an SBS Entity, since the SBS Entity rules would apply in those circumstances. The exceptions would therefore apply to an associated person of a member that is also registered as an SBS Entity where the associated person is acting in his or her capacity as an associated person of the SBS Entity.

FINRA understands that certain firms engaged in SBS activity may employ a ''dual-hatted'' personnel structure. In this structure, an affiliate of the member is registered as an SBS Entity, but the member itself is not dually-registered as an SBS Entity. However, certain personnel of the member may be ''dual-hatted'' such that they act as associated persons of the member with respect to general securities activities but as associated persons of the affiliated SBS Entity with respect to the SBS Entity's SBS activities. FINRA intends for the exceptions in proposed FINRA Rule 0180(c) to apply to SBS activities undertaken by an associated person of a member acting in his or her capacity as an associated person of an affiliated SBS Entity under the dual-hatted structure described above. FINRA is providing this guidance to promote legal certainty and provide clarity to its members regarding the application of the particular rules covered by the proposed exceptions in FINRA Rule 0180(c). The proposed rule change does not address whether or to what extent other FINRA rules not covered by proposed FINRA Rule 0180(c) might apply to a dual-hatted associated person when he or she is acting in his or her capacity as an associated person of an affiliated SBS Entity.

FINRA also notes that whether a particular individual is acting as an associated person of the member or of an SBS Entity (whether the same entity as the member or an affiliated entity) is a facts and circumstances determination and is not dependent on the particular method in which such arrangements are documented. However, FINRA reminds members that they must be able to demonstrate how a particular individual is designated and for what purposes, as well as the specific capacity in which an individual is acting with respect to any particular transaction or activity.

[39] The SEC's SBS supervision rule states: ''A security-based swap dealer or major security-based swap participant shall establish and maintain a system to supervise, and shall diligently supervise, its business and the activities of its associated persons. Such a system shall be reasonably designed to prevent violations of the provisions of applicable federal securities laws and the rules and regulations thereunder relating to its business as a security-based swap dealer or major security-based swap participant, respectively.'' 17 CFR 240.15Fh–3(h)(1). Therefore, to qualify for the exceptions in proposed FINRA Rules 0180(c) and (d), the particular SBS activity must be within the scope of the business of the SBS Entity that is subject to the SBS Entity's supervisory system. If an SBS Entity were to engage in other SBS activity that it did not consider within the scope of its business as an SBS Entity, and therefore not subject to the SEC's rules applicable to SBS Entities, the exceptions would not be available and the applicable FINRA rules would apply to that activity.

of fair dealing and good faith, be fair and balanced, and not omit any material facts or make false or exaggerated claims. The SEC's business conduct rules for SBS Entities include Exchange Act Rule 15Fh–3(g), which generally requires SBS Entities to communicate with counterparties in a fair and balanced manner based on principles of fair dealing and good faith.[40] The SEC's business conduct rules also include requirements for SBS Entities to make certain disclosures to their SBS counterparties, including disclosures of material risks and characteristics of the SBS and material incentives or conflicts of interest (Exchange Act Rule 15Fh–3(b)), daily mark disclosures (Exchange Act Rule 15Fh–3(c)) and disclosures regarding clearing rights (Exchange Act Rule 15Fh–3(d)).[41]

• FINRA Rule 2232 (Customer Confirmations) generally requires members to provide customers with written confirmations in conformity with Exchange Act Rule 10b–10,[42] along with specified additional disclosures for certain types of securities. Exchange Act Rule 15Fi–2 requires SBS Entities to provide trade acknowledgements and to establish, maintain and enforce written policies and procedures reasonably designed to obtain prompt verification of the terms of such trade acknowledgments.[43] FINRA also notes that the SEC's trade acknowledgement and verification rule provides that an SBS Entity that is also a broker or dealer, is purchasing from or selling to any counterparty, and that complies with the relevant requirements of the trade acknowledgement and verification rule, is exempt from the requirements of Exchange Act Rule 10b–10 with respect to the SBS transaction.[44]

• FINRA Rules 3110 (Supervision), 3120 (Supervisory Control System) and 3130 (Annual Certification of Compliance and Supervisory Processes) require, among other things, each member to establish and maintain a supervisory system; establish, maintain and enforce written supervisory procedures; designate principals to establish, maintain and enforce a system of supervisory control policies and procedures; designate a chief compliance officer; and submit annual certifications to FINRA related to the member's compliance policies and written supervisory procedures. The SEC's business conduct rules for SBS Entities include Exchange Act Rules 15Fh–3(h) and 15Fk–1.[45] Exchange Act Rule 15h–3(h) requires, among other things, an SBS Entity to establish and maintain a system to supervise, and to diligently supervise, its business and the activities of its associated persons; designation of at least one person with authority to carry out supervisory responsibilities; and establishment, maintenance and enforcement of written policies and procedures addressing supervision of the SBS Entity's SBS business. Exchange Act Rule 15Fk–1 requires each SBS Entity to designate a chief compliance officer and submit annual compliance reports to the SEC.

Proposed FINRA Rule 0180(d) would provide exceptions for the following FINRA Rules:

• FINRA Rule 2030 (Engaging in Distribution and Solicitation Activities with Government Entities) is FINRA's ''pay-to-play'' rule, which imposes restrictions on member firms engaging in distribution or solicitation activities with government entities. Exchange Act Rule 15Fh–6 imposes pay-to-play restrictions on SBSDs (but not MSBSPs), including similar restrictions on an SBSD engaging in SBS transactions with a municipal entity within two years after specified types of political contributions have been made to officials of the municipal entity.[46]

• FINRA Rule 2090 (Know Your Customer) generally requires that each member use reasonable diligence to know and retain essential facts concerning every customer and the authority of each person acting on behalf of such customer. The SEC's business conduct rules for SBS Entities include Exchange Act Rules 15Fh–3(a) and (e).[47] Exchange Act Rule 15Fh–3(a) generally requires SBS Entities to verify the status of their SBS counterparties, including verification that the counterparty is an ECP and whether the counterparty is a ''special entity.''[48] Exchange Act Rule 15Fh–3(e) requires each SBSD (but not MSBSP) to establish, maintain and enforce written policies and procedures reasonably designed to obtain and retain a record of the essential facts concerning each counterparty whose identify is known to the SBSD that are necessary for conducting business with such counterparty.

• FINRA Rule 2111 (Suitability) is FINRA's suitability rule, which generally requires a member or associated person to have a reasonable basis that a recommended transaction or investment strategy is suitable for the customer.[49] The SEC's business conduct rules for SBS Entities include Exchange Act Rules 15Fh–3(f) and 15Fh–5.[50] Exchange Act Rule 15Fh–3(f) imposes similar suitability obligations on SBSDs (but not MSBSPs) with respect to recommendations of SBS or trading strategies.[51] In addition, Exchange Act

[40] *See* 17 CFR 240.15Fh–3(g); Business Conduct Standards Release, *supra* note 8, at 30000–02.

[41] *See* 17 CFR 240.15Fh–3(b), (c) and (d); Business Conduct Standards Release, *supra* note 8, at 29980–93.

[42] *See* 17 CFR 240.10b–10.

[43] *See* 17 CFR 240.15Fi–2; *see generally* Trade Acknowledgment and Verification Release, *supra* note 8.

[44] *See* 17 CFR 240.15Fi–2(g); Trade Acknowledgement and Verification Release, *supra* note 8, at 39824–25.

[45] *See* 17 CFR 240.15Fh–3(h) and 15Fk–1; Business Conduct Standards Release, *supra* note 8, at 30002–07 and 30050–61.

[46] *See* 17 CFR 240.15Fh–6; Business Conduct Standards Release, *supra* note 8, at 30045–50.

[47] *See* 17 CFR 240.15Fh–3(a) and (e); Business Conduct Standards Release, *supra* note 8, at 29978–80 and 29993–94.

[48] ''Special entity'' is defined in Exchange Act Rule 15Fh–2(d) and includes certain government entities, employee benefit plans and endowments. *See* 17 CFR 240.15Fh–2(d).

[49] Specifically, FINRA Rule 2111 is composed of three main obligations: reasonable-basis suitability, customer-specific suitability, and quantitative suitability. The reasonable-basis obligation requires a member or associated person to have a reasonable basis to believe, based on reasonable diligence, that the recommendation is suitable for at least some investors. A member's or associated person's reasonable diligence must provide the member or associated person with an understanding of the potential risks and rewards associated with the recommended security or strategy. The customer-specific obligation requires that a member or associated person have a reasonable basis to believe that the recommendation is suitable for a particular customer based on that customer's investment profile, with the ability to fulfill this obligation for an institutional account if (i) the member or associated person has a reasonable basis to believe that the institutional customer is capable of evaluating investment risks independently, both in general and with regard to particular transactions and investment strategies involving a security or securities, and (ii) the institutional customer affirmatively indicates that it is exercising independent judgment in evaluating the member's or associated person's recommendations. Quantitative suitability requires a member or associated person to have a reasonable basis for believing that a series of recommended transactions, even if suitable when viewed in isolation, are not excessive and unsuitable for the customer when taken together in light of the customer's investment profile. *See* Supplementary Material .05 to FINRA Rule 2111.

[50] *See* 17 CFR 240.Fh–3(f) and Fh–5; Business Conduct Standards Release, *supra* note 8, at 29994–30000 and 30007–45.

[51] Specifically, Exchange Act Rule 15Fh–3(f)(1)(i) provides that an SBSD that recommends an SBS or trading strategy involving an SBS to a counterparty (other than an SBS Entity, swap dealer or major swap participant) must undertake reasonable diligence to understand the potential risks and rewards associated with the recommended SBS or trading strategy involving an SBS. FINRA notes that, as proposed, Exchange Act Rule 15Fh–3(f)(1)(i) would have required an SBSD to have a reasonable basis to believe, based on reasonable diligence, that the recommended SBS or trading strategy is suitable for at least some counterparties (similar to FINRA Rule 2111's reasonable-basis obligation). *See* Business Conduct Standards Release, *supra* note 8 at 29994. When adopting its final business conduct rules, the SEC modified Exchange Act Rule 15Fh–3(f)(1)(i) to ''rephrase the suitability obligation . . . to make it consistent with the CFTC's parallel suitability requirement in Commodity Exchange Act Rule 23.434(a)(1), which explicitly requires [SBSDs]

Rule 15Fh–5 applies special, enhanced requirements when SBS Entities act as counterparties to special entities.

Proposed FINRA Rule 0180(f) would provide that FINRA Rules 2231 (Customer Account Statements) and 4512 (Customer Account Information) shall not apply to members' activities and positions with respect to SBS, to the extent that the member is acting in its capacity as an SBS Entity and the customer's account solely holds SBS and collateral posted as margin in connection with such SBS, provided that the member complies with the portfolio reconciliation requirements of Exchange Act Rule 15Fi–3 with respect to such account and that such portfolio reconciliations include collateral posted as margin in connection with SBS in the account. FINRA Rule 2231 generally requires each member to provide, on at least a quarterly basis, an account statement to each customer containing a description of any securities positions, money balances or account activity during the period since the last customer account statement. FINRA Rule 4512 generally requires each member to maintain specified information for each customer account, including specified identifying information about the customer.

FINRA believes that the customer account statements required under FINRA Rule 2231 generally should reflect a holistic view of a member's relationship with its customer, including SBS transactions, positions and related collateral, if applicable. Therefore, to the extent that a customer's account includes SBS along with other securities positions or activity, or related money balances, then FINRA believes that the account statement under FINRA Rule 2231 should include SBS. However, FINRA understands that members that are also registered SBS Entities may have customer accounts that hold solely SBS and related collateral, and do not hold any other securities positions or have any other securities activity. While SBS Entities are not subject to a customer account statement requirement with respect to SBS, the SEC's risk mitigation requirements for SBS Entities include Exchange Act Rule 15Fi–3, which requires SBS Entities to engage in portfolio reconciliation with their counterparties.[52] Exchange Act Rule 15Fi–3(a) generally requires SBS Entities to engage in portfolio reconciliation for all SBS with their SBS Entity counterparties, with the frequency of such portfolio reconciliations ranging from once each business day (for SBS portfolios that include 500 or more SBS), to once each week (for SBS portfolios that include more than 50 but fewer than 500 SBS on any business day during the week), to once each calendar quarter (for SBS portfolios that include no more than 50 SBS at any time during the calendar quarter).[53] Exchange Act Rule 15Fi–3(b) requires each SBS Entity to establish, maintain, and follow written policies and procedures reasonably designed to ensure that it engages in portfolio reconciliation for all SBS with non-SBS Entity counterparties, with the frequency of such portfolio reconciliations ranging from once each calendar quarter (for SBS portfolios that include more than 100 SBS at any time during the calendar quarter) to once annually (for SBS portfolios that include no more than 100 SBS at any time during the calendar year).[54]

FINRA acknowledges that the SEC's SBS portfolio reconciliation rule differs in some respects from the customer account statement requirements under FINRA Rule 2231. For example, the frequency of portfolio reconciliations varies as described above, while customer account statements must be delivered at least quarterly. In addition, as described above, an SBS entity must have policies and procedures in place to ensure that it engages in portfolio reconciliation with non-SBS Entity counterparties, while a member must provide a customer account statement to each customer unless a specific exception under FINRA Rule 2231(b) applies. However, FINRA believes that, while not identical, Exchange Act Rule 15Fi–3 serves similar purposes to FINRA Rule 2231, such that requiring members that are SBS Entities to also provide customer account statements for accounts holding solely SBS and related collateral would be unnecessarily duplicative. Accordingly, to promote regulatory clarity and avoid unnecessary duplication, proposed FINRA Rule 0180(f) would provide an exception from FINRA Rule 2231 in the limited circumstances where the member is acting in its capacity as an SBS Entity and the account solely holds SBS and collateral posted as margin in connection with such SBS. FINRA notes that collateral in a customer's account would be included in account statements provided under FINRA Rule 2231. The proposed rule change therefore includes as a condition to the proposed exception that the member comply with Exchange Act Rule 15Fi–3 with respect to an account qualifying for the exception and include collateral in the portfolio reconciliation and dispute resolutions requirements as applied to such an account.

The SEC's risk mitigation requirements for SBS also include Exchange Act Rule 15Fi–5, which requires SBS Entities to have in place SBS trading relationship documentation with their SBS counterparties, including all terms governing the trading relationship between the SBS and its counterparty.[55] In addition, SBS Entities that are also registered broker-dealers are subject to the SEC's recordkeeping requirements under Exchange Act Rule

to understand the risk-reward tradeoff of their recommendations.'' In doing so, the SEC noted that the SEC's ''proposed formulation and the CFTC's formulation would have achieved the same purpose.'' *See id.* at 29996. The SEC also noted that the ''new formulation is also consistent with FINRA's approach to this aspect of suitability [*i.e.,* the reasonable-basis obligation as described in Supplementary Material .05(a) to FINRA Rule 2111].'' *See id.* at 29996 n.493. As with the reasonable-basis obligation in FINRA Rule 2111, SBSDs ''are always required to meet their suitability obligation in [Exchange Act] Rule 15Fh–3(f)(1)(i), regardless of whether they avail themselves of the institutional suitability alternative to meet their customer-specific obligations.'' *See id.* at 29997.

In addition, Exchange Act Rule 15Fh–3(f)(1)(ii) requires the SBSD to have a reasonable basis to believe that a recommended SBS or trading strategy involving an SBS is suitable for the counterparty (similar to FINRA Rule 2111's customer-specific obligation). Also similar to the institutional account alternative in FINRA Rule 2111, an SBSD may fulfill its obligations under Exchange Act Rule 15Fh–3(f)(1)(ii) with respect to an institutional counterparty if it complies with specified conditions, including reasonably determining that the counterparty or its agent is capable of independently evaluating investment risks with regard to the relevant SBS or trading strategy involving an SBS and that the counterparty or its agent affirmatively represents in writing that it is exercising independent judgment in evaluating the recommendations of the SBSD with regard to the relevant SBS or trading strategy involving an SBS. *See* Exchange Act Rules 15Fh–3(f)(2) and (3).

FINRA acknowledges that the SEC's suitability rule differs in some respects from FINRA's suitability requirements under FINRA Rule 2111. For example, Exchange Act Rule 15F–3(f) does not explicitly include a quantitative suitability obligation. However, FINRA believes that, while not identical, Exchange Act Rule 15Fh–3(f) serves similar purposes to FINRA Rule 2111, such that requiring members that are SBSDs to also comply with FINRA Rule 2111 in circumstances where Exchange Act Rule 15Fh–3(f) applies would be unnecessarily duplicative.

[52] *See* 17 CFR 240.15Fi–3; Risk Mitigation Release, *supra* note 8, at 6362–70. For purposes of Exchange Act Rule 15Fi–3, ''portfolio reconciliation'' is defined as any process by which counterparties to one or more SBS (1) exchange the material terms of all SBS in the SBS portfolio between the counterparties, (2) exchange each counterparty's valuation of each SBS in the SBS portfolio between the counterparties as of the close of business on the immediately preceding day and (3) resolve any discrepancy in valuations or material terms. *See* 17 CFR 240.15Fi–1(l).

[53] *See* 17 CFR 240.15Fi–3(a).

[54] *See* 17 CFR 240.15Fi–3(b).

[55] *See* 17 CFR 240.15Fi–5; Risk Mitigation Release, *supra* note 8, at 6372–6377. SEC rules also require SBS Entities to maintain records of SBS trading relationship documentation. *See* 17 CFR 17a–4(e)(12)(ii).

17a–3, which require, among other things, certain records to be kept for each SBS account.[56] These SEC rules generally require SBS Entities to obtain and keep records of certain information in connection with their SBS accounts, including SBS-specific identifying information. FINRA believes that, while not identical to FINRA Rule 4512, these SEC rules serve similar purposes, and that also applying FINRA Rule 4512 to SBS-only accounts would be duplicative. Accordingly, in order to promote regulatory clarity and avoid unnecessary duplication, FINRA believes it is appropriate to provide an exception from FINRA Rule 4512 in the limited circumstances where the member is acting in its capacity as an SBS Entity and the account solely holds SBS and collateral posted as margin in connection with such SBS. Both exceptions under proposed FINRA Rule 0180(f) would not apply to accounts holding SBS together with other securities or to members that are not also registered SBS Entities.

Finally, proposed FINRA Rule 0180(g) would provide that persons associated with a member whose functions are related solely and exclusively to SBS undertaken in such person's capacity as an associated person of an SBS Entity are not required to be registered with FINRA.[57] Generally, FINRA Rule 1210 requires that each person engaged in the investment banking or securities business of a member must be registered with FINRA as a representative or principal in each category of registration appropriate to his or her functions and responsibilities as specified in FINRA Rule 1220. Individuals seeking to become registered with FINRA generally must pass an appropriate qualification examination, and registered individuals are subject to continuing education (''CE'') requirements under FINRA Rule 1240. These registration, licensing and CE requirements would generally apply to associated persons of a member engaged in SBS activities due to the change to the definition of ''security'' to encompass SBS. Accordingly, FINRA believes that associated persons of a member who are engaged in SBS activities generally should be registered—and subject to accompanying licensing and CE requirements—as appropriate based on the scope of their activities (*e.g.,* Series 7 for general SBS activities, Series 24 for SBS principals, etc.). However, FINRA understands that members that are also registered SBS Entities may in some limited circumstances have an associated person whose securities-related activities relate solely and exclusively to transactions conducted in the individual's capacity as an associated person of the SBS Entity. Such individuals engage solely in SBS activities on behalf of the SBS Entity (and potentially non-securities activities, such as swaps), but do not engage in any other securities activities that would require registration under FINRA Rule 1210.

FINRA's current registration, licensing and CE requirements are not specifically tailored to SBS. To reduce unnecessary regulatory burdens, FINRA therefore believes it is appropriate for the proposed rule change to provide an exception at the current time from these requirements in the limited circumstances where an associated person of a member is engaged solely and exclusively in SBS activities in his or her capacity as an associated person of an SBS Entity. Under this proposed exception, such persons would not be required to register with FINRA, and therefore would not be required to pass any qualification examinations or become subject to CE requirements under FINRA Rule 1240. This proposed exception is based on FINRA's analysis of its existing registration and related requirements, and its understanding that the number of such associated persons is limited. FINRA will monitor developments with respect to the SBS activities of its members and will continue to consider whether it would be appropriate to tailor the registration and related requirements to SBS, for example through targeted SBS-related registration categories or the addition of SBS-specific content to qualification examinations or CE content. FINRA will consider whether it would be appropriate to rescind the exception under proposed FINRA Rule 0180(g) in such circumstances. The exception under proposed FINRA Rule 0180(g) would not apply to associated persons of a member engaged in any other securities activities or to associated persons of members that are not also registered SBS Entities.[58] FINRA also notes that, although individuals qualifying for the proposed exception would not be required to register with FINRA (and therefore a member firm would not be required to file a Form U4 on behalf of such individuals), they would remain associated persons of the member subject to all FINRA and SEC rules applicable to such associated persons, including fingerprinting requirements under Exchange Act Rule 17f–2.[59]

Exceptions in Connection With the SEC's Cross-Border Exception

In connection with finalizing the Title VII rulemakings, the SEC also adopted a number of rules and provided guidance to address the cross-border application of various SBS requirements. One of these rules, Exchange Act Rule 3a71–3(d), provides a conditional exception to the provisions of Exchange Act Rule 3a71–3 that otherwise would require non-U.S. persons to count—against the thresholds associated with the *de minimis* exception to the SBSD definition—SBS dealing transactions with non-U.S. counterparties when U.S. personnel arrange, negotiate or execute those transactions.[60] To qualify for this exception, all such arranging, negotiating or executing activity must be conducted by U.S. personnel in their capacity as persons associated with a registered broker-dealer or a registered SBSD that is a majority-owned affiliate of the non-U.S. person relying on the exception (the ''U.S. Registered Affiliate'').[61] Further, to qualify for the exception, the U.S. Registered Affiliate must comply with specified SBS Entity rules with respect to such SBS transactions as if the counterparties to the non-U.S. person relying on the exception also were counterparties to the U.S. Registered Affiliate and as if the U.S. Registered Affiliate were registered as an SBSD, if not so registered.[62] The

[56] *See* 17 CFR 240.17a–3; *see generally* Recordkeeping Release, *supra* note 8. FINRA notes in particular Exchange Act Rule 17a–3(a)(9)(iv), which requires an SBS Entity to keep a record, for each SBS account, of the unique identification code of the counterparty, the name and address of the counterparty, and a record of the authorization of each person the counterparty has granted authority to transact business in the SBS account. *See* 17 CFR 240.17a–3(a)(9)(iv).

[57] This exception is structured similarly to existing exceptions from registration for persons associated with a member whose functions are related solely and exclusively to certain other product types (such as municipal securities, commodities or security futures), as found in FINRA Rule 1230.

[58] FINRA notes that associated persons of SBS Entities are not independently subject to registration, licensing or CE requirements. However, an SBS Entity is prohibited from permitting an associated person that is subject to a statutory disqualification to effect or be involved in effecting SBS on behalf of the SBS Entity. *See* 15 U.S.C. 78*o*–10(b)(6). The SEC's SBS Entity registration rules also require an SBS Entity to certify that it neither knows, nor in the exercise of reasonable care should have known, of any such statutory disqualification. Such certifications must be supported by questionnaires or employment applications serving as the basis for background checks. *See* 17 CFR 240.15Fb6–2; Registration Process Release, *supra* note 8, at 48973–79.

[59] *See* 17 CFR 240.17F–2.

[60] *See* 17 CFR 240.3a71–3(d); Cross-Border Release, *supra* note 8, at 6276–92.

[61] *See* 17 CFR 240.3a71–3(d)(1)(i).

[62] *See* 17 CFR 240.3a71–3(d)(1)(ii)(A).

specified SBS Entity rules under this exception are Exchange Act Rule 15Fh–3(b) (disclosures of material risks and characteristics and material incentives or conflicts of interest), Exchange Act Rule 15Fh–3(f)(1) (recommendations and suitability), Exchange Act Rule 15Fh–3(g) (fair and balanced communications) and Exchange Act Rule 15Fi–2 (acknowledgement and verification of SBS transactions).[63]

Where a member is acting as the U.S. Registered Affiliate for a foreign affiliate pursuant to the exception in Exchange Act Rule 3a71–3(d), the member would be required to comply with the SEC's SBS Entity rules noted above. The consequence of the member not complying with these rules is that the member's foreign affiliate would be required to count such SBS toward its *de minimis* SBSD registration threshold. In these circumstances, FINRA believes it is appropriate to provide exceptions from the parallel FINRA rules to provide clarity and avoid unnecessary regulatory duplication, but only where the member is in fact complying with the specified SEC rules. Specifically, proposed FINRA Rule 0180(e) would provide that the following rules shall not apply to members' activities and positions with respect to SBS, to the extent that the member or the associated person of the member, as applicable, is arranging, negotiating or executing SBS on behalf of a non-U.S. affiliate pursuant to, and in compliance with the conditions of, the exception from counting certain SBS under Exchange Act Rule 3a71–3(d)(1): (1) FINRA Rule 2111 (Suitability); (2) FINRA Rule 2210(d) (Communications with the Public—Content Standards); and (3) FINRA Rule 2232 (Customer Confirmations).[64] As noted above, the availability of the exceptions under proposed FINRA Rule 0180(e) would be conditioned on the member's compliance with the rules specified in Exchange Act Rule 3a71–3(d)(1)(ii)(B) as if the member were the counterparty to the SBS transactions.[65]

Exemptive Authority

As discussed above, in formulating the proposed rule change, FINRA consulted with its members and reviewed its rulebook to determine whether continuing exceptions from any of its rules are appropriate. FINRA recognizes, however, that the SBS market continues to evolve and that particular circumstances may arise in which applying specific FINRA rules not otherwise covered by the proposed exceptions to SBS activities may not be appropriate or feasible. Therefore, proposed FINRA Rule 0180(i) would provide that, pursuant to the FINRA Rule 9600 Series, FINRA may, taking into consideration all relevant factors, exempt a person unconditionally or on specified terms from the application of FINRA rules (other than an exemption from the general application of paragraph (a) of proposed FINRA Rule 0180) to the person's SBS activities or positions as it deems appropriate consistent with the protection of investors and the public interest. Under this proposed provision, FINRA would consider written applications for exemptive relief pursuant to FINRA Rule 9610 from the application of specific rules to a member's SBS activities or positions. Such applications would be required to address the need for exemptive relief from specific FINRA rules on a rule-by-rule basis, and FINRA would not provide exemptive relief from the application of FINRA rules generally to a member's SBS activities or positions. Therefore, proposed FINRA Rule 0180(i) would not provide for exemptive authority from the general application of FINRA rules to SBS under proposed FINRA Rule 0180(a). Pursuant to FINRA Rule 9620, FINRA would consider such an application and issue a written decision to the requesting member, which may be made publicly available.[66] A member would have the ability to appeal such a decision pursuant to FINRA Rule 9630. FINRA believes it is appropriate and in the public interest to provide this exemptive authority so that FINRA can account for specific situations that may arise with respect to SBS in the future on a case-by-case basis.

FINRA also is proposing a conforming change to FINRA Rule 9610 to add FINRA Rule 0180 to the list of rules pursuant to which FINRA has exemptive authority.

Financial Responsibility and Operational Requirements

In June 2019, the Commission adopted final capital, margin and segregation requirements for SBS Entities, along with amendments to the existing capital and segregation requirements for broker-dealers, in the Capital, Margin, and Segregation Release. As with many of its other Title VII rulemakings, the SEC aligned the compliance date for the amendments under the Capital, Margin, and Segregation Release with the Registration Compliance Date.[67] Among other things, the Capital, Margin, and Segregation Release amended the existing net capital rule for broker-dealers, Exchange Act Rule 15c3–1,[68] in two key respects relevant to FINRA's rules:

• First, the SEC adopted new minimum net capital requirements for broker-dealers that are also registered as SBSDs, but that do not operate pursuant to the alternative net capital (''ANC'') requirements of Exchange Act Rule 15c3–1 (''Non-ANC Firms'').[69] Non-ANC Firms that are also registered as SBSDs will need to comply with a new minimum dollar net capital requirement and a new component for determining their minimum capital requirement that is based on a percentage of initial margin computed for SBS (in addition to other minimum requirements applicable to the broker-dealer).[70] These changes do not apply to broker-dealers that operate pursuant to the ANC requirements of the rule (''ANC Firms''). These new minimum net capital requirements also will not impact Non-ANC Firms that are not also registered as SBSDs, regardless of whether such Non-ANC Firms engage in SBS activities.[71]

[63] *See* 17 CFR 240.3a71–3(d)(1)(ii)(B).

[64] FINRA believes these proposed exceptions are appropriate for similar reasons as the proposed exceptions for SBS Entities in proposed FINRA Rules 0180(c) and (d). *See supra* notes 40 through 44 and 49 through 51 and accompanying text.

[65] A member acting as the U.S. Registered Affiliate under Exchange Act Rule 3a71–3(d) would remain subject to all other FINRA rules applicable to such SBS brokerage activity. *See supra* note 37.

[66] FINRA would consider any such application based on the specific circumstances described in the application and whether the requested exemptive relief would be consistent with the protection of investors and the public interest. FINRA expects that it would apply heightened scrutiny to applications for exemptive relief from members that are not also registered with the SEC as SBS Entities, and therefore not subject to the SEC's regulatory framework for SBS.

[67] *See* Capital, Margin, and Segregation Release, *supra* note 8, at 43954.

[68] 17 CFR 240.15c3–1.

[69] Generally, a broker-dealer may apply to the SEC for authorization to use the alternative method for computing net capital contained in Appendix E to Exchange Act Rule 15c3–1. *See* 17 CFR 240.15c3–1(a)(7). Such broker-dealers are known as ''ANC broker-dealers.'' There are currently five approved ANC broker-dealers. *See* SEC, Broker-Dealers Using the Alternative Net Capital Computation under Appendix E to Rule 15c3–1, *https://www.sec.gov/tm/broker-dealers-alternative-net-capital-computation*. Other broker-dealers are known as non-ANC broker-dealers and must compute net capital pursuant to the provisions of Exchange Act Rule 15c3–1.

[70] *See* 17 CFR. 240.15c3–1(a)(10).

[71] For example, the new minimum net capital requirements do not apply to a Non-ANC Firm engaged in SBS dealing activity below the *de minimis* threshold for SBSD registration, or to a Non-ANC Firm engaged in SBS brokerage activity or entering into non-dealing SBS transactions (*e.g.,* hedging). FINRA notes that the SEC also adopted

Continued

• Second, the SEC changed the minimum net capital requirements for ANC Firms, regardless of whether they transact in SBS. For ANC Firms, the SEC increased the minimum dollar net capital requirement, added a new component for determining the minimum capital requirement that is based on a percentage of initial margin computed for SBS (in addition to other minimum requirements applicable to the broker-dealer), increased the minimum tentative net capital requirement and amended the early warning notification requirement for tentative net capital.[72]

FINRA Rule 4120 (Regulatory Notification and Business Curtailment) sets forth certain early warning notification and business curtailment requirements if a member's capital falls below certain thresholds. Specifically, FINRA Rule 4120(a) requires each carrying or clearing member to notify FINRA if its net capital falls below certain specified levels.[73] FINRA Rule 4120(b) allows FINRA to restrict a member from expanding its business in certain circumstances and FINRA Rule 4120(c) allows FINRA to require a member to reduce its business if its net capital falls below certain specified levels (generally lower than those required for notification under FINRA Rule 4120(a)). These requirements are based on the minimum capital requirements applicable to a member broker-dealer under Exchange Act Rule 15c3–1. FINRA believes it is necessary to amend FINRA Rule 4120 to conform the rule to the new and increased minimum capital requirements for Non-ANC Firms that are also registered as SBSDs and for ANC Firms, as described above.[74]

FINRA Rule 4120(a) requires each carrying or clearing firm to promptly, but in any event within 24 hours, notify FINRA in writing if its net capital falls below any of the percentages specified in subparagraphs (A) through (F) of FINRA Rule 4120(a)(1). The proposed rule change would modify subparagraph (D), which applies to ANC Firms, and also add new subparagraph (E), applicable to Non-ANC Firm members that are also registered SBSDs.[75]

Existing Exchange Act Rule 15c3–1(a)(7)(i) requires an ANC Firm to maintain minimum tentative net capital of not less than $1 billion and minimum net capital of not less than $500 million. In addition, existing Exchange Act Rule 15c3–1(a)(7)(ii) requires an ANC Firm to provide an ''early warning'' notice to the SEC when its tentative net capital falls below $5 billion (or a lower threshold if the SEC has granted an ANC Firm's application to use such lower threshold). Subparagraph (D) of FINRA Rule 4120(a) is based on these net capital requirements, requiring notification to FINRA if the member is an ANC Firm and (i) its tentative net capital under Exchange Act Rule 15c3–1(c)(15) is less than 50 percent of the early warning notification amount required by Exchange Act Rule 15c3–1(a)(7)(ii) or (ii) its net capital is less than $1.25 billion. In other words, notification to FINRA is required if an ANC Firm's tentative net capital falls below $2.5 billion (or a lower amount, if the ANC Firm has been permitted to use a lower early warning notice threshold), which is half of the SEC's early warning notification amount, or its net capital falls below $1.25 billion, which is 2.5 times the SEC's net capital requirement for ANC Firms.

In the Capital, Margin, and Segregation Release, the SEC amended the net capital requirements for ANC Firms in three ways. First, the SEC raised the tentative net capital requirement for ANC Firms from $1 billion to $5 billion. Second, the SEC raised the minimum net capital requirement for ANC Firms from $500 million to the greater of $1 billion or the sum of the applicable ratio requirement under Exchange Act Rule 15c3–1(a)(1)[76] and two percent of the risk margin amount.[77] Third, the SEC raised the tentative net capital early warning notification threshold from $5 billion to $6 billion. In light of these increased capital requirements under the SEC's net capital rule, FINRA believes it is appropriate to also modify the thresholds for required notification to FINRA for ANC Firms under FINRA Rule 4120(a)(1)(D). Specifically, under the proposed rule change, an ANC Firm would be required to notify FINRA if, in addition to the conditions currently prescribed under FINRA Rule 4120(a)(1)(A), (E) and (F):

• Its tentative net capital is less than 150 percent of the minimum tentative net capital amount required by Exchange Act Rule 15c3–1(a)(7)(i)(A) (*i.e.,* $5 billion, such that the notification amount would be $7.5 billion),

• the member is subject to the aggregate indebtedness requirement of Exchange Act Rule 15c3–1(a)(1)(i), and its net capital is less than the sum of 1/10th of its aggregate indebtedness and 150 percent of the required percentage of the risk margin amount,[78] or

• the member elects to use the alternative method of computing net capital pursuant to Exchange Act Rule 15c3–1(a)(1)(ii), and its net capital is less than the sum of the level specified in Exchange Act Rule 17a–11(b)(2)[79] and 150 percent of the required percentage of the risk margin amount.[80]

FINRA believes these modified thresholds are appropriately calibrated to provide FINRA with sufficient early warning that an ANC Firm's capital levels may be deteriorating. By revising the early warning levels as proposed, the proposed rule change aligns the historical thresholds in FINRA Rule

new minimum capital requirements for MSBSPs, including that such entities must at all times have and maintain a tangible net worth. *See* Capital, Margin, and Segregation Release, supra note 8, at 43906–07. FINRA does not believe any changes to FINRA rules are necessary with respect to the new MSBSP capital requirements.

[72] *See* 17 CFR 240.15c3–1(a)(7). The compliance date for the amended minimum net capital requirements for all ANC Firms is the Registration Compliance Date, *i.e.,* October 6, 2021.

[73] As discussed below, FINRA is also proposing to apply all requirements in the FINRA Rule 4000 Series applicable to carrying or clearing firms to members that act as principal counterparty to an SBS, clear or carry an SBS, guarantee an SBS or otherwise have financial exposure to an SBS.

[74] As noted above, the SEC did not amend Exchange Act Rule 15c3–1 to apply increased minimum capital requirements to Non-ANC Firms that engage in SBS activities but that are not registered SBSDs. FINRA is therefore not proposing to amend FINRA Rule 4120 to impose any additional minimum thresholds on such members. However, FINRA notes that, as a general matter, FINRA Rule 4120 would apply to all members that engage in SBS transactions (and any related transactions) because net capital is a holistic calculation based on a firm's liquid net worth, which includes all of a firm's activities.

[75] The proposed rule change would also make non-substantive and conforming changes to other subparagraphs of FINRA Rule 4120(a) to reflect the insertion of new subparagraph (E), update cross-references to SEC rules that have been amended and reflect FINRA rulebook format conventions.

[76] *See* 17 CFR 240.15c3–1(a)(7)(i)(A). Under Exchange Act Rule 15c3–1(a)(1)(i), a broker-dealer generally may not permit its aggregate indebtedness to exceed 1500 percent of its net capital. A broker-dealer may elect not to be subject to the aggregate indebtedness standard if it complies with an alternative method of computing net capital. *See* 17 CFR 240.15c3–1(a)(1)(ii).

[77] The ''risk margin amount'' means the total initial margin for SBS. *See* 17 CFR 15c3–1(c)(17). Exchange Act Rule 15c3–1(a)(7)(i)(A) provides that initially the requirement will be two percent of the risk margin amount. However, the SEC may issue an order raising the requirement to four percent on or after the third anniversary of the amended rule's compliance date and to eight percent on or after the fifth anniversary of the amended rule's compliance date. *See* 17 CFR 15c3–1(a)(7)(i)(A)(2) and (3) and 15c3–1(a)(7)(i)(B).

[78] *See supra* note 77.

[79] *See* 17 CFR 240.17a–11(b)(2). Exchange Act Rule 17a–11 requires broker-dealers to promptly notify the SEC after the occurrence of certain events. Exchange Act Rule 17a–11(b)(2) requires such notification for broker-dealers using the alternative method of computing net capital pursuant to Exchange Act Rule 15c3–1(a)(1)(ii) when net capital is less than five percent of aggregate debit items under the Exchange Act Rule 15c3–3 reserve formula.

[80] *See supra* note 77.

4120(a) for early warning notification for ANC Firms with the revised capital requirements applicable to such firms under the SEC's amended rules. Additionally, ANC Firms historically maintain capital far in excess of the proposed amounts, so FINRA does not expect these levels to be problematic for firms to maintain.

In the Capital, Margin, and Segregation Release, the SEC also added a new minimum net capital requirement for Non-ANC Firms that are also registered as SBSDs.[81] Specifically, a Non-ANC Firm that is registered as an SBSD must maintain minimum net capital of not less than the greater of $20 million or the sum of the ratio requirements under Exchange Act Rule 15c3–1(a)(1)[82] and two percent of the risk margin amount.[83] Accordingly, FINRA believes it is necessary to add corresponding new thresholds for required notification to FINRA for Non-ANC Firms that are also registered SBSDs under new FINRA Rule 4120(a)(1)(E). Specifically, under the proposed rule change, a Non-ANC Firm that is also a registered SBSD would be required to notify FINRA if, in addition to the conditions currently prescribed under FINRA Rule 4120(a)(1)(A), (E) and (F):

• The member is subject to the aggregate indebtedness requirement of Exchange Act Rule 15c3–1(a)(1)(i), and its net capital is less than the sum of 1/10th of its aggregate indebtedness and 150 percent of the required percentage of the risk margin amount,[84] or

• the member elects to use the alternative method of computing net capital pursuant to Exchange Act Rule 15c3–1(a)(1)(ii), and its net capital is less than the sum of the level specified in Exchange Act Rule 17a–11(b)(2)[85] and 150 percent of the required percentage of the risk margin amount.[86]

FINRA believes it is appropriate to include specific thresholds for early notification to FINRA based on the new minimum net capital requirements for Non-ANC Firms that are registered SBSDs. FINRA also believes that the thresholds described above are appropriately calibrated to provide FINRA with sufficient early warning that such a firm's capital levels may be deteriorating. By defining the early warning levels as proposed, the proposed rule change aligns the historical thresholds in FINRA Rule 4120(a) for early warning notification with the new capital requirements applicable to Non-ANC Firms that are registered SBSDs under the SEC's amended rules.

FINRA Rule 4120(b) allows FINRA to require a member that carries customer accounts or clears transactions to not expand its business during any period in which any of the conditions described in paragraph (a)(1) of FINRA Rule 4120 continue to exist for more than 15 consecutive business days, provided that such condition(s) has been known to FINRA or the member for at least five consecutive business days. Since the proposed rule change would modify the conditions specified in FINRA Rule 4120(a)(1) as described above, the triggers for the application of restrictions under FINRA Rule 4120(b) would be similarly affected. However, FINRA does not believe that any conforming changes are needed at this time to the restrictions on business expansion requirements under FINRA Rule 4120(b). FINRA notes that FINRA Rule 4120(b)(3)(A)–(G) includes a non-exclusive list of activities that may constitute an ''expansion of business'' for these purposes, and FINRA Rule 4120(b)(3)(H) provides that the term ''expansion of business'' may include such other activities as FINRA deems appropriate under the circumstances, in the public interest or for the protection of investors. FINRA believes that a member firm's SBS activities would be within the scope of ''other activities'' contemplated by FINRA Rule 4120(b)(3)(H).

FINRA Rule 4120(c) allows FINRA to require a member to reduce its business if its net capital falls below any of the percentages specified in subparagraphs (A) through (F) of FINRA Rule 4120(c)(1). Similar to the proposed modifications to FINRA Rule 4120(a) described above, the proposed rule change would modify subparagraph (D) of FINRA Rule 4120(c)(1), which applies to ANC Firms, and also add new subparagraph (E), applicable to Non-ANC Firm members that are also registered SBSDs.[87]

Current subparagraph (D) of FINRA Rule 4120(c)(1) permits business curtailment if the member is an ANC Firm and (i) its tentative net capital under Exchange Act Rule 15c3–1(c)(15) is less than 40 percent of the early warning notification amount required by Exchange Act Rule 15c3–1(a)(7)(ii) or (ii) its net capital is less than $1 billion. These thresholds are based on the current broker-dealer net capital rule. As described above, the SEC amended the net capital requirements for broker-dealers in the Capital, Margin, and Segregation Release. Accordingly, under the proposed rule change, a member that is an ANC Firm would be subject to the business curtailment provisions of FINRA Rule 4120(c)(1) if, in addition to the conditions currently prescribed under FINRA Rule 4120(c)(1)(A), (E) and (F):

• Its tentative net capital is less than the amount specified under Exchange Act Rule 15c3–1(a)(7)(ii) (*i.e.,* the early warning amount, $6 billion),

• the member is subject to the aggregate indebtedness requirement of Exchange Act Rule 15c3–1(a)(1)(i), and its net capital is less than the sum of 1/12th of its aggregate indebtedness and 125 percent of the required percentage of the risk margin amount,[88] or

• the member elects to use the alternative method of computing net capital pursuant to Exchange Act Rule 15c3–1(a)(1)(ii), and its net capital is less than the sum of one percentage point below the level specified in Exchange Act Rule 17a–11(b)(2)[89] and 125 percent of the required percentage of the risk margin amount.[90]

FINRA believes these modified thresholds are appropriately calibrated to provide FINRA with the ability to require ANC Firms to reduce their business when their capital levels have deteriorated to a level that may jeopardize their ability to continue to comply with their capital requirements.

As described above, in the Capital, Margin, and Segregation Release, the SEC also added a new minimum net capital requirement for Non-ANC Firms that are also registered as SBSDs. Accordingly, the proposed rule change would add corresponding new thresholds for business curtailment for Non-ANC Firms that are also registered SBSDs under new FINRA Rule 4120(c)(1)(E). Specifically, under the proposed rule change, a Non-ANC Firm that is also a registered SBSD would be subject to the business curtailment provisions of FINRA Rule 4120(c)(1) if, in addition to the conditions currently prescribed under FINRA Rule 4120(c)(1)(A), (E) and (F):

• The member is subject to the aggregate indebtedness requirement of

[81] *See* 17 CFR 15c3–1(a)(10).

[82] *See supra* note 76.

[83] *See supra* note 77.

[84] *See supra* note 77.

[85] *See supra* note 79.

[86] *See supra* note 77.

[87] The proposed rule change would also make non-substantive and conforming changes to other subparagraphs of FINRA Rule 4120(c)(1) to reflect the insertion of new subparagraph (E), update cross-references to SEC rules that have been amended and reflect FINRA rulebook format conventions. Similar non-substantive changes would be made to paragraph (b)(1) and Supplementary Material .01 to FINRA Rule 4120 to reflect FINRA rulebook format conventions.

[88] *See supra* note 77.

[89] *See supra* note 79.

[90] *See supra* note 77.

Exchange Act Rule 15c3–1(a)(1)(i), and its net capital is less than the sum of 1/12th of its aggregate indebtedness and 125 percent of the required percentage of the risk margin amount,[91] or

• the member elects to use the alternative method of computing net capital pursuant to Exchange Act Rule 15c3–1(a)(1)(ii), and its net capital is less than the sum of one percentage point below the level specified in Exchange Act Rule 17a–11(b)(2) [92] and 125 percent of the required percentage of the risk margin amount.[93]

FINRA believes it is appropriate to include specific thresholds for business curtailment based on the new minimum net capital requirements for Non-ANC Firms that are registered SBSDs. FINRA also believes that the thresholds described above are appropriately calibrated to provide FINRA with the ability to require such firms to reduce their business when their capital levels have deteriorated to a level that may jeopardize their ability to continue to comply with their capital requirements.

Lastly, FINRA notes that FINRA Rule 4120(c)(3)(A)–(J) includes a non-exclusive list of activities that may constitute a ''business reduction'' for these purposes, and FINRA Rule 4120(c)(3)(K) provides that the term ''business reduction'' may include such other activities as FINRA deems appropriate under the circumstances, in the public interest or for the protection of investors. FINRA believes that a member firm's SBS activities would be within the scope of ''other activities'' contemplated by FINRA Rule 4120(c)(3)(K).

In addition to these conforming changes to FINRA Rule 4120, the proposed rule change would apply FINRA's financial and operational rules more broadly to firms that enter into, or otherwise have exposure to, SBS. Specifically, certain rules in the FINRA Rule 4000 Series (Financial and Operational Rules) include provisions that impose higher standards, or provide FINRA the authority to impose additional requirements, on firms that carry or clear transactions or accounts (generally referred to as ''carrying or clearing firms''). This ''tiering'' structure was built into certain rules so that firms that only introduce their customer accounts and do not have exposure to the settlement system are provided relief from the higher standards required of firms that carry or clear transactions and accounts. Below is a list of rules in the FINRA Rule 4000 Series where tiering has been employed for carrying or clearing firms and a brief description of the tiered requirements for such firms:

• FINRA Rule 4110 (Capital Compliance) includes requirements for carrying or clearing firms to keep greater net capital, seek permission for withdrawals of capital and seek approval for certain add-backs to net capital.

• FINRA Rule 4120 (Regulatory Notification and Business Curtailment) includes restrictions on expanding, or requirements to reduce business, if sufficient capital levels are not maintained.

• FINRA Rule 4521 (Notifications, Questionnaires and Reports) allows FINRA to collect additional data and require reporting of a material decline in tentative net capital.

• FINRA Rule 4522 (Periodic Security Counts, Verification and Comparison) requires more frequent security counts, verifications and comparisons than would be required under Exchange Act Rule 17a–13.[94]

• FINRA Rule 4523 (Assignment of Responsibility for General Ledger Accounts and Identification of Suspense Accounts) requires a record of primary and supervisory named individuals over general ledger bookkeeping accounts.

The intent of the tiering employed in these rules in the FINRA Rule 4000 Series is to impose higher capital, recordkeeping and operational standards on firms that carry or clear transactions and accounts, and therefore may have financial exposure to customers, other broker-dealers, central counterparties or others. FINRA believes that similar considerations apply for members with exposure to SBS. SBS are complex transactions that will, by their nature, require detailed recordkeeping, margining, legal agreements, collateral management, reconciliation and risk management. FINRA therefore believes it is appropriate to also employ tiering in the FINRA Rule 4000 Series for members that enter into SBS on a principal basis or otherwise have financial exposure to SBS. Specifically, under the proposed rule change, proposed FINRA Rule 0180(h) would provide that, for purposes of the FINRA Rule 4000 Series, all requirements that apply to a member that clears or carries customer accounts shall also apply to any member that acts as a principal counterparty to an SBS, clears or carries an SBS, guarantees an SBS or otherwise has financial exposure to an SBS.[95] FINRA believes that applying these higher standards when a member enters into SBS or otherwise has exposure to SBS is appropriate and consistent with the protection of investors and the public interest.

Margin Requirements

As discussed above, in June 2019 the Commission adopted its final Capital, Margin, and Segregation Release, with a compliance date aligned with the Registration Compliance Date.[96] Among other things, the Capital, Margin, and Segregation Release adopted new Exchange Act Rule 18a–3, which prescribes margin requirements for nonbank SBSDs with respect to uncleared SBS.[97] Generally, Exchange Act Rule 18a–3 requires a nonbank SBSD to calculate, for each account of an SBS counterparty as of the close of business of each day: (i) The amount of current exposure in the account (*i.e.,* variation margin) and (ii) the initial margin amount for the account.[98] Under Exchange Act Rule 18a–3, variation margin must be calculated by marking the position to market, while initial margin must generally be calculated using standardized haircuts, which are prescribed in Exchange Act Rule 15c3–1 for nonbank SBSDs that are registered broker-dealers.[99] Nonbank SBSDs may apply to the SEC for authorization to use models to calculate initial margin instead of the standardized haircuts (including the option to use the more risk sensitive methodology in Exchange Act Rule 15c3–1a), but nonbank SBSDs that are

[91] *See supra* note 77.

[92] *See supra* note 79.

[93] *See supra* note 77.

[94] *See* 17 CFR 240.17a–13. Exchange Act Rule 17a–13 generally requires broker-dealers to perform quarterly security counts.

[95] Although this proposed tiering provision relates to the financial responsibility and operational rules, FINRA believes it should be included as a paragraph in proposed FINRA Rule 0180 so that all provisions relating to the treatment of SBS under FINRA rules are found in a single, consolidated rule.

[96] *See* Capital, Margin, and Segregation Release, *supra* note 8, at 43954.

[97] *See* 17 CFR 240.18a–3. Exchange Act Rule 18a–3 also prescribes margin requirements for nonbank MSBSPs with respect to uncleared SBS. As discussed above, Exchange Act Rule 18a–3 generally requires SBSDs to collect or deliver variation margin, and also to collect initial margin, with respect to its SBS counterparties. However, Exchange Act Rule 18a–3 requires that a nonbank MSBSP only collect and deliver variation margin, without prescribing any initial margin requirement. *See* Capital, Margin, and Segregation Release, *supra* note 8, at 43877. As discussed below, FINRA believes it is appropriate to apply variation margin and initial margin requirements to all of its members that transact in uncleared SBS. Therefore, proposed FINRA Rule 4240 would provide an exception for members that are registered as SBSDs (and therefore subject to the variation and initial margin requirements of Exchange Act Rule 18a–3), but not for members that are registered as MSBSPs.

[98] *See* 17 CFR 240.18a–3(c)(1)(i); Capital, Margin, and Segregation Release, *supra* note 8, at 43876.

[99] *See* 17 CFR 240.18a–3(d).

registered broker-dealers must use standardized haircuts to calculate initial margin for uncleared equity SBS.[100] Based on these calculations, Exchange Act Rule 18a–3 generally requires a nonbank SBSD to collect and deliver variation margin, and to collect (but not deliver) initial margin.[101] Exchange Act Rule 18a–3 also provides certain exceptions from the margin requirements, establishes thresholds and minimum transfer amounts, specifies collateral requirements (including collateral haircuts), establishes risk monitoring requirements and includes other miscellaneous provisions, such as definitions. All nonbank SBSDs, including nonbank SBSDs that are FINRA members, will become subject to the margin requirements set forth in Exchange Act Rule 18a–3 beginning on the Registration Compliance Date.

The FINRA Rule 4200 Series sets forth margin requirements applicable to FINRA members. In particular, FINRA Rule 4210 describes the margin requirements that determine the amount of equity or ''margin'' customers are expected to maintain in their securities accounts, including margin requirements for equity and fixed income securities as well as options, warrants and security futures. Current FINRA Rule 4240 separately establishes an interim pilot program with respect to margin requirements for any transactions in CDS held in an account at a member (the ''Interim Pilot Program''). Under current FINRA Rule 0180, FINRA Rule 4210 does not apply to members' activities and positions with respect to SBS, but current FINRA Rule 4240 does apply to activities and positions within its scope. Therefore, to the extent that a FINRA member enters into SBS that are CDS, the margin requirements under the Interim Pilot Program apply to such SBS.[102] However, the Interim Pilot Program is a temporary rule, and SBS that are not CDS are not currently subject to any margin requirements under FINRA rules.

The Interim Pilot Program was originally proposed by FINRA and approved by the Commission in 2009 specifically to address concerns arising from systemic risk posed by CDS.[103] Pending the SEC's final implementation of the Title VII rulemakings, FINRA has extended the expiration date of the Interim Pilot Program a number of times, mostly recently in June 2020.[104] The Interim Pilot Program under current FINRA Rule 4240 is currently set to expire on September 1, 2021, the same date that current FINRA Rule 0180 is set to expire.[105]

In light of the finalization of the SEC's margin requirements for nonbank SBSDs under Exchange Act Rule 18a–3 and the upcoming Registration Compliance Date, FINRA believes it is appropriate and in the public interest for the Interim Pilot Program to expire and for FINRA to adopt a new margin rule specifically applicable to SBS.[106] Accordingly, under the proposed rule change, current FINRA Rule 4240 would be replaced by a new FINRA Rule 4240 on October 6, 2021 that would prescribe margin requirements for SBS. Consistent with Exchange Act Rule 18a–3—and unlike the Interim Pilot Program—proposed new Rule 4240 would apply margin requirements to all SBS, not just CDS. However, proposed new FINRA Rule 4240 would not apply to any member that is registered as an SBSD, as such members will be subject to the margin requirements of Exchange Act Rule 18a–3 as summarized above. Additionally, and consistent with the SEC's approach under the Act and Exchange Act Rule 18a–3, proposed FINRA Rule 4240 would defer to registered clearing agencies to set the margin requirements for cleared SBS, and as such would only specify new variation margin and initial margin requirements for uncleared SBS. Therefore, the specific new margin requirements prescribed under proposed FINRA Rule 4240 would only apply to uncleared SBS transacted by FINRA members that are not registered SBSDs. FINRA believes that, by applying margin requirements in these circumstances, the proposed rule change would fill an important regulatory gap, protect FINRA members against counterparty credit risk, maintain a level playing field for members and prevent regulatory arbitrage. As described in further detail below, the margin requirements under proposed FINRA Rule 4240 would be structurally aligned with the margin requirements that will apply to nonbank SBSDs under Exchange Act Rule 18a–3, with certain modifications that FINRA believes are necessary given that such members will not be subject to the SEC's comprehensive regulatory framework for SBSDs. Thus, subject to certain exceptions described in the proposed rule, proposed FINRA Rule 4240 would require members that are not SBSDs to collect and deliver variation margin on a daily basis to cover the member's current exposure to or from each uncleared SBS counterparty, and also to collect (but not deliver) initial margin from each SBS counterparty.

Proposed FINRA Rule 4240 is divided into a header followed by paragraphs (a) through (d). The header would specify the scope of the margin requirements under proposed FINRA Rule 4240. Paragraph (a) would describe the margin requirements for cleared SBS. Paragraph (b) would describe the margin requirements for uncleared SBS. Specifically, paragraph (b)(1) would set forth how variation margin must be calculated, paragraph (b)(2) would set forth how initial margin must be calculated, paragraph (b)(3) would prescribe the collection and delivery requirements for variation and initial margin, paragraph (b)(4) would specify the manner and time of collection or delivery of variation and initial margin, and paragraph (b)(5) would list certain exceptions from the margin requirements. Paragraph (c) would require members to employ specified risk monitoring procedures and guidelines for uncleared SBS. Finally, paragraph (d) would define certain terms used in proposed FINRA Rule 4240. Each of these aspects of the proposed rule change is described in further detail below.

Proposed FINRA Rule 4240 would be entitled ''Security-Based Swap Margin Requirements.'' [107] The header text to

[100] *See supra* note 99; Capital, Margin, and Segregation Release, *supra* note 8, at 43876.

[101] *See* 17 CFR 240.18a–3(c)(1)(ii).

[102] For purposes of current FINRA Rule 4240, the term ''credit default swap'' includes any product that is commonly known to the trade as a ''credit default swap'' and is an SBS as defined pursuant to Section 3(a)(68) of the Act or the rules and guidance of the SEC and its staff. *See* FINRA Rule 4240(a).

[103] *See* Securities Exchange Act Release No. 59955 (May 22, 2009), 74 FR 25586 (May 28, 2009) (Order Approving File No. SR–FINRA–2009–012).

[104] *See supra* note 16.

[105] *See supra* note 18.

[106] FINRA notes that, under the proposed rule change, proposed FINRA Rule 0180 would no longer provide an exception from current FINRA Rule 4210 applying to members' activities and positions with respect to SBS. Absent additional changes, therefore, the general margin requirements under FINRA Rule 4210 would apply to SBS. However, as described above, FINRA believes specifically listing SBS within the exceptions listed in FINRA Rule 4210, and adopting a separate, new FINRA Rule 4240 applicable to SBS, would promote legal certainty and provide clarity to its members.

[107] In addition to the new provisions under proposed FINRA Rule 4240 discussed above, the implementation of new margin requirements for SBS under proposed FINRA Rule 4240 will also require a conforming change to FINRA Rule 4220 (Daily Record of Required Margin). FINRA Rule 4220 requires each member carrying securities margin accounts for customers to make a record each day of every case in which initial or additional margin must be obtained in a customer's account. To ensure that similar records are maintained for SBS margin required under proposed new FINRA

Continued

the rule would state that each member that is a party to an SBS with a customer, broker or dealer, or other Counterparty,[108] or who has guaranteed or otherwise become responsible for any other person's SBS obligations, shall comply with the requirements of proposed FINRA Rule 4240, except that a member that is registered as an SBSD shall instead comply with Exchange Act Rule 18a–3. This provision of the proposed rule is intended to clarify that the margin requirements under proposed FINRA Rule 4240 apply in all circumstances where a member is a party to a SBS, regardless of the type of counterparty, and also where a member has financial exposure to an SBS, whether through a guarantee or other arrangements under which the member is responsible for another person's SBS obligations. FINRA believes that this provision is necessary to ensure that the proposed margin requirements adequately protect member firms against counterparty credit risk, regardless of the specific manner through which the member has become exposed to such risk. Additionally, as discussed above, this provision clarifies that members that are registered SBSDs are not subject to the proposed margin requirements because they are instead required to comply with Exchange Act Rule 18a–3. FINRA believes it should defer to the SEC's margin framework for registered SBSDs rather than impose additional or different requirements on such entities.

Proposed FINRA Rule 4240(a), entitled ''Cleared SBS Margin Requirements,'' would state that, except as provided in paragraph (b)(5) (*i.e.,* specified exceptions from proposed FINRA Rule 4240, discussed below), the margin to be maintained on any Cleared SBS is the margin on such Cleared SBS required by the Clearing Agency through which such SBS is Cleared. As discussed above, this provision clarifies that proposed FINRA Rule 4240 defers to registered clearing agencies to set the margin requirements for cleared SBS. FINRA believes that it is appropriate to defer to clearing agencies to establish margin requirements for cleared SBS in light of the SEC's comprehensive regulation of clearing agencies, including their required margin levels, under the Act.

Proposed FINRA Rule 4240(b), entitled ''Uncleared SBS Margin Requirements,'' would set forth the substantive margin requirements applicable to members that are not SBSDs when such members transact in Uncleared SBS. Paragraph (b)(1), entitled ''Current Exposure Calculation,'' would require that, as of the close of business of each business day, the member calculate with respect to each Uncleared SBS Account [109] the Counterparty's Current Exposure to the member (if positive) or the member's Current Exposure to the Counterparty (if negative). Current Exposure would be calculated as an amount equal to the net Value [110] of all Uncleared SBS in the Uncleared SBS Account plus the Value of all Variation Margin collected from the Counterparty minus the Value of all Variation margin delivered to the Counterparty.[111] This provision would define a member's Current Exposure for purposes of collecting or delivering Variation Margin under proposed FINRA Rule 4240(b)(3), discussed below, by taking into account the net Value of SBS in the Counterparty's account together with any Variation Margin that has already been collected or delivered. FINRA believes this calculation is consistent with the variation margin requirements under Exchange Act Rule 18a–3.

Proposed FINRA Rule 4240(b)(2), entitled ''Initial Margin Computation,'' would require that, as of the close of business on each business day, the member compute the Initial Margin Requirement for each Uncleared SBS Account equal to the sum of the Initial Margin Requirements on the Uncleared SBS and securities positions in that Uncleared SBS Account. The remainder of proposed FINRA Rule 4240(b)(2) describes how a member must calculate the Initial Margin Requirement, which is then used for purposes of collecting Initial Margin under proposed FINRA Rule 4240(b)(3), discussed below.[112] Under the proposed rule change, the Initial Margin Requirement would depend on the type of uncleared SBS involved, with different requirements depending on whether the uncleared SBS is (i) a ''plain vanilla'' CDS; (ii) a

---

Rule 4240, the proposed rule change would update FINRA Rule 4220 to also require such records for each member subject to proposed FINRA Rule 4240.

In addition, the proposed rule change would add new Supplementary Material .06 to FINRA Rule 4210 to clarify that a Regulation T good faith account, other than a non-securities account, is a margin account for purposes of FINRA Rule 4210. This provision is intended merely to codify FINRA's existing interpretation regarding the scope of FINRA Rule 4210. The proposed rule change would also include a parallel provision in new Supplementary Material .01 to proposed new Rule 4240.

Finally, the proposed rule change would make two other conforming changes to FINRA Rule 4210, including to add proposed new FINRA Rule 4240(e)(9) and to make a technical adjustment to FINRA Rule 4240(g)(2)(H). These proposed changes are discussed below.

[108] ''Counterparty'' would be defined under proposed FINRA Rule 4240(d)(5) to mean a person with whom a member has entered into an Uncleared SBS. An ''SBS'' would be defined in proposed FINRA Rule 4240(d)(16) by reference to the definition of ''security-based swap'' under Section 3(a)(68) of the Act and ''Uncleared'' would be defined in proposed FINRA Rule 4240(d)(18) as an SBS that is not Cleared. Under proposed FINRA Rule 4240(d)(3), an SBS would be considered Cleared if it is cleared through a Clearing Agency by or on behalf of the member, and Clearing Agency would be defined under proposed FINRA Rule 4240(4) as a clearing agency registered pursuant to Section 17A of the Act or exempted by the SEC from such registration by a rule or order pursuant to Section 17A of the Act.

[109] Under proposed FINRA Rule 4240(d)(19), an ''Uncleared SBS Account'' would be defined to mean an account with respect to a Counterparty consisting of all Uncleared SBS between the member and the Counterparty, together with long or short positions for Variation Margin in the form of securities collected or delivered, respectively, credit or debit balances for Variation Margin in the form of cash collected or delivered, respectively, and long positions or credit balances for Initial Margin collected in the form of securities or cash, respectively. The definitions of ''Variation Margin'' and ''Initial Margin'' are discussed below.

[110] ''Value'' would be defined in proposed FINRA Rule 4240(d)(20). Under this definition, the Value of one or more SBS would be the mid-market replacement cost for such SBS. The Value of a security position would be the current market value of such margin securities, as defined in FINRA Rule 4210(a)(2) and determined in accordance with FINRA Rule 4210(f)(1) (*i.e.,* the provisions of FINRA's general margin rule used to determine the current market value of margin securities). Alternatively, a member could elect to determine the Value of margin securities collected as Variation Margin or Initial Margin by applying a haircut to the current market value of such securities equal to the margin requirement that would be applicable to them under FINRA Rule 4210 if they were held in the Counterparty's margin account (in which case, however, such margin securities would not be required to be themselves margined under proposed FINRA Rule 4240(b)(2)(A)(iii)). The Value of cash in U.S. dollars would be the amount of such cash, while the Value of freely convertible foreign currency would be the amount of U.S. dollars into which the currency could be converted, provided the currency is marked-to-market daily.

[111] Under proposed FINRA Rule 4240(d)(21), ''Variation Margin'' would be defined to mean the cash or margin securities collected from, or delivered to, a Counterparty in accordance with proposed FINRA Rule 4240(b)(3)(A), as discussed below. Under proposed FINRA Rule 4240(b)(2)(A)(iii), all securities deposited as Variation Margin for Uncleared SBS would themselves be margined in accordance with FINRA Rule 4210, unless the member has chosen to haircut them for purposes of determining their Value. *See supra* note 110.

[112] Under proposed FINRA Rule 4240(d)(9), the term ''Initial Margin'' would be defined to mean all cash or marginable securities, excluding Variation Margin, received by the member for a Counterparty's Uncleared SBS Account or transferred to the Counterparty's Uncleared SBS Account from another account at the member, including margin collected from a Counterparty in accordance with proposed FINRA Rule 4240(b)(3)(B), as discussed below, that in each case have not been returned to the Counterparty or applied to an obligation of the Counterparty. Under proposed FINRA Rule 4240(b)(2)(A)(iii), all securities deposited as Initial Margin for Uncleared SBS would themselves be margined in accordance with FINRA Rule 4210, unless the member has chosen to haircut them for purposes of determining their Value. *See supra* note 110.

''plain vanilla'' SBS other than an CDS (*i.e.,* an SBS that is the economic equivalent of a margin account containing a portfolio of long or short positions in securities or options, such as a ''plain vanilla'' equity total return swap (''TRS'')); or (iii) any other type of SBS (*e.g.,* a complex CDS or equity TRS that would not be considered ''plain vanilla'' under the proposed rule, including for example a CDS swaption, or a dividend swap). FINRA believes that differentiation as to initial margin requirements among these different types of SBS is appropriate and necessary given the unique characteristics and risks posed by different SBS products.

Proposed paragraphs (b)(2)(A)(i) and (ii) would define the Initial Margin Requirements for uncleared plain vanilla CDS (referred to as ''Basic CDS'') [113] and other uncleared ''plain vanilla'' SBS (referred to as ''Basic SBS''),[114] respectively. First, the Initial Margin Requirement for an Uncleared Basic CDS would generally be computed based on the term and spread of the Uncleared Basic CDS, using the chart and offsets set out in Exchange Act Rule 15c3–1(c)(2)(vi)(P).[115] The proposed rule would therefore follow Exchange Act Rule 18a–3(d)(1)(i) by determining the Initial Margin Requirement for Uncleared Basic CDS using the haircuts applicable to such SBS under the SEC's net capital rule. FINRA believes that determining initial margin for CDS in this manner would promote regulatory consistency and reduce potential arbitrage. Additionally, the haircuts prescribed in Exchange Act Rule 15c3–1(c)(2)(vi)(P) are substantially similar to existing FINRA Rule 4240 margin requirements, so in effect the proposed requirements have already been used during the Interim Pilot Program. Second, the Initial Margin Requirement for a Basic SBS would generally be computed by applying FINRA Rule 4210 to the Equivalent Margin Account. Since an Uncleared Basic SBS would be the economic equivalent of a margin account that would otherwise be governed by the margin provisions of FINRA Rule 4210, FINRA believes it is appropriate to treat such SBS similarly.

In addition, proposed FINRA Rule 4240(b)(2)(A) would permit the Initial Margin Requirements for both Uncleared Basic CDS and Uncleared Basic SBS to be computed based on a combination of multiple SBS and securities or options positions, as applicable and subject to certain conditions. Specifically, proposed FINRA Rule 4240(b)(2)(A)(i) would provide that, if the member has a netting or collateral agreement that is legally enforceable against the Counterparty and covers any combination of Uncleared Basic CDS or securities specified in clause (iii), (iv) or (v) of Exchange Act Rule 15c3–1(c)(2)(vi)(P)(1) (*i.e.,* specified offsetting debt securities), the member may compute the Initial Margin Requirement on such combination of positions equal to the ''haircut'' on that combination under Exchange Act Rule 15c3–1(c)(2)(vi)(P)(1). Proposed FINRA Rule 4240(b)(2)(A)(ii) would similarly provide that, if the member has a netting or collateral agreement that is legally enforceable against the Counterparty and covers any combination of Uncleared Basic SBS, securities or options positions, the member may compute the Initial Margin Requirement on the combination of such positions equal to the margin that FINRA Rule 4210 would require to be maintained on the combination of Equivalent Margin Accounts for such Uncleared Basic SBS and securities or options positions. Proposed FINRA Rule 4240(b)(2)(B) would impose conditions on computing the Initial Margin Requirement using these combination methods, including that (i) securities positions must be in the Counterparty's Uncleared SBS Account or margin account at the member; (ii) securities may not be included if the member has chosen to haircut them for purposes of determining their Value; [116] (iii) options positions must be in the Counterparty's margin account at the member; (iv) no SBS, security or option positions may be included in more than one combination; and (v) no combinations may include securities or options positions for which reduced margin requirements are computed under FINRA Rule 4210(e)(1) (*i.e.,* reduced margin requirements for offsetting long and short positions) or 4210(f)(2)(F)(ii) through (f)(2)(l) (*i.e.,* various reduced margin requirements for certain options, including covered options and offsetting options positions). FINRA believes these conditions would ensure that the Initial Margin Requirement calculated using the combination method is based on securities and options positions that the member actually has in its possession and does not reflect reductions in value that would inappropriately lower the margin requirement. In addition, proposed FINRA Rule 4240(b)(2)(B) would provide that if the Initial Margin Requirement is computed on a combination as described above, the Initial Margin Requirement on the Uncleared SBS included in the combination shall be reduced (but not below zero) by the aggregate maintenance margin requirements under FINRA Rule 4210 applicable to such margin account positions. FINRA believes that this provision would appropriately take into account margin already collected under FINRA Rule 4210 with respect to such positions.[117]

The proposed rule change would not specify Initial Margin Requirements for other Uncleared SBS that do not qualify as Basic CDS or Basic SBS. Instead, proposed FINRA Rule 4240(b)(2)(A)(iv) would provide that the Initial Margin Requirement for any Uncleared SBS other than a Basic CDS or Basic SBS

[113] Under proposed FINRA Rule 4240(d)(1), a ''Basic CDS'' would be defined to mean a Basic Single Name Credit Default Swap or a Basic Narrow-Based Index Credit Default Swap. A Basic Single-Name Credit Default Swap would mean an SBS in which one party pays either a single fixed amount or periodic fixed amounts or floating amounts determined by reference to a specified notional amount, and the other party pays either a fixed amount or an amount determined by reference to the value of one or more loans, debt securities or other financial instruments issued, guaranteed or otherwise entered into by a third party (*i.e.,* the ''Reference Entity'') upon the occurrence of one or more specified credit events with respect to the Reference Entity (for example, bankruptcy or payment default). The term ''Basic Single-Name Credit Default Swap'' would also include a swap that, upon the occurrence of one or more specified credit events with respect to the Reference Entity, is physically settled by payment of a specified fixed amount by one party against delivery by the other party of eligible obligations of the Reference Entity. A Basic Narrow-Based Index Credit Default Swap would be defined to mean an SBS consisting of multiple component Basic Single-Name Credit Default Swaps.

[114] Under proposed FINRA Rule 4240(d)(2), a ''Basic SBS'' would be defined to mean an SBS, other than a CDS, under which each party is contractually obligated to provide the other the economic equivalent of a margin account containing a portfolio of long or short positions in securities or options (*i.e.,* an ''Equivalent Margin Account'').

[115] *See* 17 CFR 240.15c3–1(c)(2)(vi)(P). This provision of the SEC's broker-dealer net capital rule defines the haircuts applicable to uncleared SBS.

[116] *See supra* note 110.

[117] In connection with this proposed provision of FINRA Rule 4240(b)(2)(B), the proposed rule change would also add a new paragraph (e)(9) to FINRA Rule 4210, entitled ''Security-Based Swaps; SBS Offsets.'' Specifically, where the Initial Margin Requirement on the combination of SBS and a securities or options position in the margin account would be less than the FINRA Rule 4210 maintenance requirement on the margin account positions, proposed FINRA Rule 4210(e)(9) would reduce the FINRA Rule 4210 maintenance requirement on the margin account positions to equal the computed Initial Margin Requirement.

In addition, proposed FINRA Rule 4210(e)(9) would clarify that, except for SBS carried by a member in a portfolio margin account subject to the requirements of FINRA Rule 4210(g), as discussed below, margin requirements on SBS and positions in Uncleared SBS Accounts are determined by proposed FINRA Rule 4240, rather than FINRA Rule 4210. FINRA believes that including this express statement regarding the applicability of each of its margin rules to SBS would enhance clarity and reduce legal uncertainty for its members.

would be determined in a manner approved by FINRA pursuant to proposed FINRA Rule 4240(b)(2)(C), which would permit a member to apply to FINRA for the approval of an Initial Margin Requirement for any other type of SBS. Under the proposed rule change, any such application would be required to:

- Define the specific type of SBS covered by the application;
- describe the purpose(s) that the member and its Counterparties would have for entering that type of SBS;
- identify all variables that influence the value of that type of SBS;
- explain all risks of that type of SBS;
- propose a specific Initial Margin Requirement (not a margin model) for that type of SBS;
- explain how the proposed specific Initial Margin Requirement would adequately protect a member and its capital against each of those risks;
- attach copies of the member's SBS risk management procedures and describe the application of those procedures to that type of SBS; and
- provide the results of backtesting of the proposed specific Initial Margin Requirement over periods of significant volatility in the variables influencing the value of that type of SBS.

Proposed FINRA Rule 4240(b)(2)(C) would further provide that, if FINRA approves any such application, the approval may be unconditional or conditional, including in the form of a time-limited pilot program; may approve the use of the specific Initial Margin Requirement only by the applicant; or may take the form of a *Regulatory Notice* or other communication approving the use of the specific margin requirements by members generally. Under proposed FINRA Rule 4240(b)(2)(C), no member would be permitted to become a party to an SBS other than a Basic CDS or Basic SBS unless FINRA has approved an Initial Margin Requirement for such member's use with respect to that type of SBS. As described above, the Initial Margin Requirements for Basic CDS are based on the SEC's treatment of such SBS under its net capital rule, while the Initial Margin Requirements for Basic SBS are based on the margin that would be required for a margin account that would be the economic equivalent of such SBS. However, other types of SBS—including CDS and equity TRS with complex features—may not be easily accommodated under these frameworks, and the specific risks that accompany such SBS may not be readily apparent or quantifiable to FINRA without additional information. Moreover, as noted above SBS can be complex financial instruments that pose substantial risks to members and margin serves as an important means of protecting member firms, and thereby their customers and investors, from such risks. FINRA therefore believes that members that are not SBSDs (and therefore not subject to the SEC's comprehensive regulatory framework for registrants under Title VII of Dodd-Frank) should not be permitted to enter into other types of SBS unless and until FINRA has evaluated the risks of such SBS and approved margin requirements that adequately address such risks. If FINRA determines that a proposed margin requirement does not adequately address the risks for a particular type of SBS, FINRA would not approve the application under proposed FINRA Rule 4240(b)(2)(C), and members would not be permitted to enter into such SBS. To FINRA's knowledge, this SBS activity by members that do not plan to register as SBSDs is relatively limited.

Proposed FINRA Rule 4240(b)(3), entitled ''Collection or Delivery of Variation and Initial Margin,'' would set forth a member's obligation to collect or deliver margin as calculated pursuant to proposed FINRA Rule 4240(b)(1) and (2), described above. Paragraph (b)(3)(A) would require each member to deliver or return to each Counterparty cash or margin securities with a Value equal to the Counterparty's Current Exposure (if any) to the member, or collect or retrieve from the Counterparty cash or margin securities with a Value equal to the member's Current Exposure (if any) to the Counterparty. Paragraph (b)(3)(B) would require each member to collect from each Counterparty cash or margin securities with a Value at least equal to any Initial Margin Deficit.[118] Therefore, consistent with Exchange Act Rule 18a–3, proposed FINRA Rule 4240(b)(3) would require members that are not SBSDs to collect and deliver Variation Margin, and also to collect (but not deliver) Initial Margin, in amounts determined pursuant to the provisions of FINRA Rule 4240(b)(1) and (2) described above, for their transactions in Uncleared SBS.[119]

Proposed FINRA Rule 4240(b)(4), entitled ''Manner and Time of Collection or Delivery of Variation and Initial Margin; Prohibited Returns and Withdrawals,'' would set forth additional detailed requirements and clarifications regarding the manner and time of collection or delivery of variation and initial margin, as calculated pursuant to proposed FINRA Rules 4240(b)(1) and (2) and collected or delivered in accordance with proposed FINRA Rule 4240(b)(3), as described above. Specifically, proposed FINRA Rule 4240(b)(4) would provide for the following:

- Under proposed FINRA Rule 4240(b)(4)(A), margin would be deemed collected or returned to the member when it is received in the Counterparty's Uncleared SBS Account at the member (or transferred to such account from another account at the member).
- Under proposed FINRA Rule 4240(b)(4)(B), margin would be deemed collected or returned to the Counterparty when it is transferred from the Counterparty's Uncleared SBS Account at the member in accordance with the Counterparty's instructions or agreement with the member, which could potentially include transfer to another account of the Counterparty carried by the member.
- Under proposed FINRA Rule 4240(b)(4)(C), margin would be required to be collected or delivered pursuant to proposed FINRA Rule 4240(b)(3) as promptly as possible, but in any case no later than the close of business on the business day after the date on which the Current Exposure or Initial Margin Requirement was required to be computed in accordance with proposed FINRA Rule 4240(b)(1) or (2) (*i.e.,* margin would generally be required to be delivered or collected on a T+1 basis). Further, unless FINRA has specifically granted the member additional time, a member that has not collected margin as required by the close of business on the third business day (*i.e.,* by T+3) would be required to take prompt steps to liquidate positions in the Counterparty's Uncleared SBS Account to eliminate the margin deficiency.
- Proposed FINRA Rule 4240(b)(4)(D) would require a member to net the

[118] Under proposed FINRA Rule 4240(d)(10), the term ''Initial Margin Deficit'' would be defined as the amount, if any, by which (A) the sum of the Value of the Initial Margin in an Uncleared SBS Account and the Counterparty's Rule 4210 Excess is less than (B) the Initial Margin Requirement for the Uncleared SBS Account. A person's ''Rule 4210 Excess'' would be defined in proposed FINRA Rule 4240(d)(15) to mean the amount, if any, by which the equity (as defined in FINRA Rule 4210(a)(5)) in the Counterparty's margin account at the member exceeds the amount required by FINRA Rule 4210.

[119] To account for situations where a member is not the actual party to an SBS, but nonetheless has financial exposure for Uncleared SBS (*e.g.,* through a guarantee), proposed FINRA Rule 4240(b)(3)(C) would also require a member to collect both Variation Margin and Initial Margin from the party that has obligations under the Uncleared SBS for which the member has responsibility, to the extent that such collection would be required if the member were a party to the Uncleared SBS, unless the member can establish that such margin has been delivered to the other party.

delivery or return of Variation Margin against the collection of Initial Margin, if applicable, and would further permit a member to net the return of Initial Margin against the collection or retrieval of Variation Margin, if applicable.

• Proposed FINRA Rule 4240(b)(4)(E) would prohibit a member from returning Initial Margin to a Counterparty, or permitting a Counterparty to make a withdrawal from the Counterparty's margin account, if doing so would create or increase an Initial Margin Deficit.

FINRA believes it is appropriate and consistent with the protection of member firms and investors to require margin for uncleared SBS to be delivered or collected, as applicable, on a T+1 basis, and to further require that uncleared SBS positions be liquidated if margin is not collected within a T+3 timeframe. FINRA also believes the other clarifications described above are necessary to ensure that members and their uncleared SBS counterparties have a clear and consistent understanding of when and how margin must be delivered or collected under the proposed rule change.

Proposed FINRA Rule 4240(b)(5), entitled ''Exceptions,'' would provide eight specific exceptions from a member's general obligation to collect or deliver margin, as applicable, under proposed FINRA Rule 4240(b)(3), described above. FINRA believes the proposed exceptions would further align the requirements of proposed FINRA Rule 4240 with the margin requirements applicable to SBSDs under Exchange Act Rule 18a–3 and provide members with additional flexibility in managing their risk exposures, while still ensuring that the risks to members with respect to their uncleared SBS exposures are adequately addressed. The proposed exceptions under FINRA Rule 4240(b)(5) would include the following:

• *Clearing Agencies.* A member would not be required to deliver Variation Margin to, or collect Initial Margin or Variation Margin from, any Clearing Agency, and would also not be required to deduct otherwise required Variation Margin or Initial Margin in the computation of its net capital under Exchange Act Rule 15c3–1 or, if applicable, FINRA Rule 4110(a). FINRA believes this exception is consistent with its determination to defer to Clearing Agency margin requirements with respect to Cleared SBS.

• *Legacy SBS.* A member would be permitted to omit all (but not less than all) Legacy SBS with a Counterparty from the Counterparty's Uncleared SBS Account when computing Current Exposure and the Initial Margin Requirement, provided that the member collects and delivers margin on Legacy SBS to the extent of its contractual rights and obligations to do so.[120] However, a member would be required to take a capital deduction under Exchange Act Rule 15c3–1 or, if applicable, FINRA Rule 4110(a), to reflect the amount of any margin that it would have otherwise been required to collect if the Legacy SBS had been included in the Counterparty's Uncleared SBS Account. FINRA believes it is appropriate to provide a general exception for legacy SBS, as members would not be in a position to require their counterparties to legacy SBS to exchange margin under existing SBS agreements as would otherwise be required under proposed FINRA Rule 4240. However, in such cases FINRA believe it is appropriate to require a member to take a corresponding capital charge to account for the member's ongoing risk exposure under such SBS.

• *Multilateral Organizations.* A member would not be required to deliver Variation Margin to, or collect Initial Margin or Variation Margin from, any Multilateral Organization.[121] However, a member would be required to take a capital deduction to reflect the amount of any margin that it would otherwise have been required to collect from such a Multilateral Organization. FINRA believes it is appropriate to follow Exchange Act Rule 18a–3 by providing an exception for Multilateral Organizations and requiring the risk posed by such SBS to be accounted for in a member's capital computations.

• *Financial Market Intermediaries.* A member would not be required to collect Initial Margin from a Counterparty that is a Financial Market Intermediary (but would still be required to collect or deliver Variation Margin, as applicable).[122] In such case, a member would be required to take a capital deduction to reflect the amount of any Initial Margin that it would have otherwise been required to collect from such Financial Market Intermediary. A Counterparty that is a Financial Market Intermediary generally would be subject to a comprehensive regulatory framework, including capital requirements. FINRA therefore believes it is appropriate to account for the reduced counterparty credit risk posed by such Counterparties by permitting a member to take a capital charge in lieu of requiring such Counterparties to post Initial Margin. However, FINRA continues to believe that Variation Margin should be exchanged with such Counterparties to account for ongoing the market risk posed by such uncleared SBS.

• *Sovereign Counterparties.* A member would generally be required to deliver Variation Margin to, and collect Initial Margin or Variation Margin from, a Sovereign Counterparty.[123] However, under proposed FINRA Rule 4240(b)(5)(E), if the member has determined pursuant to policies and procedures or credit risk models established pursuant to Exchange Act Rule 15c3–1(c)(2)(vi)(l) that the Sovereign Counterparty has only a minimal amount of credit risk, the member would not be required to collect Initial Margin from such Sovereign Counterparty (but would still be required to collect or deliver Variation Margin, as applicable). In such case, a member would be required to take a capital deduction to reflect the amount of any Initial Margin that it would have otherwise been required to collect from such Sovereign Counterparty. As for Financial Market Intermediaries, FINRA believes it is appropriate to account for the reduced

[120] Under proposed FINRA Rule 4240(d)(12), a ''Legacy SBS'' would be defined as an Uncleared SBS entered into before October 6, 2021. Proposed FINRA Rule 4240(b)(2)(A)(iv) would also clarify that for any Legacy SBS for which proposed Rule 4240 does not specify an Initial Margin Requirement (*i.e.,* an SBS other than a Basic CDS, Basic SBS or other SBS for which FINRA has approved specific margin requirements), the Initial Margin Requirement must be calculated using the applicable method specified in Exchange Act Rule 15c3–1(c)(2)(vi)(P). The Initial Margin Requirement for Legacy SBS calculated under this provision would be used for purposes of determining the appropriate corresponding capital charge, as well as to determine the Initial Margin Requirement for a Legacy SBS to the extent that a member elects not to utilize the Legacy SBS exception under proposed FINRA Rule 4240(b)(5).

[121] Under proposed FINRA Rule 4240(d)(13), a ''Multilateral Organization'' would be defined to mean the Bank for International Settlements, the European Stability Mechanism, the International Bank for Reconstruction and Development, the Multilateral Investment Guarantee Agency, the International Finance Corporation, the Inter-American Development Bank, the Asian Development Bank, the African Development Bank, the European Bank for Reconstruction and Development, the European Investment Bank, the European Investment Fund, the Nordic Investment Bank, the Caribbean Development Bank, the Islamic Development Bank, the Council of Europe Development Bank, or any other multilateral development bank that provides financing for national or regional development in which the U.S. government is a shareholder or contributing member.

[122] Under proposed FINRA Rule 4240(d)(8), a ''Financial Market Intermediary'' would be defined to mean an SBSD, swap dealer, broker or dealer, FCM, bank, foreign bank, or foreign broker or dealer.

[123] Under proposed FINRA Rule 4240(d)(17), a ''Sovereign Counterparty'' would be defined as a Counterparty that is a central government (including the U.S. government) or an agency, department, ministry or central bank of a central government.

counterparty credit risk posted by highly creditworthy Sovereign Counterparties by permitting a member to take a capital charge in lieu of requiring such Counterparties to post Initial Margin. However, FINRA continues to believe that Variation Margin should be exchanged with such Counterparties to account for ongoing the market risk posed by such uncleared SBS.

• *Majority Owners; ANC Firms Transacting with Majority Owners or Registered or Foreign SBS Dealers Under Common Ownership.* FINRA understands that members may enter into uncleared SBS with affiliated entities for a variety of reasons, including for risk management purposes. FINRA does not believe a broad exception from the proposed margin requirements for uncleared SBS with all affiliates would adequately account for the risks posed to its members by uncleared SBS in such circumstances. However, FINRA does believe that two specific, more limited exceptions for SBS entered into with certain affiliates would be appropriate. First, under proposed FINRA Rule 4240(b)(5)(F), a member would not be required to collect Initial Margin from a Counterparty that is a direct or indirect owner of a majority of the equity and voting interests in the member (a ''Majority Owner'') (but would still be required to collect or deliver Variation Margin, as applicable). In such case, a member would be required to take a capital deduction to reflect the amount of any Initial Margin that it would have otherwise been required to collect from such Majority Owner. Second, under proposed FINRA Rule 4240(b)(5)(G), a member that is an ANC Firm would not be required to collect Initial Margin from a Counterparty that is a Majority Owner or a Registered or Foreign SBS Dealer under common ownership (but would still be required to collect or deliver Variation Margin, as applicable).[124] In such case, an ANC Firm member would be required to take a deduction for credit risk on such transactions computed in accordance with Exchange Act Rule 15c3–1e(c).[125] FINRA believes that the proposed exception from the Initial Margin Requirements for uncleared SBS with Majority Owners, provided that the member takes a capital charge in lieu of collecting Initial Margin, would adequately protect members in such circumstances due to the lower risk presented by Majority Owners, which typically must satisfy capital and other requirements applicable to bank holding companies and similar entities. FINRA also believes that the proposed exception for ANC Firms with respect to SBS with Majority Owners and Registered or Foreign SBS Dealer affiliates, provided that the member takes a corresponding credit risk charge, would adequately protect such members while reducing potential competitive disparity as between ANC Firms that are registered SBSDs (and therefore subject to Exchange Act Rule 18a–3) and ANC Firms that are not registered SBSDs (and therefore would be subject to proposed FINRA Rule 4240 with respect to their uncleared SBS).

• *Portfolio Margin.* Proposed FINRA Rule 4240(b)(5)(H) would provide that proposed FINRA Rule 4240 would not apply to any unlisted derivative, as defined in FINRA Rule 4120(g)(2)(H), carried by the member in a portfolio margin account subject to the requirements of FINRA Rule 4210(g) if such unlisted derivative is of a type addressed in the comprehensive written risk analysis methodology filed by the member with FINRA in accordance with FINRA Rule 4210(g)(1).[126] In addition, proposed FINRA Rule 4240 would not apply to any SBS carried in a commodity account or other account under the jurisdiction of the CFTC in accordance with an SEC rule, order or no-action letter permitting SBS and swaps to be carried and portfolio margined together in such an account. Portfolio margining provides members with the flexibility to manage their risk exposures based on a broader view of their overall relationship with a particular Counterparty. FINRA believes it is appropriate to provide an exception from proposed FINRA Rule 4240 for any SBS in a portfolio margin account if the SBS is of a type whose risk is appropriately addressed by an approved theoretical pricing model (*e.g.,* TIMS) and covered by portfolio risk management procedures filed by the member with FINRA, as well as for SBS permitted by the SEC to be portfolio margined in a commodity account. In these circumstances, the risks presented by such SBS would already be subject to a comprehensive risk management framework, and therefore FINRA does not believe it necessary to apply the proposed new margin requirements to such SBS.

Proposed FINRA Rule 4240(c), entitled ''Risk Monitoring Procedures and Guidelines,'' would require members to monitor the risk of any Uncleared SBS Accounts and maintain a comprehensive risk analysis methodology for assessing the potential risk to the member's capital over a specified range of possible market movements over a specified time period. For purposes of this requirement, members would be required to employ the following risk monitoring procedures and guidelines:

• Obtaining and reviewing the required documentation and financial information necessary for assessing the amount of credit to be extended to SBS Counterparties;

• determining and documenting the legal enforceability of netting or collateral agreements, including enforceability in the event a Counterparty becomes subject to bankruptcy or other insolvency proceedings;

• assessing the determination, review and approval of credit limits to each Counterparty, and across all Counterparties;

• monitoring credit risk exposure to the member from SBS, including the type, scope and frequency of reporting to senior management;

• the use of stress testing of accounts containing SBS contracts in order to monitor market risk exposure from individual accounts and in the aggregate;

• managing the impact of credit extended related to SBS contracts on the member's overall risk exposure;

• determining the need to collect additional margin from a particular customer or broker or dealer, including whether that determination was based upon the creditworthiness of the

[124] Under proposed FINRA Rule 4240(d)(14), a ''Registered or Foreign SBS Dealer'' would be defined to mean (i) any person registered with the SEC as an SBSD or (ii) any foreign person if the SEC has made a substituted compliance determination under Exchange Act Rule 3a71–6(a)(1) that compliance by a SBSD or class thereof with specified requirements of a foreign regulatory system that are applicable to such foreign person may satisfy the capital requirements of Section 15F(e) of the Act and Exchange Act Rule 18a–1 that would otherwise apply to such SBSD or class thereof. Therefore, the definition would cover registered SBSDs and entities that are subject to equivalent SBSD capital requirements in a foreign jurisdiction.

[125] FINRA notes that an ANC Firm transacting with a Counterparty that is its Majority Owner would also benefit from the general exception for collecting Initial Margin from Majority Owners, described above. However, under this additional exception, an ANC Firm would be permitted to take only a deduction for the credit risk on its transactions with Majority Owner counterparties as calculated in accordance with Exchange Act Rule 15c3–1e, rather than the full amount of the Initial Margin Requirement that would otherwise have applied.

[126] FINRA is also proposing a technical adjustment to the definition of ''unlisted derivative'' under FINRA Rule 4210(g)(2)(H) to clarify that, to qualify under the definition, the option, forward contract or SBS must be able to be valued by a theoretical pricing model that is approved by the SEC for valuing that type of options, forward contract or SBS.

customer or broker or dealer and/or the risk of the specific contracts;

• determining the need for higher margin requirements than required by proposed FINRA Rule 4240 and formulating the member's own margin requirements, including procedures for identifying unusually volatile positions, concentrated positions (with a particular Counterparty and across all Counterparties and customers), or positions that cannot be liquidated promptly;

• monitoring the credit exposure resulting from concentrated positions with a single Counterparty and across all Counterparties, and during periods of extreme volatility;

• identifying any Uncleared SBS Accounts with intraday risk exposures that are not reflected in their end of day positions (*e.g.,* Uncleared SBS Accounts that frequently establish positions and then trade out of, or hedge, those positions by the end of the day) and collecting appropriate margin to address those intraday risk exposures;

• identifying any Uncleared SBS Account that, in light of current market conditions, could not be promptly liquidated for an amount corresponding to the Current Exposure computed with respect to such account and determining the need for higher margin requirements on such accounts or the positions therein;

• maintaining sufficient Initial Margin in the accounts of each Counterparty to protect against the largest individual potential future exposure of an Uncleared SBS in such Counterparty's Uncleared SBS Account, as measured by computing the largest maximum possible loss that could result from the exposure; and

• increasing the frequency of calculations of Current Exposure and Initial Margin Requirements during periods of extreme volatility and for accounts with concentrated positions.

Proposed FINRA Rule 4240(c) would further require a member to review, in accordance with the member's written procedures, at reasonable periodic intervals, the member's SBS activities for consistency with these risk monitoring procedures and guidelines, and to determine whether the data necessary to apply the risk monitoring procedures and guidelines is accessible on a timely basis and information systems are available to adequately capture, monitor, analyze and report relevant data.

The risk monitoring procedures and guidelines under proposed FINRA Rule 4240(c) are similar to the risk monitoring and procedure requirements applicable to nonbank SBSDs with respect to their uncleared SBS transactions under Exchange Act Rule 18a–3.[127] These requirements are also based in part on aspects of FINRA Rule 4210, including procedures related to the need for additional margin under FINRA Rule 4210(d) and the portfolio margin risk monitoring requirements under FINRA Rule 4210(g)(1). SBS are complex financial instruments that may expose a member to significant risks, including, for example, market risk, counterparty credit risk, operational risk and legal risk. FINRA accordingly believes it is appropriate and necessary, and consistent with the protection of investors, for members with exposure to uncleared SBS to maintain a comprehensive risk monitoring program, including the specific elements described above, to address such risks.

If the Commission approves the proposed rule change, the effective date of the proposed rule change will be October 6, 2021.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[128] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that, by affirmatively addressing the treatment of SBS under FINRA rules, the proposed rule change will serve to promote regulatory clarity and consistency. FINRA also believes that this aspect of the proposed rule change is consistent with Congress's intent to define SBS as securities under the Act and its underlying regulations, and that such treatment will enhance investor protection. FINRA further believes that, by providing limited exceptions from the application of FINRA rules to SBS, the proposed rule change will promote legal certainty, provide clarity regarding the application of its rules and avoid unnecessary regulatory duplication.

The proposed rule change will also promote regulatory consistency by conforming FINRA's capital-related requirements to the SEC's amended net capital rule. FINRA also believes that, by applying higher financial responsibility and operational standards to members with financial exposure to SBS, the proposed rule change will serve to protect investors and the public interest.

Finally, the proposed rule change will also protect investors and the public interest by establishing a new margin rule for SBS applicable to members that are not registered SBSDs. FINRA believes that the proposed rule change will thereby fill an important regulatory gap, protect members against counterparty credit risk, maintain a level playing field for members and prevent regulatory arbitrage.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Economic Impact Assessment

FINRA has undertaken an economic impact assessment, as set forth below, to analyze the regulatory need for the proposed rule change, its potential economic impacts (including anticipated costs, benefits, and distributional and competitive effects, relative to the current baseline) and the alternatives considered in assessing how best to meet FINRA's regulatory objective.

1. Regulatory Need

As detailed above, the SEC has adopted final rules under Title VII of the Dodd-Frank Act implementing the new regulatory framework for SBS, including rules requiring SBS Entities to register with the SEC, business conduct and supervision requirements, risk mitigation techniques, and margin, capital and segregation requirements for SBS Entities, among many other detailed requirements. For SBS Entities, the compliance date for the SEC's key SBS requirements will be October 6, 2021, and the deadline for the first wave of SBS Entities to register is November 1, 2021. FINRA currently has in place a temporary, broad exception from the application of its rules to its members' SBS activities and positions, which will expire on September 1, 2021. In light of the upcoming Registration Compliance Date, FINRA is proposing to amend its rules as detailed above to clarify the application of its rules to SBS and take into account member's SBS activities once SBS Entities begin registering with the SEC.

2. Economic Baseline

The economic baseline for the proposed rule change is based on the relevant existing regulatory framework, existing firm practices and information

[127] *See* 17 CFR 240.18a–3(e); Capital, Margin, and Segregation Release, *supra* note 8, at 43930.

[128] 15 U.S.C. 78*o*–3(b)(6).

collected through outreach efforts. FINRA believes that the proposed rule change should be evaluated against a baseline where the SEC's new rules for SBS have come into effect and FINRA's existing exceptions have expired—*i.e.,* if current FINRA Rule 0180 were to expire as scheduled on September 1, 2021 and new FINRA Rule 0180 not adopted as proposed—as well as applying FINRA's existing margin and financial operational rules and requirements to SBS without the proposed changes described above. Under this baseline, all member firms contemplating offering SBS services to clients would be subject to FINRA's applicable rules with regard to business conduct requirements, financial responsibility and operational requirements, and margin. As discussed above, these rules as applied to SBS Entities, may in some cases be duplicative of SEC rules, and thus may impose unnecessary material obligations given the firms' activities in the space, could result in operational difficulties or be insufficient to provide appropriate risk controls. Under this scenario, some member firms may choose to limit or not provide SBS services, which may result in decreased choice and increased costs to customers.

Through outreach efforts and discussions with individual member firms, FINRA has learned about current member firm SBS activities and their preparations for the Registration Compliance Date. The majority of member firms that participated in the outreach efforts indicated that they intend to register a bank affiliate, foreign affiliate or stand-alone dealer affiliate as the SBSD. Some of the firms indicated some involvement in SBS activities on the part of their FINRA-registered associated persons, but typically in the person's capacity as an associated person of the affiliated SBSD. Firms further indicated that their SBS activities will be focused on their existing trading programs related to CDS, equity index and single-name TRS, and asset-backed security swaps. FINRA also solicited input from member firms that may conduct an SBS business below the SEC's registration thresholds. Generally, FINRA has found that the number of member firms that are planning to register as an SBSD, or engage in SBS activities below the SEC's registration thresholds, is small and concentrated in larger firms. FINRA also discussed with firms their practices with respect to margin practices for SBS transactions. Most firms reported they would be using the standard initial margin model (''SIMM'') for margin purposes,[129] and rely on existing margin collection and governance systems and infrastructure.

FINRA has also engaged with other relevant regulators, including the SEC, the CFTC and the National Futures Association (''NFA''). Through these efforts, FINRA has gained further insight into the application of the SEC's SBS rules to its member firms, as well as the similarities and differences between the SEC and CFTC regulatory frameworks. Furthermore, FINRA gathered further information about the approach taken by the NFA for regulating the activities of FCMs and other registrants engaged in swap activities. For example, FINRA notes that an FCM generally does not need to comply with NFA rules specific to swaps (*e.g.,* margin) unless it is also a registered swap dealer. Finally, FINRA discussed the implications of member firms engaging in SBS activities under Exchange Act Rule 15a–6.[130]

In parallel to the outreach efforts conducted through engagement with individual member firms, as discussed above, FINRA posted on its public website an open-ended request for feedback on how FINRA rules should be applied to SBS and invited interested parties to submit views and information via a dedicated email box.[131] The responses received largely echoed FINRA's discussion with member firms. In addition, FINRA issued *Regulatory Notice* 20–36 to solicit further comment on the proposal, including any potential economic impacts.[132] As discussed in Item II. C. of this filing, FINRA received one comment letter in response to *Regulatory Notice* 20–36.

3. Economic Impacts

FINRA has analyzed the potential costs and benefits of the proposed rule change, and the different parties that are expected to be affected. FINRA has identified member firms that engage in SBS activities and their customers as the parties that would primarily be affected by the proposed rule change. In particular, these include member firms that will register as SBSDs, firms seeking to broker SBS transactions, firms engaging in SBS activities under the *de minimis* threshold for SBSD registration, and firms engaging in SBS activities in other capacities (*e.g.,* risk management). As discussed above, based on existing information, FINRA understands that the number of such member firms is small and concentrated among larger member firms. The proposed rule change is expected to reduce regulatory arbitrage and establish a regulatory framework for FINRA member firms that wish to engage in SBS activities, without diminishing investor protections.

A. Anticipated Benefits

FINRA believes that the proposed rule change would benefit member firms by reducing regulatory uncertainty, unnecessary regulatory duplication and the potential for arbitrage with the SEC's regulatory framework for SBSDs that are not FINRA member firms. Furthermore, FINRA believes that the proposed rule change would alleviate some of the potential competitive disadvantages for FINRA member firms that wish to engage in SBS activities without registering as SBSDs. FINRA believes this goal is achievable through the increased regulatory clarity resulting from the proposed rule change. Finally, FINRA believes that the combination of these accrued benefits could incentivize member firms to engage in SBS activities. This could lead to an increase in consumer choice, and potentially increase member firms' ability to compete in SBS products.

A primary benefit of the proposed rule change is that it permits firms that are registered with the SEC to rely on relevant SEC rules governing business conduct requirements with respect to their SBS activities. In so doing, the proposed rule change ensures that there would be no unintended differences between the firms' obligations under SEC and FINRA rules and would impose no additional direct or indirect costs to firms that are registered SBSDs engaging in SBS activities. The proposed rule change is also expected to reduce potential regulatory arbitrage across the relevant regulatory frameworks of FINRA, the SEC and the CFTC. Increased consistency across regulatory frameworks would benefit member firms seeking to engage in SBS activities through multiple affiliates and those firms engaging in an SBS business without registering with the SEC.

Member firms would be expected to be able to use their existing governance and compliance systems and procedures, including in situations where member firms will have dual-hatted personnel or have an affiliate that

[129] The SIMM is a methodology proposed by ISDA to help market participants calculate initial margin on non-cleared derivatives under the framework developed by the Basel Committee on Banking Supervision and the International Organization of Securities Commissions. *See* ISDA, Standard Initial Margin Model for Non-Cleared Derivatives (December 2013), *https://www.isda.org/a/cgDDE/simm-for-non-cleared-20131210.pdf.*

[130] Exchange Act Rule 15a–6 provides conditional exemptions from registration under the Exchange Act that permit non-US broker-dealers to engage in certain activities in the US or with US persons without having to register with the SEC.

[131] *See supra* note 25.

[132] *See supra* note 26.

is registered with the CFTC as a swaps dealer. Finally, member firms are expected to benefit from the proposed exception for current rules that otherwise might otherwise apply but are not feasible or appropriate in the context of SBS activities. This will reduce operational and compliance costs for firms without diminishing investor protections. Similarly, with respect to financial responsibility and operational requirements, the proposed rule change would benefit member firms by aligning FINRA rules with SEC rules, thus reducing the costs and risks of regulatory arbitrage.

With respect to margin requirements, the proposed rule change also seeks to rely on the SEC's rules and framework to provide consistent protections and regulatory requirements. First, member firms that register as SBSDs would be exempted from the FINRA margin requirements, thus eliminating any regulatory burden that might arise from a different approach. Second, for other firms, the margin requirements for uncleared Basic CDS would conform with the standard SEC margin requirements, thus reducing risk of regulatory arbitrage. Third, the proposal is expected to benefit member firms by providing additional mitigation of counterparty risks for SBS-related activities that fall outside of the SEC regulatory framework. Fourth, the margin requirements are expected to enhance member firms' ability to compete in these products. Fifth, replacing the current FINRA Rule 4240, which by its terms is a temporary rule, with an ongoing rule would reduce regulatory uncertainty and benefit firms with respect to compliance systems and associated costs. Finally, FINRA believes that the anticipated benefits of the proposed margin requirements might accrue to counterparties, customers and the financial system as a whole, as it decreases the chance of unexpected firm failure and dampens shock transmission.

B. Anticipated Costs

FINRA believes that the proposed rule change would result in some direct costs to member firms that choose to engage in SBS activities in various capacities. In particular, member firms would be required to develop a regulatory compliance program for SBS activities and monitor for their compliance.

FINRA believes that the proposed rule change's exceptions from applying some of its rules to SBS activities benefits member firms. However, such exceptions could potentially further result in costs to member firms. These can be either near-term costs, stemming from FINRA's decision to provide exceptions for certain rules but not others, or long-term costs, if trading in SBS evolves in ways that would require a reconsideration of the exceptions.

Some costs are also expected to stem from the proposal to treat member firms with financial exposure to SBS the same as carrying or clearing firms for purposes of FINRA's financial and operational rules. However, FINRA believes that the majority of member firms that will be engaged in SBS activities already qualify as carrying or clearing firms under these rules. Thus, it is expected that any incurred compliance costs resulting from this proposed requirement would be minimal. Further, for member firms not registering as SBSDs, the proposal to align FINRA's regulatory notification and business curtailment rule requirements to the SEC's amended net capital rule may result in increased associated costs.

The proposed margin requirements may impose some costs on member firms seeking to engage in SBS activities without registering as SBSDs. The new margin requirements would require such member firms engaged in SBS activities to have comprehensive written credit risk management procedures appropriate for the business and to ensure compliance with them. Moreover, additional costs would arise from allowing firms to take a capital charge in lieu of margin, where permitted. These costs are associated with managing capital accounts, related compliance costs, and any opportunity costs that might arise from committing capital. FINRA notes that firms would be permitted to take this approach and thus would only be anticipated to do so in instances where the costs are lower than the alternative margin requirements.

FINRA recognizes that the proposal should be considered relative to alternative regulatory regimes available to member firms and their affiliates. Firms will consider whether the costs and benefits of providing SBS services are most efficient under these proposed rules, alternative domestic rules, such as those of the CFTC, or through a foreign entity. FINRA has considered the potential impacts of the proposal on competition among financial service providers and how that competition may limit investor choice or impose higher, or additional, risks or costs to investors. FINRA sought information and comments on this specific issue in *Regulatory Notice* 20–36. FINRA believes that given the current set of SBS activities, and member firms identified as engaged in such activities, the extent of such potential competitive impacts and outcomes is unclear. Moreover, FINRA believes that such competitive impacts would depend on a firm's interest in, and the scope of, its SBS activities.

4. Alternatives Considered

FINRA has considered various alternatives to the proposed rule change. For example, FINRA considered an option to allow current FINRA Rule 0180 to expire without replacing it with a new rule. This would result in no exceptions from the applications of the FINRA rules to member firms engaging in SBS activities. A different alternative that considered would be to delete the expiration date from current FINRA Rule 0180 and rely solely on the SEC's SBS regulatory framework going forward. FINRA considered similar alternatives with respect to the proposed margin requirements and amendments to its financial responsibility and operational rules. FINRA believes that the proposed rule change strikes an appropriate balance among establishing a regulatory framework for SBS activities, regulatory burdens and investor protection considerations.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

A concept proposal summarizing the proposed rule change was published for comment in *Regulatory Notice* 20–36 (October 2020).[133] One comment was received in response to the *Regulatory Notice.*[134] The comment letter is summarized below.

SIFMA expressed overall support for many aspects of the Concept Proposal, but suggested further tailoring to seek greater clarity regarding the application of FINRA rules to SBS, ensure that standalone broker-dealers are not placed at a disadvantage to broker-dealers that are also registered as SBSDs, and better harmonize certain FINRA rules with the SEC's SBS Entity rules.[135] In the Concept Proposal, FINRA noted that it was considering extending its existing exceptions under current FINRA Rule 0180 until the Registration Compliance

[133] *See Regulatory Notice* 20–36 (October 2020) (''Concept Proposal'').

[134] *See* Letter from Kyle L Brandon, Managing Director, Head of Derivatives Policy, Securities Industry and Financial Markets Association (''SIFMA''), to Jennifer Piorko Mitchell, Office of the Corporate Secretary, FINRA, dated November 16, 2020 (''SIFMA Letter'').

[135] *See* SIFMA Letter at 1.

Date on October 6, 2021.[136] SIFMA noted that, per the SEC Transitional Period Guidance, most, if not all, SBSDs will wait to register until November 1, 2021, and therefore SIFMA recommended that FINRA instead extend the expiration date of current FINRA Rule 0180 until November 1, 2021.[137] After consideration, FINRA believes that the Registration Compliance Date is the most appropriate date to implement the proposed rule change in order to align with the implementation of the SEC's Title VII rulemakings and avoid unnecessary confusion. FINRA also understands that existing, temporary exemptions from some SEC rules expire on the Registration Compliance Date, and that SBSDs are likely to register on that date to align with the expiration of those exemptions. Therefore, as discussed above, FINRA intends to extend the expiration date of current FINRA Rule 0180, as well as the interim CDS margin pilot program under current FINRA Rule 4240, to the Registration Compliance Date on October 6, 2021.[138]

In the Concept Proposal, FINRA stated that it was considering providing general exceptions from the presumption of applicability of FINRA rules to SBS for certain rules that were intended for other types of securities and could create operational difficulties if applied to SBS.[139] SIFMA supported FINRA's proposal to except these rules from the general presumption of applicability, including the FINRA Rule 6000 Series (Quotation, Order, and Transaction Reporting Facilities), the FINRA Rule 7000 Series (Clearing, Transaction and Order Data Requirements, and Facility Charges) and the FINRA Rule 11000 Series (Uniform Practice Code). SIFMA stated that providing exceptions for these rules will promote clarity, considering that these rules are not designed to apply to SBS and arguable overlap with some of the SEC's rules such as Regulation SBSR.[140] The proposed rule change would provide such exceptions under proposed FINRA Rule 0180(b).

In the Concept Proposal, FINRA stated that it was considering providing exceptions from the presumption of applicability of FINRA rules to SBS for certain business conduct rules that are similar to the SEC's new SBS Entity rules. Specifically, FINRA stated its preliminary belief that it would be appropriate to permit an SBS Entity that is a FINRA member and an associated person of an SBS Entity who is acting in his or her capacity as an associated person of an SBS Entity to comply with the parallel SEC requirements in lieu of the similar FINRA Rules.[141] FINRA noted the following rules in particular: (1) FINRA Rule 2030 (Engaging in Distribution and Solicitation Activities with Government Entities); (2) FINRA Rule 2090 (Know Your Customer); (3) FINRA Rule 2111 (Suitability); (4) FINRA Rule 2210(d) (Communications with the Public—Content Standards); (5) FINRA Rule 2232 (Customer Confirmations); and (6) FINRA Rules 3110 (Supervision), 3120 (Supervisory Control System) and 3130 (Annual Certification of Compliance and Supervisory Processes). SIFMA expressed general support for this aspect of the Concept Proposal, noting FINRA's observation that these rules would unnecessarily duplicate certain of the SEC's SBS Entity rules if they applied to SBS Entities or their associated persons.[142] However, SIFMA made four recommendations for FINRA to make certain clarifications and expand the proposed exceptions. The proposed rule change would provide these exceptions in proposed FINRA Rules 0180(c) and (d), with certain modifications as noted below.[143]

First, in the Concept Proposal, FINRA stated that the proposed exceptions would apply both where the member itself is registered as an SBS Entity and where the associated person of the member is ''dual-hatted'' as an associated person of an affiliated SBS Entity.[144] SIFMA requested that FINRA clarify the treatment of dual-hatted personnel under these proposed exceptions in two respects. First, SIFMA requested that FINRA confirm that, by adopting these exceptions and applying such exceptions to dual-hatted individuals, FINRA is not addressing whether or to what extent the rules not covered by these exceptions might apply to dual-hatted personnel when acting in their capacity as associated persons of an affiliated entity. Second, SIFMA requested that FINRA confirm that regardless of how the dual-hatting arrangement is documented, if in substance the relevant individual is designated as an associated person of an SBS Entity and is in fact acting in that capacity, then such individual would benefit from FINRA's proposed exceptions.[145] FINRA has addressed both aspects of SIFMA's request relating to dual-hatted personnel above.[146]

Second, in the Concept Proposal, FINRA noted the SEC's cross-border counting exception under Exchange Act Rule 3a71–3(d) and stated that it was considering also providing an exception for members acting in compliance with that exception from the FINRA rules that are parallel to the SEC's SBS Entity rules that are conditions of the exception.[147] SIFMA expressed support for this additional exception and requested that FINRA expand its exceptions for FINRA Rules 2111 (Suitability), 2210(d) (Communications with the Public—Content Standards) and 2232 (Customer Confirmations) to cover a FINRA member when it is acting as the registered entity for a foreign affiliate pursuant to Exchange Act Rule 3a71–3(d).[148] As discussed above, the proposed rule change would include these exceptions in proposed FINRA Rule 0180(e).

Third, SIFMA requested that FINRA also adopt exceptions from associated person registration and CE requirements in FINRA Rules 1210, 1220 and 1240 for a person associated with a broker-dealer dually registered as an SBS Entity whose securities-related activities relate solely and exclusively to transactions in SBS conducted in his or her capacity as an associated person of an SBS Entity.[149] SIFMA noted that FINRA's existing registration, proficiency testing and CE requirements are not tailored to SBS and it would therefore seem to provide little, if any, benefit to apply those requirements to such associated persons. In this regard, SIFMA noted that similar considerations led the NFA initially to exclude swaps associated persons from its proficiency testing

[136] *See* Concept Proposal at 3.

[137] *See* SIFMA Letter at 1–2; *see also supra* note 10.

[138] *See supra* note 18.

[139] *See* Concept Proposal at 4.

[140] *See* SIFMA Letter at 2. SIFMA also noted that the Concept Proposal also stated FINRA's preliminary intention to provide a general exception from FINRA Rule 2210, other than the content standards in paragraph (d). *See id.* at 2 n.3. After further consideration, FINRA does not believe a general exception from the remainder of FINRA Rule 2210 is appropriate, and therefore the proposed rule change does not provide this exception under proposed FINRA Rule 0180(b). The remainder of FINRA Rule 2210 includes specified principal approval, review, filing and recordkeeping requirements applicable to certain types of communications, as well as limitations on the use of FINRA's name and standards applicable to public appearances. FINRA believes these requirements should apply to communications relating to SBS to the extent the rule otherwise applies to the communication.

[141] *See* Concept Proposal at 4–5.

[142] *See* SIFMA Letter at 2.

[143] In addition to the modifications described above in response to SIFMA's feedback, the proposed rule change also splits these exceptions into two paragraphs of proposed FINRA Rule 0180 to account for SEC rules that apply to only SBSDs rather than all SBS Entities. *See supra* note 36.

[144] *See* Concept Proposal at 4.

[145] *See* SIFMA Letter at 3.

[146] *See supra* note 38.

[147] *See* Concept Proposal at 16 n.14.

[148] *See* SIFMA Letter at 3–4.

[149] *See* SIFMA Letter at 4.

requirements until tests tailored to swaps could be developed. SIFMA also stated that associated persons of standalone SBSDs are not subject to registration or CE requirements and, since SBSDs generally are not required to register as broker-dealers or become FINRA members, it would be inappropriate to subject associated persons of SBSDs to differing requirements solely depending on whether the SBSD happened, for other reasons, to be a FINRA member.[150] FINRA believes that an exception along the lines requested by SIFMA is appropriate, at least until such time as FINRA may develop registration, licensing and CE requirements tailored to SBS. As discussed above, the proposed rule change therefore includes proposed FINRA Rule 0180(g), which would provide that persons associated with a member whose functions are related solely and exclusively to SBS undertaken in such person's capacity as an associated person of an SBS Entity are not required to be registered with FINRA.

Finally, SIFMA requested that FINRA provide exceptions for a member dually registered as an SBS Entity from FINRA Rules 2231 (Customer Account Statements) and 4512 (Customer Account Information), in each case, for an account solely holding SBS and related collateral.[151] In the Concept Proposal, FINRA explained its preliminary belief that the account statements required under FINRA Rule 2231 should reflect a holistic view of a member's relationship with its customer, including SBS transactions and positions, if applicable. FINRA further stated that while FINRA members that are SBS Entities would also be subject to the SEC's portfolio reconciliation requirements, given the importance of customer account statements and the different purposes of the rules, under the Concept Proposal FINRA was considering not proposing an exception from FINRA Rule 2231 for members that are SBS Entities.[152] SIFMA acknowledged this rationale generally, but stated its belief that if an account only holds SBS and related collateral, the SEC's portfolio reconciliation requirement should be sufficient because it will provide the counterparty with information on a periodic basis regarding the parties' SBS portfolio and address the resolution of disputes, including collateral-related disputes.[153] SIFMA also noted that the SEC's amended recordkeeping rules, specifically Exchange Act Rule 17a–3(a)(9)(iv), cover much of the information required by FINRA Rule 4512, and that such rules are specifically tailored to SBS while FINRA Rule 4512 requires information that is unlikely to be relevant to SBS.[154] FINRA believes that limited exceptions along the lines requested by SIFMA are appropriate where an account solely holds SBS and related collateral for a counterparty to a member that is acting in its capacity as an SBS Entity. Accordingly, as discussed above, the proposed rule change includes proposed FINRA Rule 0180(f), which would provide that FINRA Rules 2231 and 4512 shall not apply to members' activities and positions with respect to SBS, to the extent that the member is acting in its capacity as an SBS Entity and the customer's account solely holds SBS and collateral posted as margin in connection with such SBS.

In the Concept Proposal, FINRA requested comment on a proposed framework for a new SBS-specific margin rule, which would replace the Interim Pilot Program under existing FINRA Rule 4240 and apply to all SBS in lieu of FINRA's general margin requirements under FINRA Rule 4210.[155] SIFMA expressed support for the steps noted by FINRA in the Concept Proposal with respect to harmonizing the new SBS-specific margin rule with the SEC's margin rule for SBSDs, including by including exceptions from Initial Margin Requirements for Sovereign Entities and Financial Market Intermediaries, as well as the Variation Margin and Initial Margin Requirements for Multilateral Organizations.[156] However, SIFMA noted that the proposed margin rule as described in the Concept Proposal would still diverge from Exchange Act Rule 18a–3 in several significant respects. SIFMA expressed concern that these differences would impose significant limitations on the ability of members that are not SBSDs to transact in SBS, including for risk management purposes. SIFMA therefore suggested that FINRA allow a member subject to the proposed new rule to opt into compliance with Exchange Act Rule 18a–3 if the member (a) is affiliated with a registered SBSD subject to Exchange Act Rule 18a–3 and (b) uses initial margin models, if any, that the SEC has approved for use by that affiliate.[157] FINRA acknowledges that proposed new FINRA Rule 4240 would diverge from Exchange Act Rule 18a–3 in some respects, which FINRA believes are important to protect its members given that members subject to the rule would not be subject to the comprehensive regulatory framework applicable to SBSDs. For example, registered SBSDs are subject to higher minimum capital requirements, and the SEC's margin requirements under Exchange Act Rule 18a–3 were designed to apply to entities subject to those higher capital requirements. FINRA notes in this regard that firms engaged in a level of SBS dealing below the *de minimis* threshold requiring SBSD registration may nonetheless elect to register as SBSDs, and thereby become subject to the SEC's comprehensive regulatory framework for such entities, including the margin requirements under Exchange Act Rule 18a–3 tailored to such entities. FINRA does not believe it would be appropriate to permit members to opt-in to only one aspect of the SEC's financial responsibility rules for SBSDs instead of complying with proposed FINRA Rule 4240, which, as described below, would in some respects provide a higher level of protection for non-SBSD members engaged in uncleared SBS than SBSDs because such members are not comprehensively regulated with respect to their SBS activities.

Alternatively, SIFMA requested that, if FINRA does not adopt its suggested opt-in approach, FINRA harmonize the new margin rule with Exchange Act Rule 18a–3 in certain respects.[158] First, SIFMA noted that the proposed new margin rule as described in the Concept Proposal would not include the same exceptions as Exchange Act Rule 18a–3, including an Initial Margin collection exception for affiliates and an exception from both Initial Margin and Variation Margin for legacy accounts. As described above, FINRA believes an exception from including Legacy SBS in a Counterparty's Uncleared SBS Account for purposes of the margin requirements under proposed FINRA Rule 4240 is appropriate to the extent

[150] *See* SIFMA Letter at 4.

[151] *See* SIFMA Letter at 5.

[152] *See* Concept Proposal at 16 n.15.

[153] *See* SIFMA Letter at 5. SIFMA also stated that although the SEC's portfolio reconciliation rule does not expressly cover collateral-related disputes, the NFA has interpreted the parallel CFTC rule to cover such disputes, and the SEC indicated that an SBS Entity that is following NFA's processes in relation to disputes would also be compliant with Exchange Act Rule 15Fi–3. *See id.* at 5 n.4. As discussed above, the proposed rule change would include as a condition to proposed FINRA Rule 0180(f) that portfolio reconciliations and related dispute resolution requirements as applied to a customer's account qualifying for the proposed exception must include SBS-related collateral.

[154] *See* SIFMA Letter at 5.

[155] *See* Concept Proposal at 8–9.

[156] *See* SIFMA Letter at 6.

[157] *See* SIFMA Letter at 7.

[158] *See* SIFMA Letter at 7.

the member does not have a contractual right or obligation to collect or deliver such margin, and is therefore including such an exception under the proposed rule change, provided that members take a corresponding capital charge to account for the risk of Legacy SBS (consistent with the SEC's approach to legacy accounts under Exchange Act Rule 18a–3). Also as described above, while FINRA does not believe a broad exception from the Initial Margin Requirements for SBS with all affiliates would be consistent with investor protection, the proposed rule change includes more limited exceptions (i) for all members, from collection of Initial Margin for SBS with Majority Owners, subject to a corresponding capital charge; and (ii) for ANC Firms, from collection of Initial Margin for SBS with Majority Owners and Registered or Foreign SBS Dealers, subject to taking a corresponding credit risk charge (as discussed in further detail below). FINRA believes these proposed exceptions, together with the proposed exception for SBS with Financial Market Intermediaries, should account for the vast majority of uncleared SBS entered into by non-SBSDs with affiliates and thus reduce the competitive disparity noted by SIFMA, while still sufficiently addressing the potential risks raised by SBS with other affiliated entities.

Second, SIFMA noted that an SBSD generally may use an approved model to calculate initial margin requirements and stated that, if standalone broker-dealers are not able to use similar models, the rule may result in competitive disparities between standalone broker-dealers and broker-dealers dually-registered as SBSDs. SIFMA therefore requested that FINRA modify the proposed margin rule to provide that, if the SEC has approved an affiliate of a standalone broker-dealer to use an initial margin model, such as the ISDA ''Standard Initial Margin Model,'' then such broker-dealer should be able to use the same model to the same extent as a broker-dealer dually-registered as an SBSD would be able to under the SEC's margin rules.[159] SIFMA further requested that the use of such a model should not be limited to products that are Basic CDS or Basic SBS.[160] FINRA believes similar considerations apply with respect to the use of SEC-approved Initial Margin models as for permitting a non-SBSD member to opt-in to Exchange Act Rule 18a–3. Proposed FINRA Rule 4240 would apply only to members that are not registered SBSDs, and therefore such members would not be subject to the comprehensive regulatory framework applicable to SBSDs, including higher capital requirements. Similarly, FINRA does not believe it would be appropriate to permit a non-SBSD member to opt-in to using models that the SEC has approved for an affiliate that is itself registered as an SBSD.

Third, SIFMA requested that, when ANC Firms transact pursuant to an exception from the proposed new margin rule, they should be permitted to use credit risk charges set forth in Exchange Act Rule 15c3–1e in lieu of capital charges computed using the Initial Margin methodology required under the proposed new margin rule.[161] SIFMA stated that this approach should not pose undue risks to ANC Firms given the significantly higher minimum net capital and tentative net capital requirements applicable to such firms, and cited the SEC's decision to allow ANC Firms to apply Exchange Act Rule 15c3–1e's credit risk charges to all derivatives transactions not subject to margin collection requirements.[162] FINRA acknowledges that not permitting all ANC Firms subject to the rule to use credit risk charges in lieu of capital charges could create certain competitive disparities as between ANC Firms that are registered SBSDs (and therefore are subject to Exchange Act Rule 18a–3) and ANC Firms that are not registered SBSDs (and therefore would be subject to the Initial Margin requirements under proposed FINRA Rule 4240). However, FINRA notes that the credit risk charges calculated under Exchange Act Rule 15c3–1e represent a fraction of the Initial Margin Requirement that would otherwise be required to be collected under proposed FINRA Rule 4240 (or to be taken as a capital deduction in certain circumstances as described above).[163] Therefore, as described above, FINRA believes it is appropriate to provide a limited exception permitting ANC Firms to use credit risk charges when they transact with registered SBSD affiliates or affiliates that are subject to comparable capital requirements in a foreign jurisdiction. FINRA believes this proposed exception should substantially address the potential competitive disparity highlighted by SIFMA, while providing the heightened protection provided by collecting the full Initial Margin Requirement, or taking the associated full capital charge in certain circumstances, for SBS with other Counterparties.

Fourth, SIFMA requested that FINRA include an Initial Margin threshold consistent with Exchange Act Rule 18a–3's $50 million threshold.[164] SIFMA noted that, because Exchange Act Rule 18a–3 includes such a threshold while FINRA's proposed new margin rule would not, members subject to the proposed margin rule would face a significant competitive disadvantage relative to SBSDs. SIFMA suggested that, if FINRA permitted a member to take a capital charge in lieu of collecting Initial Margin up to the threshold, similar to that permitted by the SEC for SBSDs, then FINRA could ensure protection against credit risks without creating an unlevel playing field or increasing market concentration. Fifth, SIFMA requested that FINRA adopt a $500,000 minimum transfer amount to minimize operational burdens and competitive disadvantages that would otherwise be imposed on broker-dealers, including when facing SBSDs, in which case broker-dealers would be required to collect or post Variation Margin when its SBSD counterparty would not.[165] FINRA acknowledges that these aspects of the proposed rule change differ from the SEC's margin rule for SBSDs under Exchange Act Rule 18a–3. However, FINRA does not believe the application of a large threshold or minimum transfer amount would be appropriate for uncleared SBS entered into by non-SBSD members that would be subject to proposed FINRA Rule 4240, as such members will not be subject to the comprehensive regulatory framework applicable to SBSDs, including higher minimum capital requirements. FINRA also notes that, from an operational perspective, member broker-dealers should already have operational processes in place for the collection of margin without any threshold or minimum transfer amount. Further, FINRA believes that adopting a threshold or minimum transfer amount under proposed FINRA Rule 4240 would incentivize restructuring of margin accounts as Basic SBS given that FINRA Rule 4210 does not provide for any threshold or minimum transfer amount. To prevent regulatory arbitrage, FINRA is therefore not proposing to include any threshold or minimum

[159] *See* SIFMA Letter at 8.

[160] *See* SIFMA Letter at 8 n.6.

[161] *See* SIFMA Letter at 8.

[162] *See* SIFMA Letter at 8–9.

[163] Specifically, these charges are the are the product of (x) 8%, (y) the counterparty risk weighting (20% for internal AAA/AA rating, 50% for internal investment grade rating or 150% for internal non-investment grade rating), and (z) a potential exposure computed using a VaR model (or if not modeled, by applying the capital rule haircut to the underlying). *See* 17 CFR 15c3–1e.

[164] *See* SIFMA Letter at 9.

[165] *See* SIFMA Letter at 9.

transfer amount under proposed FINRA Rule 4240.

Fifth, SIFMA noted that the definition of Basic CDS as described in the Concept Proposal would not seem to cover an option on a CDS, *i.e.,* CDS swaptions. SIFMA requested that FINRA change the definition of Basic CDS to include swaptions, so that swaptions are treated the same as the underlying CDS, to avoid a situation that would make it difficult for FINRA members to employ CDS swaption hedging techniques.[166] SIFMA noted that such a change would also eliminate the added costs market participants would otherwise incur in requesting approval from FINRA of the appropriate Initial Margin Requirement for swaptions. FINRA notes that there is some uncertainty regarding the appropriateness of applying the generally applicable haircut grid for CDS under Exchange Act Rule 15c3–1(c)(2)(vi)(P)(1) to CDS swaptions. As such, FINRA believes it would be beneficial for SIFMA or other market participants to submit an application for approval of an Initial Margin Requirement for CDS swaptions under proposed FINRA Rule 4240(2)(C), as described above. FINRA notes that it would consider such a request expeditiously provided that such an application included all relevant supporting information. SIFMA also expressed concern that the Basic CDS definition could be read to require physical settlement of CDS. Given the prevalence of auction settlement in the CDS market, SIFMA requested that the definition of Basic Single-Name Credit Default Swap (a component of Basic CDS) specifically contemplate auction settlement as well.[167] FINRA notes that it intends for the definition of Basic CDS, as described in greater detail above, to cover both physical and auction settlement.

Finally, SIFMA made several comments regarding paragraph (g) (the portfolio margin section) of FINRA Rule 4210:[168]

- SIFMA requested that FINRA conform FINRA Rule 4210's definitions of ''related instrument'' and ''underlying instrument'' to the definitions in Appendix A to Exchange Act Rule 15c3–1, which now include swaps and SBS. FINRA will consider these suggestions, but does not believe these changes are necessary as a part of this rulemaking.
- SIFMA further requested that FINRA clarify FINRA Rule 4210 to permit house margin and stress test requirements for portfolio margin accounts to recognize risk offsets across all types of swaps, SBS and other positions permitted in the account. FINRA notes that this request relates to ''house margin,'' which generally refers to margin requirements that a member's portfolio margin risk management procedures may impose in addition to, or parallel to, the requirements under the applicable portfolio margin model. FINRA believes that the practice of recognizing risk offsets across all types of swaps, SBS and other positions permitted in the account for purposes of calculating house margin and related stress test requirements is permissible under current FINRA Rule 4210, and FINRA does not intend to alter such permissibility under the proposed rule change.
- SIFMA also requested that FINRA clarify that SBS may be held in a portfolio margin account even if the underlier for the SBS would not be eligible for portfolio margining, given that Exchange Act Rule 18a–3 imposes no limitation on the types of SBS that can be margined using the methodology set forth in Appendix A to Exchange Act Rule 15c3–1. FINRA notes that, under the proposed rule change, the eligibility of specific SBS for portfolio margining would depend on whether such SBS can be valued by a theoretical pricing model approved by the SEC for valuing that type of SBS. As such, an SBS would be permitted to be held in a portfolio margin account if it satisfies this condition, regardless of whether the underlier for the SBS would itself be eligible for portfolio margining.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be 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–FINRA–2021–008 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–FINRA–2021–008. 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 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. 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–FINRA–2021–008 and should be submitted on or before June 2, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[169]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–10055 Filed 5–11–21; 8:45 am]

BILLING CODE 8011–01–P

[166] *See* SIFMA Letter at 9–10.

[167] *See* SIFMA Letter at 10.

[168] *See* SIFMA Letter at 6.

[169] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91786; File No. SR–NYSEArca–2020–105]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Withdrawal of a Proposed Rule Change To List and Trade the Shares of the Teucrium Water Fund Under NYSE Arca Rule 8.200–E, Commentary .02

May 6, 2021.

On November 25, 2020, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') 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 the shares of the Teucrium Water Fund under NYSE Arca Rule 8.200–E, Commentary .02.

The proposed rule change was published for comment in the **Federal Register** on December 14, 2020.[3] On January 14, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On March 9, 2021, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act [6] to determine whether to approve or disapprove the proposed rule change.[7] The Commission has received comments on the proposed rule change.[8] On May 6, 2021, the Exchange withdrew the proposed rule change (SR–NYSEArca–2020–105).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09974 Filed 5–11–21; 8:45 am]

BILLING CODE 8011–01–P

[12] 17 CFR 200.30–3(a)(57).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 91356 (March 18, 2021), 86 FR 15759 (March 24, 2021) (''Notice'').

[4] *See* proposed Rule 531(a); *see also* Notice at 15760.

[5] *See* proposed Rule 531(a); *see also* Notice at 15759. The proposed Report would not include real-time market data. *See* Notice at 15759.

[6] *See* proposed Rule 531(a)(1)–(2); *see also* Notice at 15759–60. The Exchange states that only displayed resting orders would be included in the Report, as the Exchange does not currently offer any non-displayed orders types on its options trading

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91791; File No. SR–NYSE–2020–93]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Partial Amendment No. 1, To Amend Rules 7.35 and 7.35A

May 7, 2021.

On November 3, 2020, New York Stock Exchange LLC (''NYSE'' or ''Exchange'') 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 amend Rule 7.35 regarding dissemination of Auction Imbalance Information if a security is an IPO or Direct Listing and has not had its IPO Auction or Direct Listing Auction, and Rule 7.35A regarding DMM consultations in connection with an IPO or Direct Listing. The proposed rule change was published for comment in the **Federal Register** on November 17, 2020.[3] On December 18, 2020, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change.[5] On February 12, 2021, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act [6] to determine whether to approve or disapprove the proposed rule change.[7] On April 12, 2021, the Exchange filed Partial Amendment No. 1 to the proposed rule change with the Commission and submitted Partial Amendment No. 1 for inclusion in the public comment file.[8] The Commission has received no other comment letter on the proposed rule change, as modified by Partial Amendment No. 1.

Section 19(b)(2) of the Act [9] provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for notice and comment in the **Federal Register** on November 17, 2020.[10] May 16, 2021, is 180 days from that date, and July 15, 2021, is 240 days from that date.

The Commission finds it appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change, as modified by Partial Amendment No. 1, so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[11] designates July 15, 2021, as the date by which the Commission shall either approve or disapprove the proposed rule change (File No. SR–NYSE–2020–93) as modified by Partial Amendment No. 1.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–10057 Filed 5–11–21; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 90387 (Nov. 10, 2020), 85 FR 73322 (Nov. 17, 2020) (''Notice''). Comments received on the proposed rule change are available on the Commission's website at *https://www.sec.gov/comments/sr-nyse-2020-93/srnyse202093*.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 90723 (Dec. 18, 2020), 85 FR 84446 (Dec. 28, 2020).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 91121, (Feb. 12, 2021), 86 FR 10386 (Feb. 19, 2021).

[8] In Partial Amendment No. 1, the Exchange provides additional background in support of, but does not propose any further modification to the Exchange rules in the initial proposal. *See* Letter from Martha Redding, Associate General Counsel, NYSE LLC, to Secretary, Commission (April 12, 2021). Partial Amendment No. 1 is available at *https://www.sec.gov/comments/sr-nyse-2020-93/srnyse202093-8662680-235308.pdf*.

[9] 15 U.S.C. 78s(b)(2).

[10] *See supra* note 3.

[11] 15 U.S.C. 78s(b)(2).

[12] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91787; File No. SR–EMERALD–2021–09]

Self-Regulatory Organizations; MIAX Emerald, LLC; Order Approving Proposed Rule Change To Adopt Exchange Rule 531(a), Reports, To Provide for a New ''Liquidity Taker Event Report''

May 6, 2021.

I. Introduction

On March 5, 2021, MIAX EMERALD, LLC (''MIAX Emerald'' or ''Exchange'') 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 adopt Exchange Rule (''Rule'') 531(a) to provide for a new ''Liquidity Taker Event Report'' (''Report''). The proposed rule change was published for comment in the **Federal Register** on March 24, 2021.[3] The Commission has received no comments on the proposed rule change. This order approves the proposed rule change.

II. Description of the Proposed Rule Change

The Report that the Exchange proposes to offer pursuant to new Rule 531(a) would be an historical options data product, generally available on a T+1 basis, that would provide certain information from the prior trading day to any member that wishes to subscribe to the Report.[4] The information set forth in the proposed Report would be designed to identify for any subscribing member (''Recipient Member'') the amount of time by which certain orders from the Recipient Member that may have been marketable missed an execution due to other liquidity-accessing orders responding faster to resting interest on the Exchange's book.[5] Specifically, for instances during the prior trading day where a Recipient Member attempted to execute against a resting order within 200 microseconds of the Exchange's receipt of the resting order, the proposed Report would provide time-related information and additional detail regarding the resting order, the first response to the resting order that successfully executed against the resting order, and the Recipient Member's responses that missed executing against the resting order.[6]

Proposed Rule 531(a)(1) describes this time-related information and additional detail. With regard to each resting order covered by the proposed Report, the proposed Report would provide: (A) The time the resting order was received by the Exchange; [7] (B) symbol; (C) order reference number, which is a unique reference number assigned to a new order at the time of receipt; (D) whether the Recipient Member is an affiliate of the member that entered the resting order; [8] (E) origin type (*e.g.,* priority customer, market maker); (F) side (buy or sell); and (G) displayed price and size of the resting order.[9]

With regard to the execution of the resting order, the proposed Report would provide: (A) The EBBO at the time of execution; [10] (B) the ABBO at the time of execution; [11] (C) the time the first response that executed against the resting order was received by the Exchange and the size of the execution and type of the response; [12] (D) the time difference between when the resting order was received by the Exchange and when the first response that executed against the resting order was received by the Exchange; [13] and (E) whether the response was entered by the Recipient Member.[14]

With regard to response(s) sent by the Recipient Member, the proposed Report would provide: (A) A Recipient Member identifier; (B) the time difference between when the first response that executes against the resting order was received by the Exchange and when each response sent by the Recipient Member was received by the Exchange, regardless of whether the Recipient Member's responses executed or not; [15] (C) size and type of each response submitted by the Recipient Member; and (D) response reference number, which is a unique reference number attached to the response by the Recipient Member.[16]

In addition, proposed Rule 531(a)(3) would state that the Report would only include trading data related to the Recipient Member, and would not include any other member's trading data other than that listed in paragraphs (1)(i) and (ii) of the proposed rule.[17] Further, the Exchange states that the content of the Report would be specific and tailored to the Recipient Member, and any data included in the Report that relates to a member other than the Recipient Member would be anonymized.[18]

According to the Exchange, the proposed Report is designed for members that are interested in gaining insight into latency in connection with orders that failed to execute against an order resting on the Exchange's book.[19] Exchange members have periodically requested from the Exchange's trading

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 91356 (March 18, 2021), 86 FR 15759 (March 24, 2021) (''Notice'').

[4] *See* proposed Rule 531(a); *see also* Notice at 15760.

[5] *See* proposed Rule 531(a); *see also* Notice at 15759. The proposed Report would not include real-time market data. *See* Notice at 15759.

[6] *See* proposed Rule 531(a)(1)–(2); *see also* Notice at 15759–60. The Exchange states that only displayed resting orders would be included in the Report, as the Exchange does not currently offer any non-displayed orders types on its options trading platform. *See* Notice at 15760 n.7.

[7] This would reflect, in nanoseconds, the time at which the resting order was received by the Exchange's system. *Id.* at 15760 n.8.

[8] The Exchange states that the Report would only indicate whether the Recipient Member is an affiliate of the member that entered the resting order and would not include any other information that may indicate the identity of the member that entered the resting order. *Id.* at 15760 n.12. According to the Exchange, including this information would allow the Recipient Member to better understand the scenarios in which it may execute against the orders of its affiliates. *Id.* at 15761.

[9] *See* proposed Rule 531(a)(1)(i); *see also* Notice at 15760. The Exchange states that the displayed price of the resting order may be different from the ultimate execution price when a resting order is displayed and ranked at different prices upon entry to avoid a locked or crossed market. *See* Notice at 15760 n.16.

[10] The Exchange uses the term ''EBBO'' to mean the best bid or offer on the Exchange. *See* Rule 100; *see also* Notice at 15760 n.17. If the resting order executes against multiple contra-side responses, only the EBBO at the time of the execution against the first response would be included. *See* proposed Rule 531(a)(1)(ii)(A).

[11] The Exchange uses the term ''ABBO'' or ''Away Best Bid or Offer'' to mean the best bid(s) or offer(s) disseminated by other Eligible Exchanges (defined in Rule 1400(g)) and calculated by the Exchange based on market information received by the Exchange from the Options Price Reporting Authority (''OPRA''). *See* Rule 100; *see also* Notice at 15760 n.19. If the resting order executes against multiple contra-side responses, only the ABBO at the time of the execution against the first response would be included. *See* proposed Rule 531(a)(1)(ii)(B).

[12] This time value would reflect, in nanoseconds, the time at which the response was received by the Exchange's network, which is before the response would be received by the Exchange's system. *See* Notice at 15760 n.21.

[13] This time difference would be provided in nanoseconds. *Id.* at 15760 n.22.

[14] *See* proposed Rule 531(a)(1)(ii); *see also* Notice at 15760. If not entered by the Recipient Member, this data point would be left blank so as not to include any identifying information about other member activity. *See* Notice at 15761.

[15] This time difference would be provided in nanoseconds. For purposes of calculating this duration of time, the Exchange would use the times that the resting order and the Recipient Member's response(s) are received by the Exchange's network, both of which would be before the order and response(s) would be received by the Exchange's system. *Id.* at 15760 n.23.

[16] *See* proposed Rule 531(a)(1)(iii); *see also* Notice at 15760.

[17] *See* proposed Rule 531(a)(3).

[18] *See* Notice at 15759.

[19] *Id.* at 15761.

operations personnel information concerning the timeliness of their incoming orders and efficacy of their attempts to execute against resting liquidity.[20] The Exchange states that the purpose of the proposed Report is to provide Recipient Members with this type of data in a standardized format and on an equal basis.[21] The Exchange believes that Recipient Members may use the data to optimize their models and trading patterns in an effort to yield better execution results.[22] In addition, the Exchange states that the proposed Report is based on a similar data product that another exchange offers for equity securities,[23] and that certain information that would be provided in the proposed Report, including in particular the time duration by which a Recipient Member's orders missed an execution, is similar to information that is provided in the other exchange's data product.[24] Moreover, according to the Exchange, other information that would be contained in the proposed Report already is available from existing data sources, such as OPRA and the Exchange's proprietary data feeds, or is information that the Exchange would provide as a convenience to the Recipient Member and that would be known to the Recipient Member even if not included in the Report.[25]

III. Discussion and Commission Findings

After careful review, 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.[26] In particular, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[27] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and that those rules not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As discussed above, the Exchange currently fields *ad hoc* requests from members for information regarding the timeliness of their attempts to execute against resting options liquidity on the Exchange's book.[28] The proposal is designed to offer this type of latency information in a systematized way and standardized format to any member that chooses to subscribe to the Report. As a result, the Commission believes that the proposal will make latency information for liquidity-seeking orders available to Exchanges members in a more equalized manner and will increase transparency, particularly for Recipient Members that may not have the expertise to generate the same information on their own. The Commission also believes that the proposed Report may better enable Recipient Members to increase the fill rates for their liquidity-seeking orders. At the same time, as is also discussed above, the Report is designed to prevent a Recipient Member from learning other members' sensitive trading information. The Report would not be a real-time market data product, as it would provide only historical trading data for the previous trading day, generally on a T+1 basis.[29] In addition, the data in the Report regarding incoming orders that failed to execute would be specific to the Recipient Member's orders,[30] and other information in the proposed Report regarding resting orders and executions would be anonymized if it relates to a member other than the Recipient Member.[31] Accordingly, consistent with Section 6(b)(5) of the Act, the Commission believes that the proposal is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest, and is not designed to permit unfair discrimination.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[32] that the proposed rule change (SR–EMERALD–2021–09), be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09975 Filed 5–11–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91788; File No. SR–NSCC–2021–002]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Designation of Longer Period for Commission Action and Longer Period for Comment on Proposed Rule Change To Amend the Supplemental Liquidity Deposit Requirements

May 7, 2021.

I. Introduction

On March 5, 2021, National Securities Clearing Corporation (''NSCC'') filed with the Securities and Exchange Commission (''Commission'') proposed rule change SR–NSCC–2021–002 (the ''Proposed Rule Change'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder [2] to amend its supplemental liquidity deposit requirements.[3] The Proposed Rule Change was published for comment in the **Federal Register** on March 24, 2021,[4] and the Commission has received comments in support of the changes proposed therein.[5]

---

[20] *Id.* at 15759.

[21] *Id.* The Exchange states that it intends to submit a separate rule filing with the Commission to propose fees for the Report. *Id.* at 15759 n.3.

[22] *Id.* at 15761.

[23] *Id.* at 15759 n.6 (referencing the Missed Opportunity—Latency report that is part of the Trading Insights offering of the NASDAQ Stock Market LLC (''Nasdaq'')); *see also* Nasdaq Rules, Equity Section 7, Rule 146(a)(2); Securities Exchange Act Release No. 78886 (September 20, 2016), 81 FR 66113 (September 26, 2016) (SR–NASDAQ–2016–101) (order approving Nasdaq Trading Insights data product).

[24] *See* Notice at 15760–62.

[25] *Id.*

[26] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[27] 15 U.S.C. 78f(b)(5).

[28] *See* Notice at 15759.

[29] *See* proposed Rule 531(a)(4); *see also* Notice at 15760.

[30] *See* proposed Rule 531(a)(1)(iii) and (a)(3).

[31] *See* Notice at 15759.

[32] 15 U.S.C. 78s(b)(2).

[33] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Notice of Filing, *infra* note 4, at 86 FR 15738. On March 5, 2021, NSCC also filed the proposals contained in the Proposed Rule Change as advance notice SR–NSCC–2021–801 (the ''Advance Notice'') with the Commission pursuant to Section 806(e)(1) of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 (''Clearing Supervision Act''), 12 U.S.C. 5465(e)(1), and Rule 19b–4(n)(1)(i) of the Act, 17 CFR 240.19b–4(n)(1)(i). Notice of filing of the Advance Notice was published in the **Federal Register** on March 24, 2021. Securities Exchange Act Release No. 91347 (March 18, 2021), 86 FR 15750 (March 24, 2021) (File No. SR–NSCC–2021–801).

[4] Securities Exchange Act Release No. 91350 (March 18, 2021), 86 FR 15738 (March 24, 2021) (File No. SR–NSCC–2021–002) (''Notice of Filing'').

[5] Comments are available at *https://www.sec.gov/comments/sr-nscc-2021-002/srnscc2021002.htm.* To

Section 19(b)(2) of the Act[6] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for the proposed rule change is effectively May 7, 2021.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider and take action on the proposed rule change.

Accordingly, pursuant to Section 19(b)(2) of the Act[7] and for the reasons stated above, the Commission designates June 21, 2021 as the date by which the Commission shall either approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change (File No. SR–NSCC–2021–002).

The Commission also seeks to extend the comment period to help further inform its analysis of the proposed rule change. The comment period for the proposed rule change ended on April 14, 2021.[8] As of May 5, 2021, the Commission has received numerous comment letters to the proposed rule change.[9] The Commission is extending the comment period for the proposed rule change to allow interested persons additional time to analyze the issues and prepare their comments. Accordingly, the Commission designates May 31, 2021 as the date comments should be submitted on or before.

Specifically, the Commission invites interested persons to provide views, data, and arguments concerning the proposed rule change, including whether the proposed rule change is consistent with the Act and the applicable rules or regulations thereunder. Please note that comments previously received on the substance of the proposed rule change will be considered together with comments submitted in response to this notice. Therefore, while commenters are free to submit additional comments at this time, they need not re-submit earlier comments.

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–NSCC–2021–002 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–NSCC–2021–002. 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 NSCC and on DTCC's website (*http://dtcc.com/legal/sec-rule-filings.aspx*). 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–NSCC–2021–002 and should be submitted on or before June 2, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–10054 Filed 5–11–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91784; File No. SR–CboeEDGA–2021–012]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule

May 6, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 3, 2021, Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') 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 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

Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend the fee schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/edga/*), at the Exchange's Office of the Secretary, 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

date, the comments received generally support the proposal.

[6] 15 U.S.C. 78s(b)(2).

[7] *Id.*

[8] Notice of Filing, *supra* note 4, 86 FR at 15738.

[9] *See supra* note 5. The comments received generally support the proposal, although they do not generally provide substantive analysis of the proposal.

[10] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 Exchange proposes to amend its fee schedule by eliminating Tier 2 of the Remove Volume Tiers.

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 that do not have similar self-regulatory responsibilities under the Exchange Act, to which market participants may direct their order flow. Based on publicly available information,[3] no single registered equities exchange has more than 15% of the market share. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. 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 fee changes. Accordingly, competitive forces constrain the Exchange's transaction fees, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. Additionally, in response to the competitive environment, the Exchange offers tiered pricing which provides Members opportunities to qualify for higher rebates or reduced fees where 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 for satisfying increasingly more stringent criteria.

Pursuant to footnote 7 of the Fee Schedule, the Exchange offers Remove Volume Tiers that provide a rebate to Members meeting certain volume thresholds. Specifically, Tier 2 currently provides an opportunity for Members to receive an enhanced rebate of $0.0028 per share for qualifying liquidity removing orders (*i.e.,* yielding fee codes N,[4] W,[5] 6,[6] and BB [7]), where a Member adds or removes an ADV [8] greater than or equal to 0.65% of the TCV.[9] Now, the Exchange proposes to eliminate Tier 2 of the Remove Volume Tiers. The Exchange no longer believes Tier 2 is necessary and notes the Exchange is not required to maintain such an incentive. Further, the Exchange would rather redirect future resources and funding into other programs and tiers intended to incentivize increased order flow.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[10] in general, and furthers the objectives of Section 6(b)(4),[11] in particular, as it is designed to provide 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) [12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market 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 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. The proposed rule change reflects a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members.

In particular, the Exchange believes eliminating Tier 2 of the Remove Volume Tiers is reasonable because the Exchange is not required to maintain such a tier, and Members still have a number of other opportunities and a variety of ways to receive enhanced rebates. Moreover, as noted above, the Exchange would rather redirect future resources and funding into other programs and tiers intended to incentivize increased order flow. The Exchange believes the proposal to eliminate Tier 2 of the Remove Volume Tiers is also equitable and not unfairly discriminatory because it applies to all Members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the Exchange does not believe the proposal to eliminate Tier 2 of the Remove Volume Tiers will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed change applies to all Members equally, in that no Member will continue to be eligible for the tier. As discussed above, the Exchange is not required to maintain such an incentive. Also, as previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and director their order flow, including 15 other options exchanges and off-exchange venues. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single options exchange has more than 15% of the market share.[13] Therefore, no exchange possesses significant pricing power in the execution of option order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels

[3] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (April 26, 2021), available at *https://markets.cboe.com/us/equities/market_statistics/*.

[4] Fee code N is appended to orders removing liquidity from EDGA (Tape C).

[5] Fee code W is appended to orders removing liquidity from EDGA (Tape A).

[6] Fee code 6 is appended to orders removing liquidity from EDGA, pre and post market (All Tapes).

[7] Fee code BB is appended to orders removing liquidity from EDGA (Tape B).

[8] ADV means daily volume calculated as the number of shares added to, removed from, or routed by, the Exchange, or any combination or subset thereof, per day. ADV is calculated on a monthly basis.

[9] TCV means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply.

[10] 15 U.S.C. 78f.

[11] 15 U.S.C. 78f(b)(4).

[12] 15 U.S.C. 78f(b)(5).

[13] *See supra* note 3.

at those other venues to be more favorable. Moreover, 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.'' [14] 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 as follows: ''[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 order-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 possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . . . .''.[15] Accordingly, the Exchange does not believe its proposed fee change imposes 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

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [16] and paragraph (f) of Rule 19b–4 [17] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeEDGA–2021–012 on the subject line.

Paper Comment

- 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–CboeEDGA–2021–012. 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–CboeEDGA–2021–012 and should be submitted on or before June 2, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–09970 Filed 5–11–21; 8:45 am]

BILLING CODE 8011–01–P

[14] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[15] *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–NYSEArca–2006–21)).

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91798; File No. SBSDR–2020–01]

Security-Based Swap Data Repositories; DTCC Data Repository (U.S.), LLC; Order Approving Application for Registration as a Security-Based Swap Data Repository

May 7, 2021.

I. Introduction

On December 22, 2020, DTCC Data Repository (U.S.), LLC (''DDR'') filed with the Securities and Exchange Commission (''Commission'') an application (the ''DDR Application'') on Form SDR to register as a security-based swap data repository (''SDR'') pursuant to Section 13(n)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') and 17 CFR 240.13n–1 (''Rule 13n–1'') thereunder,[1] and as a securities information processor (''SIP'') under Section 11A(b) of the Exchange Act.[2] DDR intends to operate as a registered SDR for security-based swap (''SBS'') transactions in the equity, credit, and interest rate derivatives asset classes.[3]

The Commission published notice of the DDR Application in the **Federal Register** for public comment on February 10, 2021,[4] and the

[1] 15 U.S.C. 78m(n)(1); 17 CFR 240.13n–1. A copy of DDR's application on Form SDR and non-confidential exhibits thereto are available for public viewing on the Commission's website. In 2016, DDR submitted a prior application for registration as an SDR. *See* Release No. 34–78216 (June 30, 2016), 81 FR 44379 (July 7, 2016); Release No. 34–81302 (Aug. 3, 2017), 82 FR 37276 (Aug. 9, 2017). DDR withdrew this prior application in 2018. *See* Letter from Chris Childs, Managing Director, DDR, Mar. 27, 2018, *https://www.sec.gov/divisions/marketreg/sdr/dtcc-sdr-application-withdrawal-letter-032718.pdf*.

[2] 15 U.S.C. 78k–1(b).

[3] DDR has included the interest rate asset class in its application based on feedback from potential users of its SDR services. The potential users have identified certain types of transactions that will be reported through DDR's infrastructure for interest rate derivatives as falling within the Exchange Act definition of an SBS transaction.

[4] Release No. 34–91071 (Feb. 5, 2021), 86 FR 8977 (Feb. 10, 2021) (''DDR Notice'').

Commission received in response two comment letters from the International Swaps and Derivatives Association, Inc. (''ISDA'').[5] While generally supportive of the DDR Application, ISDA Letter II includes three requests related to regulatory reporting and public dissemination, which are addressed in Part III.G. As discussed in Parts III and IV below, the Commission has carefully reviewed the DDR Application and the comments received. This order grants DDR's application to register as an SDR in the asset classes noted above, and as a SIP.

II. Background

A. SDR Registration, Duties, and Core Principles

Section 13(n) of the Exchange Act makes it unlawful for any person, unless registered with the Commission, directly or indirectly, to make use of the mails or any means or instrumentality of interstate commerce to perform the functions of an SDR.[6] To be registered and maintain registration, an SDR must comply with certain requirements and core principles described in Section 13(n), as well as any requirements that the Commission may impose by rule or regulation.[7] In 2015, the Commission adopted 17 CFR 240.13n–1 to 13n–12 under the Exchange Act to establish Form SDR, the procedures for registration as an SDR, and the duties and core principles applicable to an SDR (''SDR Rules'').[8] The Commission provided a temporary exemption from compliance with the SDR Rules and also extended exemptions from the provisions of the Dodd-Frank Act set forth in a Commission order providing temporary exemptions and other temporary relief from compliance with certain provisions of the Exchange Act concerning security-based swaps, and these temporary exemptions expired in 2017.[9]

The Commission also has adopted 17 CFR 242.900 to 909 under the Exchange Act (collectively, ''Regulation SBSR''), which governs regulatory reporting and public dissemination of security-based swap transactions.[10] Among other things, Regulation SBSR requires each registered SDR to register with the Commission as a SIP,[11] and the Form SDR constitutes an application for registration as a SIP, as well as an SDR.[12]

In 2019, the Commission stated that implementation of the SBS Reporting Rules can and should be done in a manner that carries out the fundamental policy goals of the SBS Reporting Rules while minimizing burdens as much as practicable.[13] Noting ongoing concerns among market participants about incurring unnecessary burdens and the Commission's efforts to promote harmonization between the SBS Reporting Rules and swap reporting rules, the Commission took the position that, for four years following Regulation SBSR's Compliance Date 1 in each asset class,[14] certain actions with respect to the SBS Reporting Rules would not provide a basis for a Commission enforcement action.[15] The no-action statement's relevance to DDR's application for registration as an SDR and SIP is discussed further below.

B. Standard for Registration

As noted above, to be registered with the Commission as an SDR and maintain such registration, an SDR is required to comply with the requirements and core principles described in Section 13(n) of the Exchange Act, as well as with any requirement that the Commission may impose by rule or regulation.[16] In addition, Rule 13n–1(c)(3) under the Exchange Act provides that the Commission shall grant the registration of an SDR if it finds that the SDR is so organized, and has the capacity, to be able to: (i) Assure the prompt, accurate, and reliable performance of its functions as an SDR; (ii) comply with any applicable provisions of the securities laws and the rules and regulations thereunder; and (iii) carry out its functions in a manner consistent with the purposes of Section 13(n) of the Exchange Act and the rules and regulations thereunder.[17] The Commission shall deny the registration of an SDR if it does not make any such finding.[18] Similarly, to be registered with the Commission as a SIP, the Commission must find that such applicant is so organized, and has the capacity, to be able to assure the prompt, accurate, and reliable performance of its functions as a SIP, comply with the provisions of the Exchange Act and the rules and regulations thereunder, carry out its functions in a manner consistent with the purposes of the Exchange Act, and, insofar as it is acting as an exclusive processor, operate fairly and efficiently.[19]

In determining whether an applicant meets the criteria set forth in Rule 13n–1(c), the Commission will consider the information reflected by the applicant on its Form SDR, as well as any additional information obtained from the applicant. For example, Form SDR requires an applicant to provide a list of the asset classes for which the applicant is collecting and maintaining data or for which it proposes to collect and maintain data, a description of the functions that it performs or proposes to perform, general information regarding its business organization, and contact information.[20] Obtaining this information and other information reflected on Form SDR and the exhibits thereto—including the applicant's overall business structure, financial condition, track record in providing access to its services and data, technological reliability, and policies and procedures to comply with its statutory and regulatory obligations—will enable the Commission to determine whether to grant or deny an application for registration.[21] Furthermore, the information requested in Form SDR will enable the Commission to assess whether the applicant is so organized and has the capacity to comply and carry out its functions in a manner consistent with the federal securities laws and the rules

[5] Letters from Eleanor Hsu, Director, Data and Reporting, ISDA, dated Feb. 26, 2021 (''ISDA Letter I'') and Apr. 9, 2021 (''ISDA Letter II''). ISDA Letter I did not address the substance of the DDR Application; ISDA Letter II provided comments that are discussed below.

[6] 15 U.S.C. 78m(n).

[7] *Id.*

[8] *See* Release No. 34–74246 (Feb. 11, 2015), 80 FR 14438, 14438 (Mar. 19, 2015) (''SDR Adopting Release''). In 2016, the Commission subsequently amended 17 CFR 240.13n–4 to address third-party regulatory access to SBS data obtained by an SDR. *See* Release No. 34–78716 (Aug. 29, 2016), 81 FR 60585 (Sep. 2, 2016).

[9] *See* Release No. 34–80359 (Mar. 31, 2017), 82 FR 16867 (Apr. 6, 2017).

[10] Release No. 34–74244 (Feb. 11, 2015), 80 FR 14563 (Mar. 19, 2015); Release No. 34–78321 (July 14, 2016), 81 FR 53546 (Aug. 12, 2016) (''Regulation SBSR Adopting Release''). Regulation SBSR and the SDR Rules are referred to collectively as the ''SBS Reporting Rules.''

[11] *See* 17 CFR 242.909.

[12] *See* Form SDR, Instruction 2.

[13] Release No. 34–87780 (Dec. 18, 2019), 85 FR 6270, 6347 (Feb. 4, 2020) (''ANE Adopting Release'').

[14] *See id.* Under Regulation SBSR, the first compliance date (''Compliance Date 1'') for affected persons with respect to an SBS asset class is the first Monday that is the later of: (i) Six months after the date on which the first SDR that can accept transaction reports in that asset class registers with the Commission; or (ii) one month after the compliance date for registration of SBS dealers and major SBS participants (''SBS entities''). *Id.* at 6346. The compliance date for registration of SBS entities is October 6, 2021. *See id.* at 6270, 6345.

[15] *See id.* The specific rule provisions of the SBS Reporting Rules affected by the no-action statement are discussed in Part II.B.

[16] *See* 15 U.S.C. 78m(n)(3).

[17] 17 CFR 240.13n–1(c)(3).

[18] *Id.*

[19] *See* 15 U.S.C. 78k–1(b)(3).

[20] *See* SDR Adopting Release, *supra* note 8, at 14459.

[21] *See id.* at 14458.

and regulations thereunder, including the SBS Reporting Rules.[22]

Consistent with the Commission's no-action statement in the ANE Adopting Release,[23] an entity wishing to register with the Commission as an SDR must still submit an application on Form SDR, but can address the rule provisions included in the no-action statement by discussing how the SDR complies with comparable Commodity Futures Trading Commission (''CFTC'') requirements.[24] Accordingly, in such instances the Commission will not assess an SDR application for consistency or compliance with the rule provisions included in the Commission's no-action statement. Specifically, the Commission identified the following provisions as not providing a basis for an enforcement action against a registered SDR for the duration of the relief provided in the Commission statement: Under Regulation SBSR, aspects of 17 CFR 242.901(a), 901(c)(2) through (7), 901(d), 901(e), 902, 903(b), 906(a) and (b), and 907(a)(1), (a)(3), and (a)(4) through (6); under the SDR Rules, aspects of Section 13(n)(5)(B) of the Exchange Act and 17 CFR 240.13n–4(b)(3) thereunder, and aspects of 17 CFR 240.13n–5(b)(1)(iii); and under Section 11A(b) of the Exchange Act, any provision pertaining to SIPs.[25] Thus, an SDR applicant will not need to include materials in its application explaining how it would comply with the provisions noted above, and could instead rely on its discussion about how it complies with comparable CFTC requirements.[26] The applicant may instead represent in its application that it: (i) Is registered with the CFTC as a swap data repository; (ii) is in compliance with applicable requirements under the swap reporting rules; (iii) satisfies the standard for Commission registration of an SDR under Rule 13n–1(c); and (iv) intends to rely on the no-action statement included in the ANE Adopting Release for the period set forth in the ANE Adopting Release with respect to any SBS asset class or classes for which it intends to accept transaction reports.[27]

III. Review of DDR's Application Under SBS Reporting Rules

As noted above, DDR intends to operate as a registered SDR for the equity, credit, and interest rate derivatives asset classes.[28] In its application, DDR represents that it is provisionally registered with the CFTC as a swap data repository, is in compliance with applicable requirements under the CFTC reporting rules applicable to a registered swap data repository, and intends to rely on the Commission's position outlined in the ANE Adopting Release for applicable reporting rules and SBSDR duties for the period set forth therein.[29] Below is a review of the representations made in the application materials against the SBS Reporting Rules, taking into account DDR's reliance on the Commission's position outlined in the ANE Adopting Release.

A. Organization and Governance

1. Summary of DDR's Application

DDR is a New York limited liability company and a wholly owned subsidiary of DTCC Deriv/SERV LLC (''Deriv/SERV''), which in turn is a wholly owned subsidiary of The Depository Trust & Clearing Corporation (''DTCC'').[30] DDR is governed by a board of directors (''DDR Board'').[31] The number of directors on the DDR Board is determined by Deriv/SERV as the sole LLC member of DDR.[32] The DDR Board is composed of individuals selected from the following groups: Employees of DDR's users (either fees paying users or end users) with derivatives industry experience, buy-side representatives, independents, and members of senior management or the Board of DTCC.[33] The Deriv/SERV Nominations Committee shall periodically review the composition of the DDR Board to assure that the level of representation of directors from users, management and non-users is appropriate for the interests of these constituencies in DDR.[34]

In addition, the DDR Board is responsible for the appointment and removal of the chief compliance officer (''CCO'') and approval of CCO compensation, which is at the discretion of the Board and effected by a majority vote.[35] The CCO is responsible for establishing and administering the compliance program that is designed to prevent violations of the obligations of a swap data repository under the Dodd-Frank Act and other applicable regulations and is ultimately responsible for ensuring that DDR complies with the requirements of the Commodity Exchange Act, the Securities Exchange Act and other applicable laws and regulations.[36] The CCO has oversight over all compliance functions and staff related to DDR's compliance program.[37] The duties of the CCO include, but are not limited to, the following: (a) Oversee and review DDR's compliance with applicable law in jurisdictions where DDR is registered, designated, recognized or otherwise licensed; (b) in consultation with the DDR Board or the Senior Officer, resolve any conflicts of interests that may arise, including, but not limited to, conflicts between business considerations and compliance requirements, conflicts between business considerations and compliance requirements for fair and open access, and conflicts between the management and members of the DDR Board; (c) establish and administer written policies and procedures reasonably designed to prevent violation of law; (d) take reasonable steps to ensure compliance with applicable law relating to agreements, contracts or transactions and confidentiality agreements entered into with foreign or domestic regulators; (e) establish procedures for the remediation of non-compliance issues identified by the CCO through a compliance office review, look-back, internal or external audit finding, self-reported error, or validated complaint; (f) notify the DDR Board as soon as practicable upon becoming aware of a circumstance indicating that DDR, or an individual acting on its behalf, is in non-compliance with the applicable laws of a jurisdiction in which it operates and either: (1) The non-compliance creates a risk to a user; (2) the non-compliance creates a risk of harm to the capital markets in which it operates; (3) the non-compliance is part of a pattern of non-compliance; or (4) the non-compliance may have an impact on DDR's ability to carry on business as a trade repository in compliance with applicable law; (g) establish and follow appropriate procedures for the handling, management response, remediation, retesting and closing of noncompliance issues; (h) establish and administer a

[22] *See id.* at 14458–59.

[23] *See supra* notes 13–15 and accompanying text.

[24] *See supra* note 15.

[25] The ANE Adopting Release provides additional discussion of the particular aspects of the affected rules that would not provide a basis for an enforcement action. *See* ANE Adopting Release, *supra* note 13, at 6347–48.

[26] *Id.* at 6348.

[27] *Id.* For example, an applicant need not describe in Exhibit S its functions as a SIP.

[28] *See* DDR Rulebook, Ex. HH, sec. 3.1; *see also* Disclosure Document, Ex. D6, sec. 1.

[29] *See* Form SDR, cover letter from Katherine Delp, General Manager, DTCC Data Repository (U.S.) LLC.

[30] DDR Rulebook, Ex. HH, sec. 2.1.

[31] *Id.* at sec. 2.2. Defined terms taken from the DDR Application and used or summarized in this order are intended to have the same meaning as in DDR Application.

[32] *Id.*

[33] *Id.*

[34] *Id.*

[35] *Id.* at sec. 2.3.

[36] Ex. P.

[37] *Id.*

written code of ethics; and (i) prepare and sign an annual compliance report in accordance with applicable regulations and associated recordkeeping.[38] In addition, the application provides that the CCO or a delegate thereof has the authority to investigate any potential rule violation and is responsible for enforcing sanctions related to violations and for following the procedures outlined for DDR system restrictions.[39]

The CCO, in consultation with the DDR Audit Committee, will resolve all conflicts of interest.[40] Any conflict of interest not resolved by the DDR Audit Committee shall be escalated to the DDR Board for resolution.[41] When resolving conflicts of interest involving DDR staff, the DDR CCO, DDR's senior officer, the audit committee, and the DDR Board consider all relevant facts and circumstances.[42] With regard to director conflicts of interest, the application provides that a director conflict is present whenever the interests of DDR compete with the interests of a director or any party associated with a director.[43] The application also provides that a director conflict is present whenever a director's corporate or personal interests could be reasonably viewed as affecting his or her objectivity or independence in fulfilling his or her duties.[44] According to the application materials, DDR expects its directors to act ''on the side of caution'' and immediately bring to the attention of the DDR CCO and either the Board Chairman or DDR's legal counsel any matters involving conflicts of interest.[45]

2. Discussion

Section 13(n)(7)(B) of the Exchange Act and Rule 13n–4(c)(2) thereunder require an SDR to establish governance arrangements that are transparent to fulfill public interest requirements and to support the objectives of the Federal Government, owners, and participants.[46] In addition, Rule 13n–4(c)(2) requires an SDR to (i) establish well-defined governance arrangements that include a clear organizational structure with effective internal controls; (ii) establish governance arrangements that provide for fair representation of market participants; (iii) provide representatives of market participants, including end-users, with the opportunity to participate in the process for nominating directors and with the right to petition for alternative candidates; and (iv) establish, maintain, and enforce written policies and procedures reasonably designed to ensure that senior management and each member of the board or committee that has authority to act on behalf of the board possess requisite skills and expertise to fulfill their responsibilities in the management and governance of the SDR, have a clear understanding of their responsibilities, and exercise sound judgment about the SDR's affairs.[47]

Furthermore, Rule 13n–4(b)(11) requires an SDR to designate an individual to serve as CCO, and Rule 13n–11(a) requires the SDR to identify on Form SDR the person so designated.[48] Rule 13n–11(a) also requires that the compensation, appointment, and removal of the CCO shall require approval of a majority of the SDR's board of directors.[49] Rule 13n–11(c) requires the CCO to: (i) Report directly to the board of directors or to the senior officer; (ii) review compliance with Section 13(n) of the Exchange Act and the rules thereunder; (iii) in consultation with the board or the senior officer, take reasonable steps to resolve any material conflicts of interest; (iv) be responsible for administering the policies and procedures required by Section 13(n) of the Exchange Act and the rules thereunder; (v) take reasonable steps to ensure compliance with the Exchange Act and the SDR Rules thereunder; (vi) establish procedures for the remediation of noncompliance; and (vii) establish and follow appropriate procedures for the handling, management response, remediation, retesting, and closing of noncompliance issues.[50]

Additionally, Section 13(n)(7)(C) of the Exchange Act requires an SDR to establish and enforce rules to minimize conflicts of interest in the decision-making process of the SDR and establish a process for resolving any such conflicts of interest.[51] Rule 13n–4(c)(3) under the Exchange Act provides that an SDR must: (i) Establish, maintain, and enforce written policies and procedures reasonably designed to identify and mitigate potential and existing conflicts of interest in the SDR's decision-making process on an ongoing basis; (ii) with respect to the decision-making process for resolving any conflicts of interest, require the recusal of any person involved in such conflict from such decision-making; and (iii) establish, maintain, and enforce written policies and procedures regarding the SDR's non-commercial and/or commercial use of the SBS transaction information that it receives.[52]

The Commission received no comments applicable to these requirements. As described above, the DDR Application includes provisions for the representation of market participants in the governance arrangements, as well as procedures providing an opportunity to participate in the process for nominating directors and the right to petition for alternative candidates. In addition, the DDR Application includes policies and procedures that set standards for the skills and expertise possessed by the DDR Board.

More generally, the DDR Application sets forth an organizational structure that is clear and includes provisions for internal controls. The DDR Application includes provisions for a CCO that has been designated by the DDR Board and whose compensation, appointment, and removal is set by the DDR Board. In addition, the DDR Application includes policies and procedures that require the CCO to report to the senior officer and be responsible for maintaining compliance with applicable Commission rules, investigating any suspected violations thereof, and overseeing any necessary remediation. The DDR Application includes policies and procedures that identify and mitigate conflicts of interest, require the recusal from decision-making of members of the DDR Board when involved in a conflict, and delineate the commercial and non-commercial use of SBS transaction information received.

B. Access and Information Security

1. Summary of DDR's Application

According to DDR, access to and usage of its SDR service will be available to all market participants that engage in SBS transactions, and DDR does not and will not bundle or tie its SDR services with any other services.[53] The application provides that DDR's services would be available to all market participants on a fair, open, and equal basis.[54] Further, DDR does not impose membership qualifications on users of its services beyond (i) requiring execution of membership documents, such as a user agreement, (ii) the ability to comply with the technical specifications published by DDR, and

[38] DDR Rulebook, Ex. HH, sec. 2.3.
[39] *Id.* at sec. 10.5.
[40] *Id.* at sec. 11.1.
[41] *Id.*
[42] *Id.*
[43] *Id.* at sec. 11.2.
[44] *Id.*
[45] *Id.* at sec. 11.3.
[46] 15 U.S.C 78m(n)(7)(B); 17 CFR 240.13n–4(c)(2).
[47] 17 CFR 240.13n–4(c)(2)(i)–(iv).
[48] 17 CFR 240.13n–4(b), 13n–11(a).
[49] 17 CFR 240.13n–11(a).
[50] 17 CFR 240.13n–11(c)(1)–(7).
[51] 15 U.S.C. 78m(n)(7)(C)(i), (ii).
[52] 17 CFR 240.13n–4(c)(3)(i)–(iii).
[53] *See* DDR Rulebook, Ex. HH, at sec. 1.1.
[54] *See id.*

(iii) compliance with applicable law, specifically those related to sanctions administered and enforced by the Office of Foreign Assets Control of the U.S. Department of the Treasury (''OFAC'').[55]

To be granted access to the DDR system, receive trade information, confirm or verify transactions, submit messages, or receive reports, a market participant must be onboarded as a user.[56] For those market participants that onboard, DDR will provide a mechanism for users to access the DDR system to confirm and verify transactions. Users are required to maintain at least two Super Access Coordinators (''SuperACs'') on the DDR System; SuperACs are responsible for: (1) Providing access to other individuals (referred to as ''ACs'') who are eligible to access the System and use the SDR Services on behalf of the user; and (2) removing access for any individuals who should no longer access the System on behalf of the user.[57]

To participate in the SDR services offered by DDR, each user will be required to enter into a user agreement; by entering into a user agreement each user agrees to be bound by the terms of the user agreement and DDR Operating Procedures, which incorporate terms of DDR's Rulebook.[58] In addition, the DDR Rulebook provides that each user must comply with all reasonable requests by DDR for information, documentation, or data concerning such user and related to such user's use of the DDR system as DDR may deem necessary.[59] The DDR Rulebook also states that DDR has the right to audit or inspect a user (and its facilities) with respect to its use of the DDR system, upon reasonable notice.[60] Furthermore, the DDR Rulebook provides that users must cooperate with such audits or inspections and with other inquiries by DDR concerning their use of the DDR system.[61]

The DDR Operating Procedures provide that each user agrees to defend and indemnify DDR from and against all reasonable losses, liabilities, damages, judgments, settlements, fines, costs, and expenses DDR may incur directly arising out of or directly relating to the acts or omissions of a user's participation or failure to participate (for itself or on behalf of others) in DDR's services or DDR's system, any unauthorized access to DDR's system through such user's interface with DDR's system, or any other matter directly relating to such user that is not the responsibility of DDR under the DDR Operating Procedures, except to the extent that such losses arise out of or relate to DDR's negligence or willful misconduct.[62]

With respect to prohibiting or limiting a person's access to SDR services, the DDR Rulebook outlines the process required for DDR to decline an application to become a user of SDR services.[63] For example, DDR may deny an applicant's access to the DDR system if required pursuant to applicable law (*e.g.,* due to sanctions administered and enforced by OFAC or the Canadian Government's Office of the Superintendent of Financial Institutions).[64] The DDR Rulebook provides that any such applicants would receive notice and an opportunity for a hearing in the event that DDR declines an application.[65] The DDR Rulebook also provides that, if the denial of an application is reversed,[66] such application will be accepted and the applicant granted access to the DDR system following completion of onboarding requirements.[67]

The DDR Rulebook also provides that DDR may temporarily deny access to or otherwise impose restrictions on the use of the DDR system on a user, or take such other actions as DDR deems reasonably necessary to protect its systems and other users, for (i) a violation of the DDR rules (including a failure to pay fees when due); (ii) any neglect or refusal by such user to comply with any direction DDR deems reasonably necessary to protect its systems and other users; or (iii) any error, delay, or other conduct that materially and adversely affects the operations of DDR (each a ''Subject Event'').[68] Limits to the activities, functions, or operation of users may include, but are not limited to, restricting access to the DDR system or a user's ability to submit data via a non-approved source and assessing users with all costs incurred by DDR in connection with a ''Subject Event'' and apply any deterrent financial penalties that DDR may deem necessary.[69] The DDR Rulebook provides that DDR is required to provide prompt notice to the designated regulators of any such action,[70] as well as furnish the user with a concise written statement describing the Subject Event applicable to the user.[71]

With respect to information security, the DDR Rulebook provides that DTCC has established a Technology Risk Management Team, whose role is to manage information security risk and ensure the availability, integrity, and confidentiality of the organization's information assets.[72] DDR will be responsible for monitoring the performance of DTCC regarding implementation and maintenance of information security ''within its infrastructure.'' [73] The DDR Rulebook specifies that various policies have been developed to provide the framework for both physical security and information security are routinely refreshed.[74] It also states that DDR's Technology Risk Management Team carries out a series of processes to endeavor to ensure that DDR is protected in a cost-effective and comprehensive manner, while still meeting the requirements of applicable regulations.[75] This includes preventive controls such as firewalls, appropriate encryption technology, and authentication methods.[76] Vulnerability scanning is used to identify high risks to be mitigated and managed and to measure conformance against the policies and standards.[77]

The DDR system is supported by DTCC and relies on the disaster recovery program maintained by DTCC.[78] To enable DDR to provide timely resumption of critical services should there be any disruption to its business, DDR follows these key principles for business continuity and disaster recovery: (i) Achieve recovery of critical services within a four-hour window with faster recovery time in less extreme situations; (ii) disperse staff across geographically diverse operating

[55] *See id.*

[56] *See id.*

[57] *Id.* at sec. 1.2.

[58] *Id.* at sec. 1.3.

[59] *Id.* at sec. 10.5.

[60] *Id.*

[61] *Id.*

[62] *Id.,* app. A, at sec. 9.

[63] *See* DDR Rulebook, Ex. HH, sec. 10.2.

[64] *See id.*

[65] *See id.*

[66] The DDR Notice, *supra* note 4, inadvertently misstated a provision in the DDR Rulebook. Specifically, the DDR Rulebook does not include language that states denial of an application could be reversed ''either by the DDR Board or by the Commission pursuant to Section 11A(b) of the Exchange Act.'' As noted in Part II.B, the Commission has identified Section 11A(b) as not providing a basis for an enforcement action against a registered SDR for the duration of the relief provided in the Commission statement in the ANE Adopting Release. *See supra* note 25 and accompanying text.

[67] *See* DDR Rulebook, Ex. HH, sec. 10.2.

[68] *See id.* at sec. 10.4.1.

[69] *See id.*

[70] *See id.*

[71] *See id.* at sec. 10.4.2 (setting out DDR's procedures for restrictive proceedings, including the user's response to the Subject Event written statement, the user's opportunity for a hearing, and the user's right to apply for review to the DDR Board).

[72] *Id.* at sec. 9.2.

[73] *Id.* at sec. 9.1.

[74] *Id.* at sec. 9.2.

[75] *Id.*

[76] *Id.*

[77] *Id.*

[78] *See id.* at sec. 8.1.

facilities; (iii) operate multiple back-up data centers linked by a highly resilient network technology; (iv) maintain emergency command and out-of-region operating control; (v) utilize new technology which provides high-volume, high-speed, asynchronous data transfer over distances of 1,000 miles or more; (vi) maintain processes that mitigate marketplace, operational and cyber-attack risks; (vii) test continuity plan readiness and connectivity on a regular basis ensuring that users and third-party vendors/service providers can connect to DDR's primary and back-up sites; (viii) communicate on an emergency basis with the market, users and government agency decision-makers; and (ix) evaluate, test, and utilize best business continuity and resiliency practices.[79]

2. Discussion

Rule 13n–4(c)(1)(ii) under the Exchange Act requires an SDR to permit market participants to access specific services offered by the SDR separately.[80] Rule 13n–4(c)(1)(iii) requires an SDR to establish, monitor on an ongoing basis, and enforce clearly stated objective criteria that would permit fair, open, and not unreasonably discriminatory access to services offered and data maintained by the SDR.[81] Rule 13n–4(c)(1)(iv) requires an SDR to establish, maintain, and enforce written policies and procedures reasonably designed to review any prohibition or limitation of any person with respect to access to services offered, directly or indirectly, or data maintained by the SDR and to grant such person access to such services or data if such person has been discriminated against unfairly.[82] In addition, Rule 13n–6 requires an SDR, with respect to those systems that support or are integrally related to the performance of its activities, to establish, maintain, and enforce written policies and procedures reasonably designed to ensure that its systems provide adequate levels of capacity, integrity, resiliency, availability, and security.[83]

The Commission received no comments applicable to these requirements. As described above, the DDR Application includes procedures for onboarding and maintaining ongoing access to users that are fair, open, reasonable and not unreasonably discriminatory. These procedures include user agreements that reflect clear and specific minimum standards for users to follow in seeking to access SBS data held at the SDR. The DDR Application also includes reasonable provisions for limiting, denying, and revoking access to SDR systems that include procedures for review and reconsideration of any determination related to limiting, denying, or revoking a user's access. The Commission believes that the procedures described above further help ensure that the access requirements are fair, open, and not unreasonably discriminatory. In addition, the DDR Application includes policies and procedures designed to ensure that the SDR's automated systems maintain adequate levels of capacity, integrity, resiliency, availability, and security that protect against loss of data, employ geographic diversity in their site selection, and account for service disruptions.

C. Acceptance and Use of SBS Data

1. Summary of DDR's Application

The DDR Application will provide market participants with the ability to submit data for over-the-counter (''OTC'') derivatives for credit, equity, rate, foreign exchange and other commodity asset classes.[84] DDR may reject a transaction record submitted due to the submission failing to meet DDR validations, including but not limited to the submission failing to be in a format that can be ingested by DDR, failing to meet jurisdictional requirements or failing to provide required data elements.[85] A rejected submission is deemed not to have been submitted at all with respect to reporting to the jurisdiction for which it was rejected (it is possible that one transaction record is submitted to comply with reporting obligations in more than one jurisdiction and accepted in one while rejected in another).[86] Upon submission, the DDR system will perform validation checks to ensure that each submitted record is complete and accurate, in accordance DDR's message ingestion requirements.[87] This process is completed through validation and consistency checks.[88] If the record fails these validation or consistency checks, the record will be rejected, and such rejection status will be communicated to the user(s) to correct and re-submit.[89] According to DDR, its SDR service offers an end-to-end straight through process. DDR states that, from the receipt of data, processing and maintenance of data, and dissemination of data, processes are automated and do not require manual intervention, and this straight through processing model is a key mitigant to modification or invalidation of any data.[90]

DDR's Operating Procedures provides that DDR and each user agrees that each will treat as confidential (both during and after the termination of a user's access to DDR's system) all confidential information (defined as: (i) With respect to DDR, transaction data specified in records received by DDR and any data, reports, summaries or payment amounts which may be produced as a result of processing such transaction data, and (ii) with respect to any user, the technical specifications of DDR's system (to the extent not publicly disclosed by DDR; but confidential information does not include data distributed to the public in accordance will applicable law).[91]

2. Discussion

Rule 13n–5(b)(1)(i) under the Exchange Act requires an SDR to establish, maintain, and enforce written policies and procedures reasonably designed for the reporting of complete and accurate transaction data to the SDR and to accept all transaction data that is reported in accordance with such policies and procedures.[92] Additionally, Rule 13n–5(b)(1)(ii) requires that if an SDR accepts any SBS transaction in a particular asset class, the SDR must accept all SBS transactions in that asset class that are reported to it in accordance with its policies and procedures.[93] In addition, Rule 13n–5(b)(3) requires an SDR to establish, maintain, and enforce written policies and procedures reasonably designed to ensure that the transaction data and positions that it maintains are complete and accurate.[94] Rule 13n–5(b)(5) requires an SDR to establish, maintain, and enforce written policies and procedures reasonably designed to prevent any provision in a valid SBS transaction from being invalidated or modified through the procedures or operations of the SDR.[95] Rule 13n–

[79] *See id.*

[80] 17 CFR 240.13n–4(c)(1)(ii).

[81] 17 CFR 240.13n–4(c)(1)(iii).

[82] 17 CFR 240.13n–4(c)(1)(iv).

[83] 17 CFR 240.13n–6.

[84] DDR Rulebook, Ex. HH, sec. 3.1; *see also* Disclosure Document, Ex. D6, sec. 1. Although the DDR Application concerns registration with the Commission as an SDR for credit, equity, and interest rate derivatives, as noted above, DDR is also provisionally registered with the CFTC as a swap data repository.

[85] DDR Rulebook, Ex. HH, sec. 1.3.

[86] *Id.*

[87] *Id.* at sec. 10.1.1.

[88] *Id.*

[89] *Id.*

[90] Ex. EE.

[91] DDR Rulebook, Ex. HH, app. A, sec. 8; *see also* Disclosure Document, Ex. D6, sec. 5 (DDR's privacy and confidentiality policies and procedures).

[92] 17 CFR 240.13n–5(b)(1)(i).

[93] 17 CFR 240.13n–5(b)(1)(ii).

[94] 17 CFR 240.13n–5(b)(3).

[95] 17 CFR 240.13n–5(b)(5).

5(b)(6) requires an SDR to establish procedures and provide facilities reasonably designed to effectively resolve disputes over the accuracy of the transaction data and positions that are recorded in the SDR.[96]

Furthermore, Section 13(n)(5)(F) of the Exchange Act and Rule 13n–4(b)(8) thereunder each require an SDR to maintain the privacy of any and all SBS transaction information that the SDR receives.[97] In addition, Rule 13n–9(b)(1) requires an SDR to establish, maintain, and enforce written policies and procedures reasonably designed to protect the privacy of any and all SBS transaction information that the SDR receives and that include policies and procedures to protect the privacy of any and all SBS transaction information that the SDR shares with affiliates and non-affiliated third parties.[98] Rule 13n–9(b)(2) also requires an SDR to establish, and maintain safeguards, policies, and procedures reasonably designed to prevent the misappropriation or misuse, directly or indirectly, of any confidential information received by the SDR, material non-public information, or intellectual property, such as trading strategies or portfolio positions, by: (i) Limiting access to such information and intellectual property; (ii) having standards for trading by persons associated with the SDR for their personal benefit or the benefit of others; and (iii) having adequate oversight to ensure compliance with these safeguards, policies, and procedures.[99]

The Commission received no comments applicable to these requirements. As described above, the DDR Application includes policies and procedures designed to protect transaction data and its systems by restricting access to users, who are obligated to comport with DDR's rules in a manner that facilitates DDR's compliance with its obligations under Commission rules. The Commission views this approach as reasonable. Access to DDR's systems to view trade data or verify information should be conditioned such that DDR retains the ability to protect the data, its systems, and its users. The Commission notes that DDR retains the responsibility, among other things, to ensure that its policies and procedures are reasonably designed to: (i) Ensure trade data reported to it is complete and accurate, as required under Rule 13n–5(b)(1); (ii) ensure that its systems provide adequate levels of capacity, integrity, resiliency, availability and security, as required under Rule 13n–6; and (iii) ensure that it protects the privacy and confidentiality of transaction information, as required under Rule 13n–9(b). Additionally, the DDR Application includes procedures designed to ensure that any valid provisions of trade information are not modified or invalidated, and these procedures include controls that are regularly audited and processing systems designed to prevent unauthorized changes to SBS information. The Commission also believes that DDR provides procedures and facilities reasonably designed to effectively resolve disputes over the accuracy of the transaction data and positions that are recorded in the SDR.

Furthermore, the DDR Application contains policies and procedures regarding both data security and the privacy of SBS data, the latter of which includes in each case procedures limiting access to SBS data to employees with either direct or support responsibilities related to systems that maintain the data, and that limit the use of such data in all cases to the performance of job responsibilities. The Commission believes that such policies and procedures also establish a standard for the trading practices of personnel that prevents the use of the data for personal benefit or the benefit of others. In addition, DDR has policies and procedures that, when taken together with policies and procedures regarding the duties of the CCO,[100] are reasonably designed to protect the privacy of SBS transaction information, including information shared with affiliates and third parties, through adequate oversight to ensure compliance with the policies and procedures described above.

D. Fees

1. Summary of DDR's Application

The DDR Application includes DDR's fee schedules.[101] There are two types of fees, Position Maintenance Fees and Account Management Fees.[102] DDR charges a monthly ''Position Maintenance Fee,'' based on the number of positions open at any time during the applicable month and which decreases as the number of open positions increases on a tiered basis.[103] Position count includes positions even if terminated or exited prior to the month end.[104] Platforms, as that term is defined by Commission rules,[105] are not charged position maintenance fees.[106] For a position where a clearing agency (''Clearer'') is a counterparty, the Clearer shall be responsible for the Position Maintenance Fee, less a 75% reduction.[107] For all other positions, the Reporting Side, as that term is defined by Commission rules,[108] will be responsible for Position Maintenance Fees.[109] For entities grouped as a single account with subaccounts (''Grouped Accounts''), positions will be aggregated for purposes of determining position count threshold and to determine the applicable tiered Position Maintenance Fees.[110]

In addition to the Position Maintenance Fee, the application indicates that DDR will charge an annual ''Account Management Fee,'' currently set at $1,200.00, that will apply to all accounts and will be prorated in the year the account is opened.[111] Accounts may be set up on an individual entity basis or, in certain instances, as Grouped Accounts, such as a corporate family [112] that chooses to structure its account as a single account with subaccounts for affiliates or an asset manager that chooses to structure its account as a single account with subaccounts for its managed funds. Grouped Accounts will be charged one Account Management Fee.[113]

DDR's fee policy further provides that users will have the option to elect to enter into a long-term commitment for a period ending December 31, 2024 (''Long Term Commitment''), which would reduce the applicable Position Maintenance Fee and Account

[96] 17 CFR 240.13n–5(b)(6).

[97] *See* 15 U.S.C. 78m(n)(5)(F); 17 CFR 240.13n–4(b)(8), 240.13n–9.

[98] 17 CFR 240.13n–9.

[99] *See* 17 CFR 240.13n–9(b)(2).

[100] *See supra* Part III.A (describing policies and procedures regarding the CCO and conflicts of interest).

[101] *See* Ex. M. Additionally, DDR provides a fee schedule for DDR Users on its website at *http://www.dtcc.com/derivatives-services/global-trade-repository/gtr-us*.

[102] *See* Ex. M.

[103] The Position Maintenance Fees only apply for a position count of five hundred or more open positions during any month. *See id.* For examples of the calculation of the Position Maintenance Fee, see Annex A to Exhibit M of the application.

[104] *See* Ex. M.

[105] *See* 17 CFR 242.900(v) (defining ''platform'' as a national securities exchange or security-based swap execution facility that is registered or exempt from registration).

[106] *See* Ex. M.

[107] *See id.*

[108] *See* 17 CFR 242.900(gg) (defining ''reporting side'' as the side of a security-based swap identified by Rule 901(a)(2) as having the duty to report the transaction).

[109] *See* Ex. M.

[110] *See id.*

[111] *See id.*

[112] DDR organizes its users into families (each, a ''Family'') as directed by the users (through User Agreements or in such other manner as designated by DDR from time to time) that desire to be so organized. *See* DDR Rulebook, Ex. HH, app. A, sec. 2.

[113] *See* Ex. M.

Management Fee by ten percent, exclusive of tax, for the duration of the Long-Term Commitment.[114] If the Long Term Commitment is terminated prior to the end of the applicable Long Term Commitment period, DDR explains that the non-Clearer User will be subject to an early termination fee equal to: (a) The difference between the total amount of fees due after application of the Long Term Commitment incentive and the total amount of fees that would have been due during the applicable portion of the Long Term Commitment period had no incentive been provided (''Total Incentive Provided''); plus (b) the greater of five percent of the Total Incentive Provided or $500.00.[115]

2. Discussion

Section 13(n)(7)(A) of the Exchange Act prohibits an SDR (unless necessary or appropriate to achieve the purposes of the Exchange Act) from: (i) Adopting any rule or taking any action that results in any unreasonable restraint of trade; or (ii) imposing any material anti-competitive burden on the trading, clearing, or reporting of transactions.[116] Rule 13n–4(c)(1)(i) under the Exchange Act also requires an SDR to ensure that any dues, fees, or other charges that it imposes, and any discounts or rebates that it offers, are fair and reasonable and not unreasonably discriminatory.[117] It also requires that such dues, fees, other charges, discounts, or rebates be applied consistently across all similarly situated users of the SDR's services.[118] In discussing the fee provisions of the SDR Rules, the Commission stated that it would take a flexible approach in evaluating the fairness and reasonableness of an SDR's fees and charges on a case-by-case basis, recognizing that there may be instances in which an SDR could charge different users different prices for the same or similar services.[119]

The Commission received no comments applicable to these requirements. As described above, the DDR Application describes fees that include a fixed component and a variable component that increases with the usage of SDR services. The Commission notes that such a fee structure is generally in line with the economics of recordkeeping services for security-based swaps, which involve a fixed cost investment and marginal costs of operation.[120] The fixed component of DDR's fees would be consistent with the applicant recovering the fixed costs investment associated with setting up and maintaining a user account, while the variable component would be consistent with the applicant recovering marginal costs of operation, *i.e.,* costs that increase with the provision of SDR services to the user.

With regard to DDR's fee schedule, which imposes an annual Account Management Fee of $1,200 and a Positions Maintenance Fee that varies as a function of the number of open positions each month, the fees are identical to those charged to customers reporting swap transactions in credit, equity, and interest rate products pursuant to CFTC reporting rules and, as such, appear consistent with the Commission's own requirements.[121] Specifically, the Commission believes it is reasonable for DDR to establish similar fees across its CFTC and Commission reporting requirements where its obligations require similar levels of services and infrastructure. The Commission believes that the DDR Application sets fees at levels that are fair and reasonable and not unreasonably discriminatory.

E. Recordkeeping

1. Summary of DDR's Application

The DDR Rulebook provides that DDR will maintain all information as required by applicable law as well as maintain swap and security-based swap data throughout the existence of the swap and security-based swap and for fifteen years following termination of the swap or security-based swap or as otherwise required by applicable regulations.[122] The records will be readily accessible throughout the life of a swap or security-based swap and for five years following its termination and shall be in an electronic format that is non-rewriteable and non-erasable.[123] For the remainder of the retention period, the swap or security-based swap record will be retrievable within three business days.[124] In the event DDR ceases doing business or ceases to be a registered or designated trade repository it shall continue, for a period of not less than five years or upon transfer to the Designated Regulator or its designee or another registered or designated trade repository for that jurisdiction, to preserve, maintain, and make accessible to each Designated Regulator or its designee, the records and data required by Applicable Regulation in accordance with DDR's Wind-Down Policies and Procedures document.[125]

2. Discussion

Rule 13n–5(b)(4) of the Exchange Act requires an SDR to maintain transaction data and related identifying information for not less than five years after the SBS expires and historical positions for not less than five years in a place and format that is readily accessible and usable to the Commission and other persons with authority to access or view such information and in an electronic format that is non-rewriteable and non-erasable.[126] Rule 13n–7 requires an SDR to make and keep current books and records relating to its business for at least five years, and for the first two years, keep such records in a place that is immediately available to representatives of the Commission for inspection and examination.[127] In addition, Rule 13n–5(b)(8) requires an SDR to make and keep current a plan to ensure that the transaction data and positions that are recorded in the SDR continue to be maintained in accordance with Rule 13n–5(b)(7),[128] including procedures for transferring the transaction data and positions to the Commission or its designee.[129]

The Commission received no comments applicable to these requirements. As described above, the DDR Application provides for the recordkeeping of SBS transaction data for at least five years following the termination of the transaction,[130] and will be readily accessible throughout the life of a security-based swap in an electronic format that is non-rewriteable and non-erasable.[131] In addition, DDR provides for the transferring of

[114] *See id.*

[115] *See id.*

[116] 15 U.S.C. 78m(n)(7)(A).

[117] 17 CFR 240.13n–3(c)(1)(i).

[118] *Id.*

[119] *See* SDR Adopting Release, *supra* note 8, at 14479. In making this statement, however, the Commission also noted that charging different users different prices for the same or similar services cannot be unreasonably discriminatory.

[120] *See generally* Regulation SBSR Adopting Release, *supra* note 10, at 53551 (stating that the provision of recordkeeping services for security-based swaps involves a predominantly fixed cost investment with low marginal costs of operation).

[121] *See* DDR Fee Schedule—CFTC Reporting, Oct. 1, 2016, *http://www.dtcc.com/~/media/Files/Downloads/Data-and-Repository-Services/GTR/US-DDR/DDR_Fees.pdf.*

[122] DDR Rulebook, Ex. HH, sec. 1.4.1.

[123] *Id.*

[124] *Id.*

[125] *Id.*

[126] 17 CFR 240.13n–5(b)(4).

[127] 17 CFR 240.13n–7.

[128] Rule 13n–5(b)(7) states that, if an SDR ceases doing business or ceases to be registered pursuant to Section 13(n) of the Exchange Act, the SDR must continue to preserve, maintain, and make accessible the transaction data and historical positions required to be collected, maintained, and preserved by this section in the manner required by the Exchange Act and the rules and regulations thereunder and for the remainder of the period required by this section. 17 CFR 240.13n–5(b)(7).

[129] 17 CFR 240.13n–8.

[130] *See* DDR Rulebook, Ex. HH, sec. 1.4.1.

[131] *See id.*

transaction data and positions to the Commission via reports designed to provide visibility into positions and the status of submitted trades and also provides for direct electronic access to data reported to DDR in satisfaction of the Commission's regulatory requirements both for the Commission and, where such access is permitted by applicable law and any relevant Memorandum of Understanding or other arrangement, the Commission's designee.

F. Disclosure

1. Summary of DDR's Application

DDR publishes a disclosure document to provide a summary of information regarding its service offerings and the SBS data it maintains.[132] Specifically, the disclosure document sets forth a description of the following: (i) A description of access to services offered and swap data maintained; (ii) criteria for those seeking to connect to or link with its SDR; (iii) criteria for those seeking to connect to or link with DDR systems; (iv) policies and procedures with respect to DDR systems safeguards; (v) policies and procedures related to privacy and confidentiality; (vi) policies and procedures regarding its non-commercial and commercial use of transaction data; [133] (vii) procedures for dispute resolution; (viii) fees, rates, dues and other charges; and (ix) governance arrangements.[134]

2. Discussion

Rule 13n–10 under the Exchange Act requires that, before accepting any SBS data from a market participant or upon a market participant's request, an SDR shall furnish to the market participant a disclosure document that contains certain written information, which must reasonably enable the market participant to identify and evaluate accurately the risks and costs associated with using the SDR's services.[135] This written information must contain the following: (i) The SDR's criteria for providing others with access to the services offered and data it maintains; (ii) its criteria for those seeking to connect to or link with the SDR; (iii) a description of its policies and procedures regarding its safeguarding of data and operational reliability, as described in Rule 13n–6; (iv) a description of its policies and procedures reasonably designed to protect the privacy of SBS transaction information that it receives, as described in Rule 13n–9(b)(1); (v) a description of its policies and procedures regarding its noncommercial and commercial use of SBS transaction information that it receives, as described in Rule 13n–5(b)(6); (vi) a description of its dispute resolution procedures, as described in Rule 13n–5(b)(6); (vii) a description of all the SDR's services, including any ancillary services; and (viii) the SDR's updated schedule of any dues; unbundled prices, rates or other fees for all of its services, including ancillary services; any discounts or rebates offered; and the criteria to benefit from such discounts or rebates; and (ix) a description of its governance arrangements.[136]

The Commission received no comments applicable to these requirements. As described throughout this order, the DDR Application includes extensive discussion of DDR's policies and procedures with respect to access,[137] the use of SBS transaction information,[138] service offerings, including ancillary services,[139] and governance arrangements.[140] The Commission believes that the DDR Disclosure Document presents a reasonably comprehensive view of the applicant's overall service offering, from which a potential user could identify and evaluate accurately the risks and costs associated with using the SDR's services.[141] In addition, regarding the requirement to furnish the document to market participants, the Commission understands that DDR publishes similar disclosure documents on its website,[142] and anticipates the same for the DDR Disclosure Document relevant to this application.

G. Regulatory Reporting and Public Dissemination

As a registered SDR, DDR would carry out an important role in the regulatory reporting and public dissemination of SBS transactions. As noted above, DDR stated that it intends to rely on the no-action statement included in the ANE Adopting Release for the period set forth in the ANE Adopting Release with respect to SBS asset classes. Therefore, DDR was not required to include materials in its application explaining how it would comply with the provisions of the SBS Reporting Rules noted in the no-action statement.[143] Instead, DDR may rely on its discussion about how it complies with comparable CFTC requirements pertaining to regulatory reporting and public dissemination of swap transactions.

In the no-action statement, the Commission stated that an applicant ''will not need to include materials in its application explaining how it would comply with the provisions [specifically noted as not providing a basis for a Commission enforcement action during the pendency of the statement].'' [144] The applicant ''could instead rely on its discussion about how it complies with comparable CFTC requirements.'' [145] In its application, DDR provided exhibits that adapted its policies and procedures for regulatory reporting and public dissemination of swaps for use in the SBS market. The Commission believes that, with respect to its role in the regulatory reporting and public dissemination of SBS transactions, DDR has satisfied the approach described by the Commission in the no-action

[132] *See* Disclosure Document, Ex. D6.

[133] *See also* DDR Rulebook, Ex. HH, sec. 6.3 (''As part of the SDR Services, DDR receives and collects swap and security-based swap data in the ordinary course of its business from various Market Participants and registered entities for the purpose of maintaining a centralized recordkeeping facility for swaps and security-based swaps. The collection and maintenance of this data is designed to enhance the transparency, promote standardization and reduce systemic risk by making this data available to regulators and the public pursuant to Applicable Law. Therefore, access to data maintained by DDR to Market Participants is generally prohibited, except to either counterparty to that particular swap or security-based swap, such counterparty's authorized third party service providers or other parties specifically authorized by the User or counterparty pursuant to Rule 1.3 or 6.4, or to other regulators or entities in accordance with Rule 6.5 below. DDR shall not, as a condition of the reporting of swap or security-based swap transaction data, require a Reporting Party to consent to the use of reported data for commercial or business purposes. DDR shall not make commercial use of real-time swap data prior to its public dissemination.'').

[134] *See id.*

[135] 17 CFR 240.13n–10.

[136] *See id.*

[137] *See supra* Part III.B (describing policies and procedures with respect to access and information security).

[138] *See supra* Part III.C (describing policies and procedures with respect to acceptance and use of SBS data).

[139] *See supra* Part III.D (describing policies and procedures with respect to fees).

[140] *See supra* Part III.A (describing policies and procedures with respect to governance arrangements, the duties of the CCO, and conflicts of interest).

[141] *See* DDR Disclosure Document, Ex. D6.

[142] *See, e.g., https://www.dtcc.com/-/media/Files/Downloads/Data-and-Repository-Services/GTR/US-DDR/DDR_Disclosure.pdf https://www.dtcc.com/-/media/Files/Downloads/Data-and-Repository-Services/GTR/US-DDR/DDR_Disclosure.pdf* (publishing a disclosure document pursuant to CFTC requirements).

[143] However, the DDR Application includes provisions explaining how DDR would require users to identify SBS, as required by Rule 901(c)(1) of Regulation SBSR. *See* Ex. HH2, sec. 4.4 (regarding Unique Product Identifiers). The DDR Application also includes a provision explaining how DDR would comply with a condition to the no-action statement included in the ANE Adopting Release. *See* Ex. GG2, sec. 15.2.3.2 (providing, in the case of a credit security-based swap, for dissemination of a capped notional size of $5 million if the true notional size of the transaction is $5 million or greater).

[144] ANE Adopting Release, *supra* note 13, at 6348.

[145] *Id.*

statement regarding the information and representations sufficient to support its approval for registration as an SDR and SIP.[146]

ISDA Letter II included three requests with respect to the DDR Application. First, ISDA stated that the DDR Rulebook should ''discuss 'Counterparty 2' identifiers that will be permitted under the new [CFTC] swap data reporting rules.'' [147] To the extent that this suggestion involves changes to DDR's systems, policies, and procedures for complying with future CFTC requirements, they are not part of DDR's existing systems, policies, and procedures and thus are not germane to the application being considered by the Commission. However, the Commission expects that DDR will, in the future, explain to its participants how changes made to the systems, policies, and procedures for complying with CFTC swap data reporting requirements will impact the reporting of security-based swap transactions.

Second, ISDA expressed support for the approach to unique trade identifiers in the DDR Rulebook, but for clarity requested adding appropriate references to the Unique Swap Identifier (''USI'') required by CFTC rules.[148] The no-action statement in the ANE Adopting Release does not impose any obligations on DDR to utilize a particular vocabulary when referring to data elements that will be utilized for both SEC and CFTC transaction reporting, so this request does not affect the Commission's evaluation of the DDR Application against the relevant statutory standards for registration as an SDR and as a SIP.

Third, ISDA notes that, although the specifications in the DDR Rulebook ''technically align'' with the SEC requirement that an SDR publicly disseminate immediately upon receipt, SDRs are also built to delay public dissemination under CFTC requirements. ISDA suggests that complying with the SEC requirement would require SDRs to incur the cost of adding functionality to disseminate immediately under Regulation SBSR, and ISDA therefore requests that the SEC align its requirement with the CFTC requirement.[149] To the extent ISDA is requesting that the Commission modify the no-action statement in response to ISDA's comment, the Commission declines to do so. Furthermore, because this comment pertains to a Commission position and not to the DDR Application, it does not affect the Commission's review of the DDR Application under the relevant statutory standards for registration as an SDR and as a SIP.[150]

IV. Evaluation of DDR's Application and Commission Findings

Consistent with the standard for registration previously described in Part II.B,[151] the Commission has considered whether DDR is so organized, and has the capacity, to be able to assure the prompt, accurate, and reliable performance of its functions as an SDR, comply with any applicable provisions of the securities laws and the rules and regulations thereunder, and carry out its functions in a manner consistent with the purposes of Section 13(n) of the Exchange Act and the rules and regulations thereunder. The Commission finds that DDR meets these criteria for registration as an SDR for the reasons described throughout this order.

To evaluate DDR's application to register as a SIP, and consistent with the standard for registration previously described in Part II.B,[152] the Commission has considered whether DDR is so organized, and has the capacity, to be able to assure the prompt, accurate, and reliable performance of its functions as a SIP, comply with the provisions of the Exchange Act and the rules and regulations thereunder, carry out its functions in a manner consistent with the purposes of the Exchange Act, and, insofar as it is acting as an exclusive processor, operate fairly and efficiently. The Commission finds that DDR meets these criteria for registration as a SIP for the reasons described throughout this order.

V. Conclusion

For the reasons discussed above, the Commission finds that DDR meets the applicable requirements for registration as an SDR, including those standards set forth in Section 13(n) of the Exchange Act and Commission rules and regulations thereunder, and the applicable requirements for registration as a SIP under Section 11A(b) of the Exchange Act.

It is hereby ordered that the application for registration as a security-based swap data repository and a securities information processor filed by DTCC Data Repository (U.S.), LLC (File No. SBSDR–2020–01) pursuant to Sections 13(n) and 11A(b) of the Exchange Act be, and hereby is, *approved*.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–10065 Filed 5–11–21; 8:45 am]

BILLING CODE 8011–01–P

[146] Because DDR has elected to rely on the no-action statement, *see supra* note 29, the Commission has not evaluated the DDR Application against any provisions of Regulation SBSR specifically noted as not providing a basis for a Commission enforcement action during the pendency of the statement.

[147] ISDA Letter II at 3. The comment refers to revisions to Parts 43 and 45 adopted by the CFTC in September 2020, which include requirements for reporting new data elements as well as changes to how existing data elements should be reported. *See* Part 43 revisions, available at: *www.cftc.gov/sites/default/files/2020/11/2020–21568a.pdf;* Part 45 revisions, available at: *www.cftc.gov/sites/default/files/2020/11/2020–21569a.pdf.*

[148] *See* ISDA Letter II at 3.

[149] *See id.* at 5.

[150] Under the CFTC's reporting rules, an SDR must publicly disseminate swap transaction and pricing data as soon as technologically practicable after such data is received, unless such swap transaction and pricing data is subject to a time delay described in § 43.5, in which case the swap transaction and pricing data shall be publicly disseminated in the manner described in § 43.5. *See* 17 CFR 43.3(b)(1). In addition, Appendix C to Part 43 provides clarification of the time delays for public dissemination set forth in § 43.5. An SDR subject to the CFTC's Part 43 rules must disseminate transaction and pricing data with a time delay if the transaction falls within § 43.5, and must disseminate transaction and pricing data ''as soon as technologically practicable'' if it does not. The Commission's no-action statement recognized that security-based swap transactions do not fall within § 43.5 or Appendix C of Part 43. *See* ANE Adopting Release, *supra* note 13, at 6347. Accordingly, an SDR, when utilizing CFTC rather than SEC protocols for dissemination of a security-based swap transaction, would not impose the time delay required for a swap transaction that falls within § 43.5. Nevertheless, to offer some accommodation for certain large-sized security-based swaps based on a single credit instrument or a narrow-based index of credit instruments, the Commission established a size cap of ''$5MM+'' for any transaction having a true notional size of $5 million or greater. As explained in the Commission's no-action statement, this cap is also applied by the Financial Industry Regulatory Authority when disseminating transaction reports of economically similar cash debt securities. *See id.* at 6347, n.768.

[151] *See supra* notes 16–18 and accompanying text.

[152] *See supra* note 19 and accompanying text.

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Approved for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the projects approved by rule by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: April 1–30, 2021.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and

Secretary to the Commission, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.net*. Regular mail inquiries May be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, receiving approval for the consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22(f) for the time period specified above:

Water Source Approval—Issued Under 18 CFR 806.22(f)

1. Chief Oil & Gas, LLC; Pad ID: Martino Drilling Pad #1; ABR–201604001.R1; Albany Township, Bradford County, Pa.; Consumptive Use of Up to 2.5000 mgd; Approval Date: April 2, 2021.

2. ARD Operating, LLC; Pad ID: Eugene P Nelson Pad A; ABR–201103036.R2; Cascade Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: April 2, 2021.

3. Range Resources—Appalachia, LLC; Pad ID: Bobst Mountain Hunting Club #18H–#23H Drilling Pad; ABR–201103031.R2; Cogan House Township, Lycoming County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: April 2, 2021.

4. Chesapeake Appalachia, L.L.C.; Pad ID: Franclaire; ABR–201012011.R2; Braintrim Township, Wyoming County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: April 12, 2021.

5. Chesapeake Appalachia, L.L.C.; Pad ID: Sensinger; ABR–201104002.R2; Franklin Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: April 12, 2021.

6. EXCO Resources (PA), LLC; Pad ID: Doebler Drilling Pad #1; ABR–201012033.R2; Penn Township, Lycoming County, Pa.; Consumptive Use of Up to 8.0000 mgd; Approval Date: April 12, 2021.

7. Diversified Production, LLC; Pad ID: Whippoorwill; ABR–201102024.R2; Shippen Township, Cameron County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: April 12, 2021.

8. SWN Production Company, LLC; Pad ID: PU–KK Valentine-Soliman Pad; ABR–201103008.R2; Lenox Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: April 12, 2021.

9. SWN Production Company, LLC; Pad ID: PU–II Ransom Stas Pad; ABR–201103007.R2; Lenox Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: April 12, 2021.

10. ARD Operating, LLC; Pad ID: COP Tr 728 C; ABR–201104004.R2; Watson Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: April 12, 2021.

11. ARD Operating, LLC; Pad ID: COP Tr 728 D; ABR–201104001.R2; Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: April 12, 2021.

12. SWN Production Company, LLC; Pad ID: TI–14 Connolly A Pad; ABR–201511006.R2; Liberty Township, Tioga County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: April 13, 2021.

13. SWN Production Company, LLC; Pad ID: TI–19 Connolly B—Pad; ABR–201511007.R2; Liberty Township, Tioga County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: April 13, 2021.

14. Seneca Resources Company, LLC; Pad ID: Yourgalite 1119; ABR–201012056.R2; Farmington Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: April 13, 2021.

15. Chesapeake Appalachia, L.L.C.; Pad ID: Fausto; ABR–201101015.R2; Litchfield Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: April 15, 2021.

16. BKV Operating, LLC; Pad ID: Baker West (Brothers); ABR–201103049; Forest Lake Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: April 15, 2021.

17. SWN Production Company, LLC; Pad ID: Price Pad; ABR–201104017.R2; Lenox Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: April 15, 2021.

18. Chief Oil & Gas, LLC; Pad ID: Noble Drilling Pad #1; ABR–201104015.R1; Lathrop Township, Susquehanna County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: April 19, 2021.

19. EXCO Resources (PA), LLC; Pad ID: Houseknecht Drilling Pad #1; ABR–201012014.R2; Davidson Township, Sullivan County, Pa.; Consumptive Use of Up to 8.0000 mgd; Approval Date: April 19, 2021.

20. SWN Production Company, LLC; Pad ID: PU–CC Valentine-Price Pad; ABR–201104019.R2; Lenox Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.9900 mgd; Approval Date: April 19, 2021.

21. Cabot Oil & Gas Corporation; Pad ID: LymanJ P1; ABR–201104018.R2; Springville Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: April 19, 2021.

22. Chesapeake Appalachia, L.L.C.; Pad ID: Moody; ABR–201104027.R2; Springfield Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: April 26, 2021.

23. Chief Oil & Gas, LLC; Pad ID: Taylor Drilling Pad #1; ABR–201104024.R2; Lenox Township, Susquehanna County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: April 26, 2021.

24. Chief Oil & Gas, LLC; Pad ID: Polovitch West Drilling Pad #1; ABR–201104025.R2; Nicholson Township, Wyoming County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: April 26, 2021.

25. Chesapeake Appalachia, L.L.C.; Pad ID: Stempel; ABR–201104020.R2; Asylum Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: April 26, 2021.

26. XTO Energy, Inc.; Pad ID: Renn Unit A; ABR–201103033.R2; Jordan Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: April 26, 2021.

27. Chesapeake Appalachia, L.L.C.; Pad ID: Crain; ABR–201104028.R2; Rome Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: April 27, 2021.

28. Chesapeake Appalachia, L.L.C.; Pad ID: Hulslander; ABR–201104021.R2; Smithfield Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: April 27, 2021.

29. Chesapeake Appalachia, L.L.C.; Pad ID: Kingsley; ABR–201104029.R2; Smithfield Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: April 27, 2021.

30. Chesapeake Appalachia, L.L.C.; Pad ID: MPC New; ABR–201104030.R2; Cherry Township, Sullivan County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: April 27, 2021.

Approvals by Rule—Issued Under 18 CFR 806.22(f)—Revocation

31. Chief Oil & Gas, LLC; Pad ID: Crandall Drilling Pad #1; ABR–201202013.R2; Ridgebury Township, Bradford County, Pa.; Revocation Date: April 1, 2021.

32. ARD Operating, LLC; Pad ID: COP Tr 356 Pad F; ABR–201007124.R1; Cummings Township, Lycoming County, Pa.; Revocation Date: April 2, 2021.

Dated: May 7, 2021.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2021–10029 Filed 5–11–21; 8:45 am]

BILLING CODE 7040–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Commission Meeting

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: The Susquehanna River Basin Commission will conduct its regular business meeting on June 17, 2021, from Harrisburg, Pennsylvania. Details concerning the matters to be addressed at the business meeting are contained in the Supplementary Information section of this notice. Also the Commission published a document in the **Federal Register** on April 13, 2021, concerning its public hearing on May 6, 2021, in Harrisburg, Pennsylvania.

DATES: The meeting will be held on Thursday, June 17, 2021, at 9 a.m.

ADDRESSES: The meeting will be conducted digitally from the Susquehanna River Basin Commission, 4423 N Front Street, Harrisburg, PA 17110.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: 717–238–0423; fax: 717–238–2436.

SUPPLEMENTARY INFORMATION: The business meeting will include actions or presentations on the following items: (1) Election of Commission officers for FY2022; (2) a resolution regarding environmental justice; (3) reconciliation of FY2022 budget; (4) ratification of contracts/grants; (5) proposed Water Resources program for 2022–2024; (6) amendments to the *Comprehensive Plan for the Water Resources of the Susquehanna River Basin*; and (7) Regulatory Program projects.

This agenda is complete at the time of issuance, but other items may be added, and some stricken without further notice. The listing of an item on the agenda does not necessarily mean that the Commission will take final action on it at this meeting. When the Commission does take final action, notice of these actions will be published in the **Federal Register** after the meeting. Any actions specific to projects will also be provided in writing directly to project sponsors.

Due to the COVID–19 orders, the meeting will be conducted telephonically and there will be no physical public attendance. The public is invited to attend the Commission's business meeting. You can access the Business Meeting through a computer (Audio and Video) by following the link: *https://srbc.webex.com/srbc/j.php?MTID=mfff80216a899be862056c07b1a4dce6b* then enter meeting number 133 849 0863 and password U8wvzbbk2p5. You may also participant telephonically by dialing 1–877–668–4493 and entering the meeting number 133 849 0863 followed by the # sign.

Written comments pertaining to items on the agenda at the business meeting may be mailed to the Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, Pennsylvania 17110–1788, or submitted electronically through *www.srbc.net/about/meetings-events/business-meeting.html.* Such comments are due to the Commission on or before June 15, 2021. Comments will not be accepted at the business meeting noticed herein.

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806, 807, and 808.

Dated: May 7, 2021.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2021–10030 Filed 5–11–21; 8:45 am]

BILLING CODE 7040–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Grandfathering (GF) Registration Notice

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists Grandfathering Registration for projects by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: April 1–30, 2021.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.net.* Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists GF Registration for projects, described below, pursuant to 18 CFR 806, Subpart E for the time period specified above:

Grandfathering Registration Under 18 CFR Part 806, Subpart E

1. HP Hood LLC—Arkport NY Plant, GF Certificate No. GF–202104162, Village of Arkport, Steuben County, N.Y.; Well 1 and consumptive use; Issue Date: April 12, 2021.

2. Village of Endicott—Public Water Supply System, GF Certificate No. GF–202104163, Village of Endicott, Broome County, N.Y.; Ranney Well, South 28 Well, and South 5 Well; Issue Date: April 14, 2021.

3. East Petersburg Borough—Public Water Supply System, GF Certificate No. GF–202104164, East Petersburg Borough, Lancaster County, Pa.; Vaughn Rd Well; Issue Date: April 14, 2021.

4. Allan Myers Materials PA, Inc.—Talmage Quarry, GF Certificate No. GF–202104165, Upper Leacock Township, Lancaster County, Pa.; consumptive use; Issue Date: April 23, 2021.

Dated: May 7, 2021.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2021–10031 Filed 5–11–21; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Request To Dispose 10.3 Acres of Land at Dillant-Hopkins Airport, Swanzey, NH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Request for public comments.

SUMMARY: Notice is being given that the FAA is considering a request from the City of Keene to dispose of 10.3 acres of land at Dillant-Hopkins Airport, Swanzey, NH, under the provisions of 49 U.S.C. 47107(h)(2).

The land is no longer needed for aviation purposes and may be disposed of by the airport. Ninety percent of the proceeds will be returned to the Federal Aviation Administration and used for a future airport grant. The remaining ten percent will be remitted to the City of Keene and placed in the airport's operation and maintenance fund. An avigation easement will be placed over the property to ensure compatibility with airport operations and airspace protection.

DATES: Comments must be received on or before June 11, 2021.

ADDRESSES: You may send comments using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov,* and follow the instructions on providing comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W 12–140, 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.

Interested persons may inspect the request and supporting documents by contacting the FAA at the address listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Mr. Jorge E. Panteli, Compliance and Land Use Specialist, Federal Aviation Administration New England Region Airports Division, 1200 District Avenue, Burlington, Massachusetts 01803. Telephone: 781–238–7618.

Issued in Burlington, Massachusetts, on May 7, 2021.

Julie Seltsam-Wilps,

Deputy Director, ANE–600.

[FR Doc. 2021–10060 Filed 5–11–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2021–0044]

Petition for Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that on March 22, 2021, Norfolk Southern Corporation (NS) petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 213. FRA assigned the petition Docket Number FRA–2021–0044.

Specifically, NS is requesting relief from 49 CFR 213.233(b)(3), and (c), which require track inspections to be conducted visually by railroad track inspectors at certain frequencies based on class of track. NS is petitioning to replace 49 CFR 213.233 visual track inspection requirements with a combination of automated and visual inspections. Proposed automated inspections would be performed by Track Geometry Measurement Systems three times per month, and visual inspections would be performed at least twice per month, for each track segment.

In support of its petition, NS references data and analysis from its ongoing Track Inspection Test Program, Docket Number FRA–2019–0099. Through the three phases, NS notes that track geometry defects have a continued downward trend, indicating overall improvement in track quality. NS states that the relief would positively impact safety by increasing defect identification and remediation, reduce employee exposure to potential hazards, and facilitate maintenance program planning.

A copy of the petition, as well as any written communications concerning the petition, if any, are available for review online at *www.regulations.gov*.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing for these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

• *Website: http://www.regulations.gov*. Follow the online instructions for submitting comments.

• *Fax:* 202–493–2251.

• *Mail:* Docket Operations Facility, U.S. Department of Transportation (DOT), 1200 New Jersey Ave. SE, W12–140, Washington, DC 20590.

Communications received by June 28, 2021 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy*. See also *https://www.regulations.gov/privacy-notice* for the privacy notice of *regulations.gov*.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety Chief Safety Officer.

[FR Doc. 2021–10051 Filed 5–11–21; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2021–0050]

Petition for Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that on March 6, 2021, the Southern California Railway Museum (SCRM) petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR 230.17, *One thousand four hundred seventy-two (1472) service day inspection*. FRA assigned the petition Docket Number FRA–2021–0050.

For locomotive SCRM VC 2, SCRM requests to extend the period in which the 1472 service day inspection must be completed until November 21, 2021, which is the date at which the locomotive's next annual inspection is due. At the end of the proposed extension period, SCRM VC 2 will have a total of less than 320 service days, which is less than 22% of the 1472 service day allowance. SCRM states that the extension would allow it to continue operating the locomotive for fundraising purposes and aligning the 1472 service day inspection with the annual inspection would potentially improve SCRM's financial challenges due to less revenue in the previous year.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov*.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

• *Website: http://www.regulations.gov*. Follow the online instructions for submitting comments.

• *Fax:* 202–493–2251.

• *Mail:* Docket Operations Facility, U.S. Department of Transportation (DOT), 1200 New Jersey Ave. SE, W12–140, Washington, DC 20590.

Communications received by June 28, 2021 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacy-notice* for the privacy notice of *regulations.gov*.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety Chief Safety Officer.

[FR Doc. 2021–10052 Filed 5–11–21; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2021–0032]

Agency Information Collection Activities; Notice and Request for Comments; Consolidated Vehicles' Owner's Manual Requirements for Motor Vehicles and Motor Vehicle Equipment

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a reinstatement with modification of a previously approved information collection.

SUMMARY: The National Highway Traffic Safety Administration invites public comments about our intention to request approval from the Office of Management and Budget (OMB) to reinstate a previously-approved information collection with modification. Before a Federal agency can collect certain information from the public, it must receive approval from OMB. Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections. This document describes a collection of information for which NHTSA intends to seek OMB approval on Vehicle Owner's Manual Requirements for Motor Vehicles and Motor Vehicle Equipment.

DATES: Written comments should be submitted by July 12, 2021.

ADDRESSES: You may submit comments, identified by NHTSA docket number identified above, through any of the following methods:

- *Electronic submissions:* Go to the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail or Hand Delivery:* Docket Management, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.
- *Instructions:* All submissions must include the agency name and docket number for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.
- *Privacy Act:* Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *https://www.transportation.gov/privacy.*
- *Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the street address listed above. Follow the online instructions for accessing the dockets via internet.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact James Myers, NHTSA, 1200 New Jersey Avenue SE, West Building, Room W43–320, NRM–100, Washington, DC 20590. Mr. Myers' telephone number is 202–366–1810. Please identify the relevant collection of information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following: (a) 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; (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) how to enhance the quality, utility, and clarity of the information to be collected; and (d) how 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, *e.g.*, permitting electronic submission of responses. In compliance with these requirements, NHTSA asks for public comments on the following proposed collection of information for which the agency is seeking approval from OMB.

Title: Consolidated Vehicle Owner's Manual Requirements for Motor Vehicles and Motor Vehicle Equipment.

OMB Control Number: 2127–0541.

Type of Request: Request for reinstatement with modification of a previously approved collection of information.

Type of Review Requested: Regular.

Requested Expiration Date of Approval: 3 years from date of approval.

Abstract: The National Traffic and Motor Vehicle Act, authorizes the Secretary of Transportation (NHTSA by delegation), at 49 U.S.C. 30111, to issue Federal Motor Vehicle Safety Standards (FMVSS) that set performance standards for motor vehicles and items of motor vehicle equipment. Further, the Secretary (NHTSA by delegation) is authorized, at 49 U.S.C. 30117, to require manufacturers to provide information to first purchasers of motor vehicles or items of motor vehicle equipment related to performance and safety in printed materials that are attached to or accompany the motor vehicle or item of motor vehicle equipment. NHTSA has exercised this authority to require manufacturers to provide certain specified safety information to be readily available to consumers and purchasers of motor vehicles and items of motor vehicle

equipment. This information is most often provided in vehicle owners' manuals and the requirements are found in 49 CFR parts 563, 571, and 575. This information collection request only covers requirements or requests to provide information that is not provided verbatim in the regulation or standard. The information requirements or requests are included in: Part 563, ''Event data recorders;'' FMVSS No. 108, ''Lamps, reflective devices, and associated equipment;'' FMVSS No. 110, ''Tire selection and rims;'' FMVSS No. 138, ''Tire Pressure Monitoring Systems;'' FMVSS No. 202a, ''Head restraints;'' FMVSS No. 205, ''Glazing materials;'' FMVSS No. 208, ''Occupant crash protection;'' FMVSS No. 210, ''Seat belt assembly anchorages;'' FMVSS No. 213, ''Child restraint systems;'' FMVSS No. 226, ''Ejection mitigation;'' FMVSS No. 303, ''Fuel System Integrity of Compressed Natural Gas Vehicles;'' section 575.103, ''Truck-camper loading;'' section 575.104, ''Uniform tire quality grading standards;'' and section 575.105, ''Vehicle rollover.''

Part 563—Event data recorders. Section 563.11 requires manufacturers of vehicles equipped with event data recorders (EDRs) to provide a prescribed statement (provided verbatim) in the owner's manual,[1] which is not an information collection. Section 563.11 also states that the owner's manual may include additional information about the form, function, and capabilities of the EDR, in supplement to the required statement. This voluntary disclosure of information is an information collection for which NHTSA is seeking approval. There is a slight burden for respondents to include the voluntary additional information in their owner's manuals. The vehicle manufacturers which provide this additional information in the owner's manual incur minimal burden. We conservatively estimate that half of the 406 vehicle models for light duty vehicles will have owner's manuals that contain this supplemental information and that the burden for updating and reviewing this information will be 1 hour per model line. This would result in 203. annual burden hours (203 vehicle model lines × 1 hour of time × 1 manual per model).

It is estimated that the word content in the owner's manual required by Part 563 would be 100 text words. Hence, the cost burden to vehicle manufacturers is estimated to be $30,566.25 (17,100,939 total vehicles × 50% of vehicles including added language in the owner's manuals × 100 text words × 1.1 production factor × 0.25 printing factor × $0.00013 per word). Cost burdens for this regulation were not included in the previous information collection request.

FMVSS No. 108, ''*Lamps, reflective devices, and associated equipment.*'' This standard requires that certain lamps and reflective devices with certain performance levels be installed on motor vehicles to assure that the roadway is properly illuminated, that vehicles can be readily seen, and the signals can be transmitted to other drivers sharing the road during day, night, and inclement weather. Because the specific manner in which headlamp aiming is to be performed is not regulated (only the performance of the device is), aiming devices manufactured or installed by different vehicle and headlamp manufacturers may work in significantly different ways. To assure that one particular type of aiming system, the Vehicle headlamp aiming device (VHAD) can be correctly aimed, this standard requires that instructions for proper use of VHAD systems be part of the vehicle as a label, or optionally, be placed in the vehicle owner's manual.

It is estimated that manufacturers no longer equip passenger vehicles, trucks, buses, trailers, or motorcycles with VHAD headlamp systems. If vehicles were equipped with VHAD headlamps, for one model line with new VHAD headlamps, the time to collect the required information, prepare technical input, and review for accuracy of the required information placed for publication in the owner's manual template is estimated to be 4 hours per manual. In a carry-over vehicle owner's manual, we estimate that it would take a vehicle manufacturer 1 hour to review the required information for continued accuracy relating to VHAD systems. Section 571.108 permits each manufacturer a choice in placing headlamp aiming instruction in the owner's manual or on a label affixed to the vehicle. We estimate about half of the VHAD aiming applications would be on labels attached to the VHAD, with the remainder (50%) using information in the owner's manual to convey the necessary information. Therefore, the number of annual burden hours imposed on manufacturers whose vehicles are subject to FMVSS No. 108 would be determined from the number of model lines produced annually (of which an estimated 25% are new and 75% are non-new, a repeat of previous years' model lines) multiplied by the portion of vehicles equipped with VHAD headlamps multiplied by the estimated number of hours required to assemble the required information (estimated to be 4 hours of review for new vehicles and 1 hour to review the information for non-new vehicles). The printing cost burden for these owner's manuals would be the number of vehicles produced annually multiplied by the portion of vehicles equipped with VHAD headlamps, multiplied by certain printing factors (an estimated 500 text words required per owner's manual, a 1.1 multiplier to account for aftermarket manuals, a 0.25 printing factor, and a $0.00013 cost per word). Because manufacturers no longer equip passenger vehicles, trucks, buses, trailers, or motorcycles with VHAD headlamp systems, NHTSA estimates the burden hours as 0 hours, and the printing cost at $0.

FMVSS No. 110, ''*Tire selection and rims.*'' This standard specifies requirements for tire selection to prevent tire overloading. The vehicle's normal load and maximum load on the tire shall not be greater than applicable specified limits. The standard requires a permanently affixed vehicle placard specifying vehicle capacity weight, designated seating capacity, manufacturer-recommended cold tire inflation pressure, and manufacturer's recommended tire size. The standard further specifies rim construction requirements, load limits of non-pneumatic spare tires, and labeling requirements for non-pneumatic spare tires, including a required placard. Owner's manual information is required for non-pneumatic spare tires.

Currently, manufacturers do not equip current passenger vehicles, trucks, buses, trailers, or motorcycles with non-pneumatic spare tires. If vehicles were equipped with non-pneumatic spare tires, the number of annual burden hours imposed on manufacturers who choose to equip their vehicles with this equipment would be determined from the number of model lines produced annually (of which an estimated 25% are new and 75% are on-new, a repeat of previous years' model lines) multiplied by the portion of vehicle models equipped with non-pneumatic spare tires multiplied by the estimated number of hours required to assemble the required information (estimated to be 4 hours of review for new vehicles and 1 hour to review the information for non-new vehicles). The product of these factors would provide the number of hours required by manufacturers to produce necessary information to place into an owner's manual ''master'' for printing. The printing cost burden for these owner's manuals would be the number of vehicles produced annually multiplied by the portion of vehicles

[1] 49 CFR 563.11(a).

equipped with non-pneumatic spare tires, multiplied by certain printing factors (an estimated 500 text words required per owner's manual, a 1.1 multiplier to account for aftermarket manuals, a 0.25 printing factor, and a $0.00013 cost per word). Because manufacturers do not equip current passenger vehicles, trucks, buses, trailers, or motorcycles with non-pneumatic spare tires, NHTSA estimates the hour burden as 0 hours, and the printing cost at $0.

FMVSS No. 138, ''Tire pressure monitoring systems.'' This standard specifies requirements for a tire pressure monitoring system to warn the driver of an under-inflated tire condition. Its purpose is to reduce the likelihood of a vehicle crash resulting from tire failure due to operation in an under-inflated condition. The standard requires the owner's manual to include specific information on the low-pressure warning telltale and the malfunction indicator telltale.

The information required by FMVSS No. 138 to be included in the owner's manual is provided verbatim and may be taken from the Federal regulation in its entirety. FMVSS No. 138, also states that the owner's manual may include additional information about the low-pressure telltale and the malfunction indicator telltale. NHTSA estimates the burden to be 1 hour for the respondents to format their owner's manuals to include the text and additional information. There is an average of 438 model lines each year that include tire pressure monitoring information in the owner's manual. Therefore, NHTSA estimates the total annual burden hours for § 571.138 to be 438 hours (438 model lines × 1 manual per model × 1 hour).

It is estimated that the information required by FMVSS No. 138 in the owner's manual is equivalent to 400 words of text. This would result in $244,530 in cost burden to the respondents (17,100,000 vehicles × 400 words of text × 1.1 production factor × 0.25 printing factor × $0.00013 per word).

FMVSS No. 202a, ''Head restraints.'' This standard specifies requirements for head restraints. The standard, which seeks to reduce whiplash injuries in rear collisions, currently requires head restraints for front outboard designated seating positions in passenger cars and in light multipurpose passenger vehicles, trucks and buses with a gross vehicle weight rating of 4,536 kg or less and specifies requirements for optionally provided rear outboard seat head restraints in the same vehicles. The standard requires that vehicle manufacturers include information in owner's manuals for vehicles manufactured on or after September 1, 2008. The owner's manual must clearly identify which seats are equipped with head restraints. If the head restraints are removable, the owner's manual must provide instructions on how to remove the head restraint by a deliberate action distinct from any act necessary for adjustment, and how to reinstall the head restraints. The owner's manual must warn that all head restraints must be reinstalled to properly protect vehicle occupants. Finally, the owner's manual must describe, in an easily understandable format, the adjustment of the head restraints and/or seat back to achieve appropriate head restraint position relative to the occupant's head.

It is estimated that 438 model lines need to be reviewed annually, but only a fraction (25 percent) need major revision each year. It is further estimated that it would take 5 hours to complete the major revisions. The remaining fraction of model lines (75 percent) only require reverification of existing information. The total annual burden hours are estimated to be 876 hours (438 model lines × 0.25 needing revision × 5 hours plus 438 model lines × 0.75 needing revision × 1 hour).

The word count required to disclose the required head restraint information in the owner's manual is estimated to be 1,200 words. The annual cost burden to the respondents to include the information required by FMVSS No. 202a in the owner's manual is $733,590 (17,100,000 vehicles × 1,200 words of text × 1.1 production factor × 0.25 printing factor × $0.00013 per word).

FMVSS No. 205, ''Glazing materials.'' This standard specifies requirement for all glazing material used in windshields, windows, and interior partitions of motor vehicles. Its purpose is to reduce injuries resulting from impact to glazing surfaces, to ensure a necessary degree of transparency in motor vehicle windows for driver visibility, and to minimize the possibility of occupants being thrown through the vehicle windows in collisions. More detailed information regarding the care and maintenance of plastic glazing items, such as a glass-plastic windshield, is required to be placed in the vehicle owner's manual.

It is estimated that the burden to provide information in the owner's manual for detailed care and maintenance is minimal because manufacturers already provide this type of information in the vehicle cleaning and maintenance section of the owner's manual. NHTSA estimates a burden for each manual of 1 hour because manufacturers would need to verify that detailed care and maintenance information has been included in their cleaning and maintenance section of the owner's manual. The annual estimated burden from § 571.205 is 176.0 hours (176 model lines × 1 manual per model × 1 hour).

The word count required in the owner's manual is estimated to be 210 words. Only buses and low speed vehicles currently use plastic type glazing, so NHTSA estimates there are 17,400 new vehicles each year that include glazing information in the owner's manual. The annual cost burden to the respondents to include the information required by FMVSS No. 205 is $130.15 (17,400 vehicles × 210 words of text × 1.1 production factor × 0.25 printing factor × $0.00013 per word).

FMVSS No. 208, ''Occupant crash protection.'' This standard specifies requirements for both active and passive occupant crash protection systems for passenger cars, multipurpose passenger vehicles, trucks, and small buses. Certain safety features, such as air bags, or the care and maintenance of air bag systems, are required to be explained to the owner by means of the owner's manual. For example, the owner's manual must describe the vehicle's air bag system and provide precautionary information about the proper positioning of the occupants, including children. The owner's manual must also warn that no objects should be placed over or near the air bag covers. There is also required information about the operation of seat belt assemblies and other information that could total up to about 20 pages in the owner's manual. This material would also need to be kept current with the latest technical information on an annual basis.

A conservative estimated burden to produce the required text and information is 16 hours (or 2 days). It is also estimated that a fraction (25 percent) of the model lines would require updates annually. The remaining fraction of model lines (75 percent) only require reverification (1-hour burden) of existing information. This would result in 2,750 annual burden hours (579 vehicle model lines × 0.25 percent that need updating × 16 hours of time plus 579 model lines × 0.75 needing revision × 1 hour).

It is estimated that the word content in the owner's manual required by FMVSS No. 208 would be 5,400 text words. Hence, the cost burden to vehicle manufacturers is estimated to be $3,397,680 (17,600,000 total vehicles × 5,400 text words × 1.1 production factor × 0.25 printing factor × $0.00013 per word).

FMVSS No. 210, ''*Seat belt assembly anchorages.*'' This standard specifies requirements for seat belt assembly anchorages to ensure effective occupant restraint and to reduce the likelihood of failure in a crash. FMVSS No. 210 requires that manufacturers place the following information in the vehicle owner's manual: (a) An explanation that child restraints are designed to be secured by means of the vehicle's seat belts, and (b) a statement alerting vehicle owners that children are always safer in the rear seat.

It is estimated that it would take a vehicle manufacturer no more than 1 hour per vehicle model line to assemble all of the FMVSS No. 210 information for inclusion in the owner's manual. This would result in 438 annual burden hours (438 vehicle model lines × 1 manual per model × 1 hour).

It is estimated that the word content in the owner's manual required by FMVSS No. 210 would be 400 text words. Hence, the cost burden to vehicle manufacturers is estimated to be $244,530 (17,100,000 total vehicles × 400 text words × 1.1 production factor × 0.25 printing factor × $0.00013 per word).

FMVSS No. 213, ''*Child restraint systems.*'' This standard specifies requirements for child restraint systems and requires that manufacturers provide consumers with detailed information relating to child safety in air bag-equipped vehicles. The vehicle owner's manual must include information about the operation and do's and don'ts of built-in child seats. However, as stated in FMVSS No. 213, the information must be made available on strategically placed labels within the vehicles, in addition to the vehicle's owner's manual. Thus, it is assumed that the burden hours would be minimal since the information is already available from the information required to produce the labels. This would result in 579 annual burden hours (579 vehicle model lines × 1 manual per model × 1 hour).

It is estimated that the recurring information required for child safety in the owner's manual would be 500 text words. Hence, the cost burden to vehicle manufacturers is estimated to be $314,600 (17,600,000 total vehicles × 500 text words × 1.1 production factor × 0.25 printing factor × $0.00013 per word).

FMVSS No. 226, ''*Ejection mitigation.*'' This standard establishes vehicle requirements intended to reduce the partial and complete ejection of vehicle occupants through side windows in crashes, particularly rollover crashes. The standard applies to passenger cars, and to multipurpose passenger vehicles, trucks, and buses with a gross vehicle weight rating of 4,536 kg (10,000 pounds) or less. Written information must be provided that describes any ejection mitigation countermeasure that deploys in the event of a rollover and a discussion of the readiness indicator with a list of the elements of the system being monitored by the indicator, a discussion of the purpose and location of the telltale, and instructions to the consumer on the steps to take if the telltale is illuminated.

It is estimated that it would take a vehicle manufacturer no more than 8 hours to compile the required material and it is estimated that a fraction (25 percent) would need major revisions each year. The remaining fraction of model lines (75 percent) only require reverification (1-hour burden) of existing information. This would result in 1,204.5 annual burden hours (438 vehicle model lines × 1 manual per model × 0.25 (percent that need updating) × 8 hours of time plus 438 model lines × 1 manual per model × 0.75 (percent needing revision) × 1 hour).

It is estimated that the word content in the owner's manual required by FMVSS No. 226 would be 3,000 text words. Hence, the cost burden to vehicle manufacturers is estimated to be $1,833,975 (17,100,000 total vehicles × 3,000 text words × 1.1 production factor × 0.25 printing factor × $0.00013 per word).

FMVSS No. 303, ''*Fuel System Integrity of Compressed Natural Gas Vehicles.*'' This standard specifies requirements for the integrity of motor vehicle fuel systems using compressed natural gas (CNG), including the CNG fuel systems of bi-fuel, dedicated, and dual fuel CNG vehicles. This regulation requires manufacturers to permanently label CNG vehicles, near the vehicle refueling connection, with service pressure information and the statement ''See instructions on fuel container for inspection and service life.'' Manufacturers of CNG vehicles shall also provide a first purchaser this information in either an owner's manual or a one-page document. The service pressure information required for the owner's manuals under FMVSS No. 303 is developed by manufacturers as part of their routine engineering development for their vehicles. Therefore, there is a slight burden of 1 hour for respondents to include this information in their owner's manuals. This would result in 18 annual burden hours (18 vehicle model lines × 1 manual per model × 1 hour of time).

It is estimated that no more than 50 words are required in the owner's manual to comply with the requirements in FMVSS No. 303. There are conservatively 20,000 CNG vehicles produced annually. Hence, the cost burden to CNG vehicle manufacturers is estimated to be $35.75 (20,000 total units × 50 text words × 1.1 production factor × 0.25 printing factor × $0.00013 per word). Cost burdens for this regulation were not included in the previous information collection request.

Section 575.103, ''*Truck-camper loading.*'' This regulation requires manufacturers of slide-in campers to affix to each camper a label that contains information relating to identification and proper loading of the camper and to provide more detailed loading information in the owner's manual. This regulation also requires manufacturers of trucks that would accommodate slide-in campers to specify the cargo weight ratings and the longitudinal limits within which the center of gravity for the cargo weight rating should be located. The information required for the owner's manuals under section 575.103 is developed by manufacturers as part of their routine engineering development for their vehicles. The figures to include in truck and slide-in camper owner's manuals are provided in the regulation. Therefore, there is a slight 1-hour burden for respondents to include this information in their owner's manuals. This would result in 35 annual burden hours (35 vehicle model lines × 1 manual per model × 1 hour of time).

It is estimated that 480 words are minimally required in the owner's manual to comply with § 575.103. There are approximately 2,300,000 pickup trucks and 11,000 truck camper units produced annually. These total to an annual production of 2,311,000 units. Hence, the cost burden to vehicle manufacturers is estimated to be $39,656.76 (2,311,000 total units × 480 text words × 1.1 production factor × 0.25 printing factor × $0.00013 per word).

Section 575.104, ''*Uniform tire quality grading standards.*'' This regulation requires manufacturers of motor vehicles to inform the drivers of the type and quality of the tires with which their vehicles are equipped. A statement, which manufacturers shall include in the owner's manual, is provided in the regulation in its entirety or equivalent form. Hence there is a slight 1-hour burden on the respondents for inclusion of this information into their owner's manuals. This would result in 579 annual burden hours (579 vehicle model lines × 1 manual per model × 1 hour of time).

It is estimated that 390 words are minimally required in the owner's manual to comply with § 575.104. There are approximately 13,857,300 vehicles covered by this regulation. Hence, the cost burden to vehicle manufacturers is estimated to be $193,205.41 (13,857,300 total vehicles × 390 text words × 1.1 production factor × 0.25 printing factor × $0.00013 per word). Cost burdens for this regulation were not included in the previous information collection request.

Section 575.105, ''*Vehicle rollover.*'' This regulation requires manufacturers of utility vehicles [2] to alert the drivers of those vehicles that they have a higher possibility of rollover than other vehicle types and to advise them of steps that can be taken to reduce the possibility of rollover and/or to reduce the likelihood of injury in a rollover. A statement, which manufacturers shall include in the owner's manual, is provided in the regulation in its entirety or equivalent form. Hence there is a slight 1-hour burden on the respondents for inclusion of this information into their owner's manuals. This would result in 18 annual burden hours (18 vehicle model lines × 1 manual per model × 1 hour of time).

It is estimated that 117 words are minimally required in the owner's manual to comply with § 575.105. There are approximately 2,700,000 utility vehicles with 4-wheel drive and a wheelbase of 110 inches or less. Therefore, the cost burden to vehicle manufacturers is estimated to be $11,293.43 (2,700,000 total vehicles × 117 text words × 1.1 production factor × 0.25 printing factor × $0.00013 per word). Cost burdens for this regulation were not included in the previous information collection request.

Description of the Need for the Information and Proposed Use of the Information: The Federal program for reducing highway fatalities, injuries and crashes is likely to be adversely affected if the information is not collected, since consumers would not be made readily aware of certain important safety provisions that apply to critical components of their vehicles and would not have a readily accessible source of information when circumstances require such information.

Affected Public: Vehicle manufacturers.

Estimated Number of Respondents: 52.

Frequency: On occasion.

Number of Responses: 52.

Estimated Total Annual Burden Hours: 7,315.

Estimated Total Annual Burden Hours Cost: $368,969.

The labor costs associated with these burden hours are derived by using hourly labor rates published by the Bureau of Labor Statistics (BLS). For the burden hours associated with compiling the owner's manual information required under the FMVSSs, NHTSA uses the mean hourly wage of $35.41 per hour for ''Technical Writers'' (occupational code 27–3042).[3] BLS estimates that hourly wages represent approximately 70.2% of total compensation for private industry workers.[4] Therefore, NHTSA estimates the labor cost associated with less senior Technical Writers to be $50.44 per hour. The total labor cost associated with the burden hours of this information collection are determined by multiplying the annual burden hours by $50.44; therefore, the total annual labor costs are estimated to be $368.968.60 in each of the next three years.

The table below summarizes the total hour burden and associated labor costs estimates.

ESTIMATED HOUR BURDEN AND ASSOCIATED LABOR COSTS SUMMARY TABLE

Part/section	Brief title	Estimated total annual burden hours	Estimated total annual labor costs at $50.44/hour
563	Event Data Recorders	203	$10,239.32
571.108	Lighting	0	0.00
571.110	Tire Selection and Rims	0	0.00
571.138	Tire Pressure Monitoring	438	22,092.72
571.202a	Head Restraints	876	44,185.44
571.205	Glazing	176	8,877.44
571.208	Crash Protection	2,750	138,710.00
571.210	Seat Belt Anchors	438	22,092.72
571.213	Child Restraints	579	29,204.76
571.226	Ejection Mitigation	1,205	60,780.20
571.303	CNG Fuel Systems	18	907.92
575.103	Truck-Camper Loading	35	1,765.40
575.104	Tire Quality	579	29,204.76
575.105	Utility Vehicles	18	907.92
Totals		7,315	368,968.60 or 368,969

Estimated Annual Printing Burden Cost: $7,043,793.

The total annual cost to the respondents for information published in vehicles' owner's manuals is summarized in the table below.

[2] 49 CFR 575.105 states *Utility vehicles* means multipurpose passenger vehicles (other than those which are passenger car derivatives) which have a wheelbase of 110 inches or less and special features for occasional off-road operation.

[3] May 2019 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 336100—Motor Vehicle Manufacturing, *https://www.bls.gov/oes/current/naics4_336100.htm#27-0000.*

[4] *https://www.bls.gov/news.release/pdf/ecec.pdf.* Accessed March 20, 2020. Table 1. Employer Costs for Employee Compensation by ownership [March 2020], *https://www.bls.gov/news.release/ecec.t01.htm.*

Part/section	Brief title	Estimated total costs to respondents
563	Event Data Recorders	$30,566.25
571.108	Lighting	0.00
571.110	Tire Selection and Rims	0.00
571.138	Tire Pressure Monitoring Systems	244,530.00
571.202a	Head Restraints	733,590.00
571.205	Glazing	130.15
571.208	Occupant Crash Protection	3,397,680.00
571.210	Seat Belt Assembly Anchors	244,530.00
571.213	Child Restraints Systems	314,600.00
571.226	Ejection Mitigation	1,833,975.00
571.303	Fuel System Integrity of Compressed Natural Gas Vehicles	35.75
575.103	Truck-Camper Loading	39,656.76
575.104	Uniform Tire Quality Grading Standards	193,205.41
575.105	Vehicle Rollover	11,293.43
Total Costs		7,043,792.75 or 7,043,793

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (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 the use of automated collection techniques or other forms of information technology. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2021–09984 Filed 5–11–21; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Petition for Exemption From the Federal Motor Vehicle Theft Prevention Standard; Toyota Motor North America, Inc.

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition for exemption.

SUMMARY: This document grants in full the Toyota Motor North America, Inc.'s (Toyota) petition for exemption from the Federal Motor Vehicle Theft Prevention Standard (theft prevention standard) for its Corolla Cross vehicle line beginning in model year (MY) 2022. The petition is granted because the agency has determined that the antitheft device to be placed on the line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard.

DATES: The exemption granted by this notice is effective beginning with the 2022 model year.

FOR FURTHER INFORMATION CONTACT: Carlita Ballard, Office of International Policy, Fuel Economy, and Consumer Programs, NHTSA, West Building, W43–439, NRM–310, 1200 New Jersey Avenue SE, Washington, DC 20590. Ms. Ballard's phone number is (202) 366–5222. Her fax number is (202) 493–2990.

SUPPLEMENTARY INFORMATION: Under 49 U.S.C. Chapter 331, the Secretary of Transportation (and the National Highway Traffic Safety Administration (NHTSA) by delegation) is required to promulgate a theft prevention standard to provide for the identification of certain motor vehicles and their major replacement parts to impede motor vehicle theft. NHTSA promulgated regulations at 49 CFR part 541 (theft prevention standard) to require parts-marking for specified passenger motor vehicles and light trucks. Pursuant to 49 U.S.C. 33106, manufacturers that are subject to the parts-marking requirements may petition NHTSA, by delegation, for an exemption for a line of passenger motor vehicles equipped with an antitheft device as standard equipment that NHTSA decides is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements. In accordance with this statute, NHTSA promulgated 49 CFR part 543, which establishes the process through which manufacturers may seek an exemption from the theft prevention standard.

49 CFR 543.5 provides general submission requirements for petitions and states that each manufacturer may petition NHTSA for an exemption of one vehicle line per model year. Among other requirements, manufacturers must identify whether the exemption is sought under section 543.6 or section 543.7. Under section 543.6, a manufacturer may request an exemption by providing specific information about the antitheft device, its capabilities, and the reasons the petitioner believes the device to be as effective at reducing and deterring theft as compliance with the parts-marking requirements. Section 543.7 permits a manufacturer to request an exemption under a more streamlined process if the vehicle line is equipped with an antitheft device (an ''immobilizer'') as standard equipment that complies with one of the standards specified in that section.[1]

[1] 49 CFR 543.7 specifies that the manufacturer must include a statement that their entire vehicle line is equipped with an immobilizer that meets one of the following standards:

(1) The performance criteria (subsections 8 through 21) of C.R.C, c. 1038.114, *Theft Protection and Rollaway Prevention (in effect March 30, 2011),* as excerpted in appendix A of [part 543];

(2) National Standard of Canada CAN/ULC–S338–98, *Automobile Theft Deterrent Equipment and Systems: Electronic Immobilization* (May 1998);

(3) United Nations Economic Commission for Europe (UN/ECE) Regulation No. 97 (ECE R97), *Uniform Provisions Concerning Approval of Vehicle Alarm System (VAS) and Motor Vehicles with*

Continued

Section 543.8 establishes requirements for processing petitions for exemption from the theft prevention standard. As stated in section 543.8(a), NHTSA processes any complete exemption petition. If NHTSA receives an incomplete petition, NHTSA will notify the petitioner of the deficiencies. Once NHTSA receives a complete petition the agency will process it and, in accordance with section 543.8(b), will grant the petition if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of part 541.

Section 543.8(c) requires NHTSA to issue its decision either to grant or to deny an exemption petition not later than 120 days after the date on which a complete petition is filed. If NHTSA does not make a decision within the 120-day period, the petition shall be deemed to be approved and the manufacturer shall be exempt from the standard for the line covered by the petition for the subsequent model year.[2] Exemptions granted under part 543 apply only to the vehicle line or lines that are subject to the grant and that are equipped with the antitheft device on which the line's exemption was based, and are effective for the model year beginning after the model year in which NHTSA issues the notice of exemption, unless the notice of exemption specifies a later year.

Sections 543.8(f) and (g) apply to the manner in which NHTSA's decisions on petitions are to be made known. Under section 543.8(f), if the petition is sought under section 543.6, NHTSA publishes a notice of its decision to grant or deny the exemption petition in the **Federal Register** and notifies the petitioner in writing. Under section 543.8(g), if the petition is sought under section 543.7, NHTSA notifies the petitioner in writing of the agency's decision to grant or deny the exemption petition.

This grant of petition for exemption considers Toyota Motor North America, Inc.'s (Toyota) petition for its Corolla Cross vehicle line beginning in MY 2022.

I. Specific Petition Content Requirements Under 49 CFR 543.6

Pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention,* Toyota petitioned for an exemption for its specified vehicle line from the parts-marking requirements of the theft prevention standard, beginning in MY 2022. Toyota petitioned under 49 CFR 543.6, *Petition: Specific content requirements,* which, as described above, requires manufacturers to provide specific information about the antitheft device installed as standard equipment on all vehicles in the line for which an exemption is sought, the antitheft device's capabilities, and the reasons the petitioner believes the device to be as effective at reducing and deterring theft as compliance with the parts-marking requirements.

More specifically, section 543.6(a)(1) requires petitions to include a statement that an antitheft device will be installed as standard equipment on all vehicles in the line for which the exemption is sought. Under section 543.6(a)(2), each petition must list each component in the antitheft system, and include a diagram showing the location of each of those components within the vehicle. As required by section 543.6(a)(3), each petition must include an explanation of the means and process by which the device is activated and functions, including any aspect of the device designed to: (1) Facilitate or encourage its activation by motorists; (2) attract attention to the efforts of an unauthorized person to enter or move a vehicle by means other than a key; (3) prevent defeating or circumventing the device by an unauthorized person attempting to enter a vehicle by means other than a key; (4) prevent the operation of a vehicle which an unauthorized person has entered using means other than a key; and (5) ensure the reliability and durability of the device.[3]

In addition to providing information about the antitheft device and its functionality, petitioners must also submit the reasons for their belief that the antitheft device will be effective in reducing and deterring motor vehicle theft, including any theft data and other data that are available to the petitioner and form a basis for that belief,[4] and the reasons for their belief that the agency should determine that the antitheft device is likely to be as effective as compliance with the parts-marking requirements of part 541 in reducing and deterring motor vehicle theft. In support of this belief, the petitioners should include any statistical data that are available to the petitioner and form the basis for the petitioner's belief that a line of passenger motor vehicles equipped with the antitheft device is likely to have a theft rate equal to or less than that of passenger motor vehicles of the same, or a similar, line which have parts marked in compliance with part 541.[5]

The following sections describe Toyota's petition information provided pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention.* To the extent that specific information in Toyota's petition is subject to a properly filed confidentiality request, that information was not disclosed as part of this notice.[6]

II. Toyota's Petition for Exemption

In a petition dated November 19, 2020, as supplemented with additional information submitted on April 6, 2021,[7] Toyota requested an exemption from the parts-marking requirements of the theft prevention standard for the Corolla Cross vehicle line beginning with MY 2022.

In its petition, Toyota provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for the Corolla Cross vehicle line. Toyota stated that its MY 2022 Corolla Cross vehicle line will be installed with an engine immobilizer device as standard equipment, as required by 543.6(a)(1). Toyota also stated that it will offer two entry/start systems on its Corolla Cross vehicle line. Specifically, Toyota stated that it will offer a ''smart entry and start'' system or a ''transponder key and start'' system on its vehicle line. Specifically, key components of the ''smart entry and start'' system will include a certification engine control unit (ECU), engine switch, steering lock ECU, security indicator, door control receiver, electrical key, ID code box, and an engine control module (ECM). Key components of the ''transponder key and start'' system will include a transponder key ECU assembly, transponder key coil, security indicator, ignition key and an ECM. Toyota stated that there will also be position switches installed on the vehicle to protect the hood and doors from unauthorized tampering/opening. Toyota further explained that locking the doors can be accomplished through use of a key, wireless switch or its smart entry system, and that unauthorized tampering with the hood or door without using one of these methods will cause the position switches to trigger its

Regard to Their Alarm System (AS) in effect August 8, 2007; or

(4) UN/ECE Regulation No. 116 (ECE R116), *Uniform Technical Prescriptions Concerning the Protection of Motor Vehicles Against Unauthorized Use* in effect on February 10, 2009.

[2] 49 U.S.C. 33106(d).

[3] 49 CFR 543.6(a)(3).

[4] 49 CFR 543.6(a)(4).

[5] 49 CFR 543.6(a)(5).

[6] 49 CFR 512.20(a).

[7] As discussed above, per 49 CFR 543.8(a), NHTSA processes the petition once the manufacturer submits all the information required by 49 CFR part 543.

antitheft device to operate. Toyota will not incorporate an audible and visual alarm system on its vehicle line.

Pursuant to Section 543.6(a)(3), Toyota explained that its ''smart entry and start'' system is activated when the engine switch is pushed from the ''ON'' ignition status to any other status. The certification ECU then performs the calculation for the immobilizer and the immobilizer signals the ECM to activate the device. Toyota stated that key verification is also performed after the driver pushes the engine switch. Specifically, after the driver pushes the engine switch, the certification ECU and steering lock ECU receive confirmation of a valid key, and the certification ECU allows the ECM to start the engine. Toyota stated that the ''transponder key and start'' system is activated when the ignition key is turned from the ''ON'' position to some other status and the key is removed, allowing the immobilizer to activate and signal the ECM. Toyota also stated that in both systems, a security indicator is installed notifying the users and others inside and outside the vehicle with the status of the immobilizer. Toyota further explained that the security indicator flashes continuously when the immobilizer is activated, and turns off when it is deactivated.

As required in section 543.6(a)(3)(v), Toyota provided information on the reliability and durability of its proposed device. To ensure reliability and durability of the device, Toyota conducted tests based on its own specified standards. Toyota provided a detailed list of the tests conducted (*i.e.,* high and low temperature operation, strength, impact, vibration, electro-magnetic interference, etc.). Toyota stated that it believes that its device is reliable and durable because it complied with its own specific design standards and the antitheft device is installed on other vehicle lines for which the agency has granted a parts-marking exemption. As an additional measure of reliability and durability, Toyota stated that its vehicle key cylinders are covered with casting cases to prevent the key cylinder from easily being broken. Toyota further explained that there are approximately 10,000 combinations for inner cut keys which makes it difficult to unlock the doors without using a valid key because the key cylinders would spin out and cause the locks to not operate.

Toyota stated that the 2022 model year is the first year that the first Corolla Cross model with immobilizers installed as standard equipment is available, and accordingly at the time of the petition submission, theft rate data for the MY 2022 Corolla Cross vehicle line is not available. However, Toyota compared its proposed device to other devices NHTSA has determined to be as effective in reducing and deterring motor vehicle theft as would compliance with the parts-marking requirements. Toyota compared its proposed device to that which has been installed on the Toyota RAV4 and RAV4 HV vehicle line, which was granted a parts-marking exemption from 49 CFR part 541 by the agency beginning with MY 2014 vehicles. Toyota also referenced the NHTSA theft rate data published for the RAV4 and RAV4 HV showing an overall passenger motor vehicle's average of stolen rates in calendar year 2014 of 1.15 per thousand vehicles produced which the RAV4 vehicles had a theft rate of 0.36. (see 82 FR 28246). Therefore, Toyota concluded that the antitheft device proposed for its Corolla Cross vehicle line is no less effective than those devices on the lines for which NHTSA has already granted full exemption from the parts-marking requirements. Toyota stated that it believes that installing the immobilizer device as standard equipment reduces the theft rate for the Corolla Cross vehicle line and expects it to experience comparable effectiveness and ultimately be more effective than parts-marking labels.

III. Decision To Grant the Petition

Pursuant to 49 U.S.C. 33106 and 49 CFR 543.8(b), the agency grants a petition for exemption from the parts-marking requirements of part 541, either in whole or in part, if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of part 541. The agency finds that Toyota has provided adequate reasons for its belief that the antitheft device for its vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard. This conclusion is based on the information Toyota provided about its antitheft device. NHTSA believes, based on Toyota's supporting evidence, the antitheft device described for its vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard.

The agency concludes that Toyota's antitheft device will provide the five types of performance features listed in section 543.6(a)(3): Promoting activation; attracting attention to the efforts of unauthorized persons to enter or operate a vehicle by means other than a key; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

The agency notes that 49 CFR part 541, Appendix A–1, identifies those lines that are exempted from the theft prevention standard for a given model year. 49 CFR 543.8(f) contains publication requirements incident to the disposition of all part 543 petitions. Advanced listing, including the release of future product nameplates, the beginning model year for which the petition is granted and a general description of the antitheft device is necessary in order to notify law enforcement agencies of new vehicle lines exempted from the parts-marking requirements of the theft prevention standard.

If Toyota decides not to use the exemption for its requested vehicle line, the manufacturer must formally notify the agency. If such a decision is made, the line must be fully marked as required by 49 CFR 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if a manufacturer to which an exemption has been granted wishes in the future to modify the device on which the exemption is based, the company may have to submit a petition to modify the exemption. Section 543.8(d) states that a part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the antitheft device on which the line's exemption is based. Further, section 543.10(c)(2) provides for the submission of petitions ''to modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in the exemption.'' [8]

For the foregoing reasons, the agency hereby grants in full Toyota's petition for exemption for the Corolla Cross vehicle line from the parts-marking requirements of 49 CFR part 541, beginning with its MY 2022 vehicles.

[8] The agency wishes to minimize the administrative burden that section 543.10(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting part 543 to require the submission of a modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be de minimis. Therefore, NHTSA suggests that if a manufacturer with an exemption contemplates making any changes, the effects of which might be characterized as de minimis, it should consult the agency before preparing and submitting a petition to modify.

Issued under authority delegated in 49 CFR 1.95 and 501.8.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2021–09982 Filed 5–11–21; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2021–0031]

Agency Information Collection Activities; Notice and Request for Comment; Motorcycle Helmets (Labeling)

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Notice and request for comments on a reinstatement of a previously approved collection of information.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) invites public comments about our intention to request approval from the Office of Management and Budget (OMB) for a reinstatement of a previously approved collection of information entitled ''Motorcycle Helmets (Labeling)'' (OMB Control Number: 2127–0518). Before a Federal agency can collect certain information from the public, it must receive approval from OMB. Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatement of previously approved collections. This document describes NHTSA's information collection on motorcycle helmet labeling.

DATES: You should submit your comments early enough to ensure that Docket Management receives them no later than July 12, 2021.

ADDRESSES: You may submit comments (identified by the DOT Docket ID Number above) by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, 20590–0001 between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9322 before coming.
- *Fax:* 202–493–2251.

All submissions must include the agency name and docket number for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket, go to *http://www.regulations.gov* or the street address listed above. Follow the online instructions for accessing the dockets online. To be sure someone is there to help you at the street address, please call (202) 366–9322 before coming.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Mr. Christian Nguyen, U.S. Department of Transportation, NHTSA, 1200 New Jersey Avenue SE, West Building Room W43–418, NRM–130, Washington, DC 20590. Mr. Christian Nguyen's telephone number is 202–366–2365 and fax number is 202–366–7002. Please identify the relevant collection of information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following: (a) 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; (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) how to enhance the quality, utility, and clarity of the information to be collected; (d) how 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, *e.g.* permitting electronic submission of responses. In compliance with these requirements, NHTSA asks for public comments on the following proposed collection of information for which the agency is seeking approval from OMB.

Title: Motorcycle Helmets (Labeling).

OMB Control Number: 2127–0518.

Type of Request: Reinstatement of a previously approved collection of information.

Type of Review Requested: Regular.

Requested Expiration Date of Approval: Three years from the approval date.

Summary of the Collection of Information: The National Traffic and Motor Vehicle Safety Act authorizes the Secretary of Transportation (NHTSA by delegation), at 49 U.S.C. 30111, to issue Federal Motor Vehicle Safety Standards (FMVSS) that set performance standards for motor vehicles and items of motor vehicle equipment. Vehicle and equipment manufacturers must certify that their vehicles or equipment comply with these standards. Further, the Secretary (NHTSA by delegation) is authorized, at 49 U.S.C. 30117, to require manufacturers to provide information to first purchasers of motor vehicles or motor vehicle equipment when the vehicle or equipment is purchased, in the form of printed matter placed in the vehicle or attached to the vehicle or motor vehicle equipment.

Using this authority, NHTSA issued the initial FMVSS No. 218, ''Motorcycle helmets,'' in 1974. Motorcycle helmets are devices used to protect motorcyclists from head injury in motor vehicle accidents. The standard requires the manufacturer to label every helmet it produces to indicate compliance with the requirements of the Standard. The certification label consists of the symbol ''DOT,'' the term ''FMVSS No. 218,'' the word ''CERTIFIED,'' the precise model designation, and the manufacturer's name and/or brand on the outer shell of the helmet towards the posterior bottom edge. Manufacturers are also required to label every helmet to provide helmet owners with important safety information including manufacturer's name, discrete size, month and year of manufacture, and specific instructions

to the purchaser. FMVSS No. 218, S5.6 requires that each helmet shall be labeled permanently and legibly in a manner such that the label(s) can be read easily without removing padding or any other permanent part.

Description of the Need for the Information and Proposed Use of the Information: The labeling requirement in the Standard supports the Department of Transportation's strategic goal in safety, by ensuring that motorcycle helmets are manufactured and certified to the performance requirements of the Standard. NHTSA uses this information for enforcement purposes to ensure that manufacturers certify compliance with the Standard. State and local law enforcement use this information to enforce helmet-use laws, and consumers use the information to make decisions when purchasing motorcycle helmets.

Affected Public: Motorcycle helmet manufacturers.

Estimated Number of Respondents: 45.

Frequency: On occasion.

Estimated Total Annual Burden Hours: 9,100 hours.

NHTSA estimates that 3,250,000 motorcycle helmets are manufactured annually by 45 motorcycle helmet manufacturers. NHTSA also estimates that 10 seconds are spent labeling each helmet. Therefore, the estimated total annual burden hours for the collection of information required in FMVSS No. 218 is 9,100 hours (3,250,000 × 10 seconds, rounded).

For the labor costs associated with the burden hours for affixing labels to helmets, NHTSA uses the average wage of $22.59 per hour for ''Assemblers and Fabricators'' (occupational code 51–2000) published by the Bureau of Labor Statistics (BLS).[1] BLS estimates that wages represent approximately 70.2% of total compensation for private industry workers.[2] Therefore, NHTSA calculates the labor cost associated with Assemblers and Fabricators to be $32.18 per hour ($22.59 ÷ 0.702). Multiplying that hourly rate by the estimated 9,100 labor hours needed to affix labels yields an estimated total annual labor cost of $292,838 ($32.18 × 9,100 hours). The total estimated burden hours and associated labor costs are detailed in the table below:

Number of respondents (helmet manufacturers)	Number of helmets produced annually (per respondent) (rounded)	Time to affix label per helmet (seconds)	Estimated total annual burden hours (per respondent) (rounded)	Total labor cost per hour	Labor cost (per respondent)	Total burden hours (rounded)	Total labor cost
45	72,000	10	200	$32.18	$6,500	9,100	$292,838

Estimated Total Annual Burden Cost: $1,137,500.

The total annual cost to the respondents is estimated to be $1,137,500. NHTSA estimates that the printing and material cost per helmet is $0.35. The total annual cost to respondents is calculated by multiplying the printing and material cost ($0.35) by the estimated 3,250,000 responses (helmets produced) per year ($0.35 × 3,250,000). The total estimated annual burden costs are detailed in the table below:

Number of respondents (helmet manufacturers)	Number of helmets produced annually per respondent (rounded)	Printing and material cost per helmet	Annual printing and material cost per manufacturer (rounded)	Total number of helmets produced annually	Estimated total annual printing and material costs
45	72,000	$0.35	$25,200.00	3,250,000	$1,137,500.00

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (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 the use of automated collection techniques or other forms of information technology.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2021–09985 Filed 5–11–21; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Petition for Exemption From the Federal Motor Vehicle Theft Prevention Standard; Mazda Motor Corporation

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition for exemption.

SUMMARY: This document grants in full the Mazda Motor Corporation (Mazda) petition for exemption from the Federal Motor Vehicle Theft Prevention Standard (theft prevention standard) for its confidential vehicle line beginning in model year (MY) 2023. The petition is granted because the agency has determined that the antitheft device to be placed on the line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard. Mazda also requested confidential treatment for specific information in its petition. Therefore, no confidential information provided for purposes of this notice has been disclosed.

[1] May 2019 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 336100—Motor Vehicle Manufacturing, *https://www.bls.gov/oes/current/naics4_336100.htm#51-0000.*

[2] Table 1. Employer Costs for Employee Compensation by ownership, September 2020, *https://www.bls.gov/news.release/ecec.t01.htm.*

DATES: The exemption granted by this notice is effective beginning with the 2023 model year.

FOR FURTHER INFORMATION CONTACT: Carlita Ballard, Office of International Policy, Fuel Economy, and Consumer Programs, NHTSA, West Building, W43–439, NRM–310, 1200 New Jersey Avenue SE, Washington, DC 20590. Ms. Ballard's phone number is (202) 366–5222. Her fax number is (202) 493–2990.

SUPPLEMENTARY INFORMATION: Under 49 U.S.C. Chapter 331, the Secretary of Transportation (and the National Highway Traffic Safety Administration (NHTSA) by delegation) is required to promulgate a theft prevention standard to provide for the identification of certain motor vehicles and their major replacement parts to impede motor vehicle theft. NHTSA promulgated regulations at 49 CFR part 541 (theft prevention standard) to require parts-marking for specified passenger motor vehicles and light trucks. Pursuant to 49 U.S.C. 33106, manufacturers that are subject to the parts-marking requirements may petition NHTSA, by delegation, for an exemption for a line of passenger motor vehicles equipped with an antitheft device as standard equipment that NHTSA decides is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements. In accordance with this statute, NHTSA promulgated 49 CFR part 543, which establishes the process through which manufacturers may seek an exemption from the theft prevention standard.

49 CFR 543.5 provides general submission requirements for petitions and states that each manufacturer may petition NHTSA for an exemption of one vehicle line per model year. Among other requirements, manufacturers must identify whether the exemption is sought under section 543.6 or section 543.7. Under section 543.6, a manufacturer may request an exemption by providing specific information about the antitheft device, its capabilities, and the reasons the petitioner believes the device to be as effective at reducing and deterring theft as compliance with the parts-marking requirements. Section 543.7 permits a manufacturer to request an exemption under a more streamlined process if the vehicle line is equipped with an antitheft device (an ''immobilizer'') as standard equipment that complies with one of the standards specified in that section.[1]

Section 543.8 establishes requirements for processing petitions for exemption from the theft prevention standard. As stated in section 543.8(a), NHTSA processes any complete exemption petition. If NHTSA receives an incomplete petition, NHTSA will notify the petitioner of the deficiencies. Once NHTSA receives a complete petition the agency will process it and, in accordance with section 543.8(b), will grant the petition if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of part 541.

Section 543.8(c) requires NHTSA to issue its decision either to grant or to deny an exemption petition not later than 120 days after the date on which a complete petition is filed. If NHTSA does not make a decision within the 120-day period, the petition shall be deemed to be approved and the manufacturer shall be exempt from the standard for the line covered by the petition for the subsequent model year.[2] Exemptions granted under part 543 apply only to the vehicle line or lines that are subject to the grant and that are equipped with the antitheft device on which the line's exemption was based, and are effective for the model year beginning after the model year in which NHTSA issues the notice of exemption, unless the notice of exemption specifies a later year.

Sections 543.8(f) and (g) apply to the manner in which NHTSA's decisions on petitions are to be made known. Under section 543.8(f), if the petition is sought under section 543.6, NHTSA publishes a notice of its decision to grant or deny the exemption petition in the **Federal Register** and notifies the petitioner in writing. Under section 543.8(g), if the petition is sought under section 543.7, NHTSA notifies the petitioner in writing of the agency's decision to grant or deny the exemption petition.

This grant of petition for exemption considers Mazda Motor Corporation's (Mazda) petition for its confidential vehicle line beginning in MY 2023. Mazda's petition is granted under 49 U.S.C. 33106 and 49 CFR 543.8(c), which state that if the Secretary of Transportation (NHTSA, by delegation) does not make a decision about a petition within 120 days of the petition submission, the petition shall be deemed to be approved and the manufacturer shall be exempt from the standard for the line covered by the petition for the subsequent model year. Separately, based on the information provided in Mazda's petition, NHTSA has determined that the antitheft device to be placed on its vehicle line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard.

I. Specific Petition Content Requirements Under 49 CFR 543.6

Pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention,* Mazda petitioned for an exemption for its specified vehicle line from the parts-marking requirements of the theft prevention standard, beginning in MY 2023. Mazda petitioned under 49 CFR 543.6, *Petition: Specific content requirements,* which, as described above, requires manufacturers to provide specific information about the antitheft device installed as standard equipment on all vehicles in the line for which an exemption is sought, the antitheft device's capabilities, and the reasons the petitioner believes the device to be as effective at reducing and deterring theft as compliance with the parts-marking requirements.

More specifically, section 543.6(a)(1) requires petitions to include a statement that an antitheft device will be installed as standard equipment on all vehicles in the line for which the exemption is sought. Under section 543.6(a)(2), each petition must list each component in the antitheft system, and include a diagram showing the location of each of those components within the vehicle. As required by section 543.6(a)(3), each petition must include an explanation of the means and process by which the device is activated and functions, including any aspect of the device designed to: (1) Facilitate or encourage its activation by motorists; (2) attract attention to the efforts of an unauthorized person to enter or move a vehicle by means other than a key; (3) prevent defeating or circumventing the device by an unauthorized person attempting to enter a vehicle by means

[1] 49 CFR 543.7 specifies that the manufacturer must include a statement that their entire vehicle line is equipped with an immobilizer that meets one of the following standards:

(1) The performance criteria (subsections 8 through 21) of C.R.C, c. 1038.114, *Theft Protection and Rollaway Prevention (in effect March 30, 2011),* as excerpted in appendix A of [part 543];

(2) National Standard of Canada CAN/ULC–S338–98, *Automobile Theft Deterrent Equipment and Systems: Electronic Immobilization* (May 1998);

(3) United Nations Economic Commission for Europe (UN/ECE) Regulation No. 97 (ECE R97), *Uniform Provisions Concerning Approval of Vehicle Alarm System (VAS) and Motor Vehicles with Regard to Their Alarm System (AS)* in effect August 8, 2007; or

(4) UN/ECE Regulation No. 116 (ECE R116), *Uniform Technical Prescriptions Concerning the Protection of Motor Vehicles Against Unauthorized Use* in effect on February 10, 2009.

[2] 49 U.S.C. 33106(d).

other than a key; (4) prevent the operation of a vehicle which an unauthorized person has entered using means other than a key; and (5) ensure the reliability and durability of the device.[3]

In addition to providing information about the antitheft device and its functionality, petitioners must also submit the reasons for their belief that the antitheft device will be effective in reducing and deterring motor vehicle theft, including any theft data and other data that are available to the petitioner and form a basis for that belief,[4] and the reasons for their belief that the agency should determine that the antitheft device is likely to be as effective as compliance with the parts-marking requirements of part 541 in reducing and deterring motor vehicle theft. In support of this belief, the petitioners should include any statistical data that are available to the petitioner and form the basis for the petitioner's belief that a line of passenger motor vehicles equipped with the antitheft device is likely to have a theft rate equal to or less than that of passenger motor vehicles of the same, or a similar, line which have parts marked in compliance with part 541.[5]

The following sections describe Mazda's petition information provided pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention.* To the extent that specific information in Mazda's petition is subject to a properly filed confidentiality request, that information was not disclosed as part of this notice.[6]

II. Mazda's Petition for Exemption

In a petition dated November 26, 2020, Mazda requested an exemption from the parts-marking requirements of the theft prevention standard for its confidential vehicle line beginning with MY 2023.

In its petition, Mazda provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for the confidential vehicle line. Mazda stated that its MY 2023 confidential vehicle line will be installed with a passive, transponder based, electronic engine immobilizer antitheft device as standard equipment. Key components of its antitheft device will include a powertrain control module (PCM), immobilizer control module, security indicator light, coil antenna, transmitter with transponder key (transponder key), low frequency (LF) antenna, radio frequency (RF) receiver and a low frequency unit (LFU). The device will not provide any visible or audible indication of unauthorized vehicle entry (*i.e.,* flashing lights or horn alarm) as standard equipment; however, Mazda stated that its device will incorporate a security indicator light which will provide a visual confirmation on the protection status of the antitheft device.

Pursuant to section 543.6(a)(3), Mazda explained that there are two methods of initiating the antitheft device operation process. Specifically, Mazda stated that the immobilizer system monitors two codes: (1) The transponder code, which the immobilizer control module checks with the transponder located in the transmitter; and (2) the immobilizer code, which the immobilizer control module checks with the powertrain's electronic control module. Mazda also stated that there are two means of checking the transponder code: (1) When the immobilizer control module communicates with the transmitter which includes a transponder by LF antenna and receives a reply of transmitter in the RF receiver; and (2) when the immobilizer control module communicates with the transponder by coil antenna which is located in the push button start. If the transponder code matches with the immobilizer control module by either method mentioned above, and the ignition is turned to the ON position, the immobilizer control module checks the powertrain's electronic control module with immobilizer code. Mazda further stated that the vehicle's engine can only be started if the immobilizer code matches the code previously programmed into the immobilizer control module. If the immobilizer code does not match, the engine will be disabled. Communications between the immobilizer system control function and the powertrain's electronic control module are encrypted. Mazda also stated that there are more than 15×10^6 different transponder codes, and each transponder is hard coded with a unique code at the time of manufacture.

As required in section 543.6(a)(3)(v), Mazda provided information on the reliability and durability of its proposed device. To ensure reliability and durability of the device, Mazda conducted tests based on its own specified standards. Mazda provided a detailed list of the tests conducted (*i.e.,* low/high temperature exposure operation, high temperature endurance, thermal cycling, thermal shock resistance, thermal shock endurance, humidity temperature cycling, high temperature and humidity endurance, water, dust, vibration, connector and lead/lock strength, chemical resistance, electromagnetic field, power line variations, DC stresses, electrostatic discharge and push button start strength) and stated that it believes the device is reliable and durable since it complied with its own specified requirements for each test. Additionally, Mazda stated that its device is extremely reliable and durable because it is computer-based and does not rely on any mechanical or moving parts. Mazda further stated that any attempt to slam-pull its vehicle's ignition will have no effect on a thief's ability to start the vehicle without the correct code being transmitted to the electronic control modules.

Mazda provided data from the Highway Loss Data Institute (HLDI), National Crime Information Center (NCIC), and Insurance Institute for Highway Safety (IIHS) on the effectiveness of other similar antitheft devices installed on vehicle lines in support of its belief that its device will be at least as effective as those comparable devices. Specifically, Mazda stated that its device was installed on certain MY 1996 Ford vehicles as standard equipment, (*i.e.,* all Ford Mustang GT and Cobra models, Ford Taurus LX, and SHO models and Ford Sable LS models). In MY 1997, Mazda installed its immobilizer device on the entire Ford Mustang vehicle line as standard equipment. When comparing 1995 model year Mustang vehicle thefts (without immobilizers) with MY 1997 Mustang vehicle thefts (with immobilizers), Mazda referenced the National Crime Information Center's (NCIC) theft information which showed that there was a 70% reduction in theft experienced when comparing MY 1997 Mustang vehicle thefts (with immobilizers) to MY 1995 Mustang vehicle thefts (without immobilizers). Mazda recognized that NHTSA requested data for vehicle sets that are as similar as possible to the vehicle for which the petition is written;[7] however, Mazda stated that there is no comparable data for a Mazda vehicle of the same body style before and after the implementation of an immobilizer system, because all of Mazda's similar vehicles have been equipped with a standard immobilizer from the onset of manufacture. In light of these considerations, Mazda stated that the NCIC and HLDI data provided supported its belief that the immobilizer system described in its petition will prove to be as, if not more effective,

[3] 49 CFR 543.6(a)(3).

[4] 49 CFR 543.6(a)(4).

[5] 49 CFR 543.6(a)(5).

[6] 49 CFR 512.20(a).

[7] See 85 FR 55368 (Sep. 8, 2020).

than the parts marking requirements of part 541 in reducing vehicle theft.

III. Decision To Grant the Petition

Pursuant to 49 U.S.C. 33106 and 49 CFR 543.8(b), the agency grants a petition for exemption from the parts-marking requirements of part 541, either in whole or in part, if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of part 541 or if deemed approved under 49 U.S.C. 33106(d). As discussed above, in this case, Mazda's petition is granted under 49 U.S.C. 33106(d).

However, separately, NHTSA also finds that Mazda has provided adequate reasons for its belief that the antitheft device for its vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard. This conclusion is based on the information Mazda provided about its antitheft device. NHTSA believes, based on Mazda's supporting evidence, that the antitheft device described for its vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard.

The agency concludes that Mazda's antitheft device will provide four types of performance features listed in section 543.6(a)(3): Promoting activation; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

The agency notes that 49 CFR part 541, Appendix A–1, identifies those lines that are exempted from the theft prevention standard for a given model year. 49 CFR 543.8(f) contains publication requirements incident to the disposition of all part 543 petitions. Advanced listing, including the release of future product nameplates, the beginning model year for which the petition is granted and a general description of the antitheft device is necessary in order to notify law enforcement agencies of new vehicle lines exempted from the parts-marking requirements of the theft prevention standard.

If Mazda decides not to use the exemption for its requested vehicle line, the manufacturer must formally notify the agency. If such a decision is made, the line must be fully marked as required by 49 CFR 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if a manufacturer to which an exemption has been granted wishes in the future to modify the device on which the exemption is based, the company may have to submit a petition to modify the exemption. Section 543.8(d) states that a part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the antitheft device on which the line's exemption is based. Further, section 543.10(c)(2) provides for the submission of petitions ''to modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in the exemption.'' [8]

For the foregoing reasons, the agency hereby announces a grant in full of Mazda's petition for exemption for the confidential vehicle line from the parts-marking requirements of 49 CFR part 541, beginning with its MY 2023 vehicles.

Issued under authority delegated in 49 CFR 1.95 and 501.8.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2021–09983 Filed 5–11–21; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Petition for Exemption from the Federal Motor Vehicle Theft Prevention Standard; North American Subaru, INC.

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition for exemption.

SUMMARY: This document grants in full the North American Subaru, Inc.'s (Subaru) petition for exemption from the Federal Motor Vehicle Theft Prevention Standard (theft prevention standard) for its Toyota GR 86 vehicle line beginning in model year (MY) 2022. The petition is granted because the agency has determined that the antitheft device to be placed on the line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard. Subaru also requested confidential treatment for specific information in its petition. Therefore, no confidential information provided for purposes of this notice has been disclosed.

DATES: The exemption granted by this notice is effective beginning with the 2022 model year.

FOR FURTHER INFORMATION CONTACT: Carlita Ballard, Office of International Policy, Fuel Economy, and Consumer Programs, NHTSA, West Building, W43–439, NRM–310, 1200 New Jersey Avenue SE, Washington, DC 20590. Ms. Ballard's phone number is (202) 366–5222. Her fax number is (202) 493–2990.

SUPPLEMENTARY INFORMATION: Under 49 U.S.C. Chapter 331, the Secretary of Transportation (and the National Highway Traffic Safety Administration (NHTSA) by delegation) is required to promulgate a theft prevention standard to provide for the identification of certain motor vehicles and their major replacement parts to impede motor vehicle theft. NHTSA promulgated regulations at 49 CFR part 541 (theft prevention standard) to require parts-marking for specified passenger motor vehicles and light trucks. Pursuant to 49 U.S.C. 33106, manufacturers that are subject to the parts-marking requirements may petition NHTSA, by delegation, for an exemption for a line of passenger motor vehicles equipped with an antitheft device as standard equipment that NHTSA decides is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements. In accordance with this statute, NHTSA promulgated 49 CFR part 543, which establishes the process through which manufacturers may seek an exemption from the theft prevention standard.

49 CFR 543.5 provides general submission requirements for petitions and states that each manufacturer may petition NHTSA for an exemption of one vehicle line per model year. Among other requirements, manufacturers must identify whether the exemption is sought under section 543.6 or section 543.7. Under section 543.6, a manufacturer may request an exemption by providing specific information about the antitheft device, its capabilities, and the reasons the petitioner believes the device to be as effective at reducing and deterring theft as compliance with the parts-marking requirements. Section

[8] The agency wishes to minimize the administrative burden that section 543.10(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting part 543 to require the submission of a modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be de minimis. Therefore, NHTSA suggests that if a manufacturer with an exemption contemplates making any changes, the effects of which might be characterized as de minimis, it should consult the agency before preparing and submitting a petition to modify.

543.7 permits a manufacturer to request an exemption under a more streamlined process if the vehicle line is equipped with an antitheft device (an ''immobilizer'') as standard equipment that complies with one of the standards specified in that section.[1]

Section 543.8 establishes requirements for processing petitions for exemption from the theft prevention standard. As stated in section 543.8(a), NHTSA processes any complete exemption petition. If NHTSA receives an incomplete petition, NHTSA will notify the petitioner of the deficiencies. Once NHTSA receives a complete petition the agency will process it and, in accordance with section 543.8(b), will grant the petition if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of part 541.

Section 543.8(c) requires NHTSA to issue its decision either to grant or to deny an exemption petition not later than 120 days after the date on which a complete petition is filed. If NHTSA does not make a decision within the 120-day period, the petition shall be deemed to be approved and the manufacturer shall be exempt from the standard for the line covered by the petition for the subsequent model year.[2] Exemptions granted under part 543 apply only to the vehicle line or lines that are subject to the grant and that are equipped with the antitheft device on which the line's exemption was based, and are effective for the model year beginning after the model year in which NHTSA issues the notice of exemption, unless the notice of exemption specifies a later year.

Sections 543.8(f) and (g) apply to the manner in which NHTSA's decisions on petitions are to be made known. Under section 543.8(f), if the petition is sought under section 543.6, NHTSA publishes a notice of its decision to grant or deny the exemption petition in the **Federal Register** and notifies the petitioner in writing. Under section 543.8(g), if the petition is sought under section 543.7, NHTSA notifies the petitioner in writing of the agency's decision to grant or deny the exemption petition.

This grant of petition for exemption considers North American Subaru, Inc.'s (Subaru) petition for its Toyota GR 86 vehicle line beginning in MY 2022. Subaru is the manufacturer of the Toyota GR 86 vehicle line as defined in 49 U.S.C. 32101(5), and is the manufacturer of the vehicle line as indicated on the label required by 49 CFR part 567. Accordingly, NHTSA determined that Subaru can use its one exemption request per model year for the Toyota GR 86 vehicle line beginning in MY 2022.

Subaru's petition is granted under 49 U.S.C. 33106 and 49 CFR 543.8(c), which state that if the Secretary of Transportation (NHTSA, by delegation) does not make a decision about a petition within 120 days of the petition submission, the petition shall be deemed to be approved and the manufacturer shall be exempt from the standard for the line covered by the petition for the subsequent model year. Separately, based on the information provided in Subaru's petition, NHTSA has determined that the antitheft device to be placed on its vehicle line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard.

I. Specific Petition Content Requirements Under 49 CFR 543.6

Pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention,* Subaru petitioned for an exemption for its specified vehicle line from the parts-marking requirements of the theft prevention standard, beginning in MY 2022. Subaru petitioned under 49 CFR 543.6, *Petition: Specific content requirements,* which, as described above, requires manufacturers to provide specific information about the antitheft device installed as standard equipment on all vehicles in the line for which an exemption is sought, the antitheft device's capabilities, and the reasons the petitioner believes the device to be as effective at reducing and deterring theft as compliance with the parts-marking requirements.

More specifically, section 543.6(a)(1) requires petitions to include a statement that an antitheft device will be installed as standard equipment on all vehicles in the line for which the exemption is sought. Under section 543.6(a)(2), each petition must list each component in the antitheft system, and include a diagram showing the location of each of those components within the vehicle. As required by section 543.6(a)(3), each petition must include an explanation of the means and process by which the device is activated and functions, including any aspect of the device designed to: (1) Facilitate or encourage its activation by motorists; (2) attract attention to the efforts of an unauthorized person to enter or move a vehicle by means other than a key; (3) prevent defeating or circumventing the device by an unauthorized person attempting to enter a vehicle by means other than a key; (4) prevent the operation of a vehicle which an unauthorized person has entered using means other than a key; and (5) ensure the reliability and durability of the device.[3]

In addition to providing information about the antitheft device and its functionality, petitioners must also submit the reasons for their belief that the antitheft device will be effective in reducing and deterring motor vehicle theft, including any theft data and other data that are available to the petitioner and form a basis for that belief,[4] and the reasons for their belief that the agency should determine that the antitheft device is likely to be as effective as compliance with the parts-marking requirements of part 541 in reducing and deterring motor vehicle theft. In support of this belief, the petitioners should include any statistical data that are available to the petitioner and form the basis for the petitioner's belief that a line of passenger motor vehicles equipped with the antitheft device is likely to have a theft rate equal to or less than that of passenger motor vehicles of the same, or a similar, line which have parts marked in compliance with part 541.[5]

The following sections describe Subaru's petition information provided pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention.* To the extent that specific information in Subaru's petition is subject to a properly filed confidentiality request, that information was not disclosed as part of this notice.[6]

[1] 49 CFR 543.7 specifies that the manufacturer must include a statement that their entire vehicle line is equipped with an immobilizer that meets one of the following standards:

(1) The performance criteria (subsections 8 through 21) of C.R.C, c. 1038.114, *Theft Protection and Rollaway Prevention (in effect March 30, 2011),* as excerpted in appendix A of [part 543];

(2) National Standard of Canada CAN/ULC–S338–98, *Automobile Theft Deterrent Equipment and Systems: Electronic Immobilization* (May 1998);

(3) United Nations Economic Commission for Europe (UN/ECE) Regulation No. 97 (ECE R97), *Uniform Provisions Concerning Approval of Vehicle Alarm System (VAS) and Motor Vehicles with Regard to Their Alarm System (AS)* in effect August 8, 2007; or

(4) UN/ECE Regulation No. 116 (ECE R116), *Uniform Technical Prescriptions Concerning the Protection of Motor Vehicles Against Unauthorized Use* in effect on February 10, 2009.

[2] 49 U.S.C. 33106(d).

[3] 49 CFR 543.6(a)(3).

[4] 49 CFR 543.6(a)(4).

[5] 49 CFR 543.6(a)(5).

[6] 49 CFR 512.20(a).

II. Subaru's Petition for Exemption

In a petition dated November 11, 2020, Subaru requested an exemption from the parts-marking requirements of the theft prevention standard for the Toyota GR 86 vehicle line beginning with MY 2022.

In its petition, Subaru provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for the Toyota GR 86 vehicle line. Subaru stated that its MY 2022 Toyota GR 86 vehicle line will be installed with an engine immobilizer device as standard equipment, as required by 543.6(a)(1). Subaru also stated it will offer a ''Smart Key'' system on all trim lines, which includes keyless access and push start functions. Specifically, key components of the ''smart entry'' system will include a keyless access engine control unit (ECU), steering lock ECU, engine ECU, an interior antenna, push button ignition switch, and an access key. Subaru also stated that there is a diagnosis tool used to perform a key ID code registration to the immobilizer module. Subaru stated that its antitheft device will also include an alarm system as standard equipment. Subaru stated that its alarm system will monitor door status and key ID, and opening of a door or hood will activate the alarm system. Subaru further stated that visual and audio features will attract attention to the efforts of an unauthorized person to enter or move the vehicle by sounding the vehicle's horn and illuminating the 4-way flashing hazard lamps.

Pursuant to section 543.6(a)(3), Subaru explained the means and process by which the immobilizer device is activated and functions. Subaru stated that its antitheft system and immobilization features are designed and constructed within the vehicle's overall CAN (controller area network) electrical architecture which means the antitheft system cannot be separated by rerouting or tapping into particular wires or connectors. Subaru further stated that the immobilization features will prevent operation of the vehicle by preventing the starting or operation of the engine even if an unauthorized person was to gain entry into the vehicle.

Subaru stated that its Toyota GR 86 ''smart key'' system is activated when the ignition is at the ''OFF'' position or the door is opened/closed while propulsion system is off and ignition is at the ''ON'' or ''ACC'' position. Deactivation occurs after the driver gets in the vehicle with the access key and pushes the button ignition switch while pressing the brake pedal, random codes are then transmitted to the access key from the keyless access ECU through the interior antenna. Once the access key receives the signal, it returns the encrypted code. When pushing the push button ignition switch once again, the power is turned off and the security indicator lamp blinks. Subaru stated that this method of activation will facilitate and encourage its activation by motorists because it requires nothing more than the removal of the key from the ignition switch when the vehicle is not being used.

As required in section 543.6(a)(3)(v), Subaru provided information on the reliability and durability of its proposed device. To ensure reliability and durability of the device, Subaru conducted tests based on its own specified standards and provided a detailed list of the tests conducted. Subaru stated that it believes that its device is reliable and durable because it complied with its own specific design standards and the antitheft device is installed on other vehicle lines for which the agency has granted a parts-marking exemption.

Subaru stated that its theft rates have been low per the National Insurance Crime Bureau's 2019 report on America's 10 most stolen vehicles. However, Subaru compared its proposed device to other Subaru antitheft devices that NHTSA has determined to be as effective in reducing and deterring motor vehicle theft as would compliance with the parts-marking requirements. Specifically, Subaru stated that the theft rate of the MY 2008 Impreza (not parts marked, standard engine immobilizer) decreased by almost 51% as compared to the MY 2007 Impreza (parts marked with optional engine immobilizer). Subaru stated that the antitheft system included on the Toyota GR 86 vehicle line is the same system employed on the Subaru Ascent car line, for which NHTSA determined that the system was likely as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard.[7]

Subaru also stated that the National Crime Information Center's (NCIC) theft data showed that there was a 70% reduction in theft experienced when comparing the MY 1987 Ford Mustang vehicle thefts (with immobilizers) to MY 1995 Ford Mustang vehicle thefts (without immobilizers). On the basis of the above and other cited comparisons, Subaru has concluded that its proposed immobilizer system is no less effective than those devices installed on lines for which NHTSA has already granted full exemptions.

III. Decision to Grant the Petition

Pursuant to 49 U.S.C. 33106 and 49 CFR 543.8(b), the agency grants a petition for exemption from the parts-marking requirements of part 541, either in whole or in part, if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of part 541 or if deemed approved under 49 U.S.C. 33106(d). As discussed above, in this case, Subaru's petition is granted under 49 U.S.C. 33106(d).

However, separately, NHTSA also finds that Subaru has provided adequate reasons for its belief that the antitheft device for its vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard. This conclusion is based on the information Subaru provided about its antitheft device. NHTSA believes, based on Subaru's supporting evidence, that the antitheft device described for its vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard.

The agency concludes that Subaru's antitheft device will provide the five types of performance features listed in section 543.6(a)(3): Promoting activation; attracting attention to the efforts of unauthorized persons to enter or operate a vehicle by means other than a key; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

The agency notes that 49 CFR part 541, Appendix A–1, identifies those lines that are exempted from the theft prevention standard for a given model year. 49 CFR 543.8(f) contains publication requirements incident to the disposition of all part 543 petitions. Advanced listing, including the release of future product nameplates, the beginning model year for which the petition is granted and a general description of the antitheft device is necessary in order to notify law enforcement agencies of new vehicle lines exempted from the parts-marking requirements of the theft prevention standard.

[7] 82 FR 57650 (Dec. 06, 2017).

If Subaru decides not to use the exemption for its requested vehicle line, the manufacturer must formally notify the agency. If such a decision is made, the line must be fully marked as required by 49 CFR 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if a manufacturer to which an exemption has been granted wishes in the future to modify the device on which the exemption is based, the company may have to submit a petition to modify the exemption. Section 543.8(d) states that a part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the antitheft device on which the line's exemption is based. Further, section 543.10(c)(2) provides for the submission of petitions ''to modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in the exemption.'' [8]

For the foregoing reasons, the agency hereby announces a grant in full of Subaru's petition for exemption for the Toyota GR 86 vehicle line from the parts-marking requirements of 49 CFR part 541, beginning with its MY 2022 vehicles.

Issued under authority delegated in 49 CFR 1.95 and 501.8.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2021–09981 Filed 5–11–21; 8:45 am]

BILLING CODE 4910–59–P

[8] The agency wishes to minimize the administrative burden that section 543.10(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting part 543 to require the submission of a modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be de minimis. Therefore, NHTSA suggests that if a manufacturer with an exemption contemplates making any changes, the effects of which might be characterized as de minimis, it should consult the agency before preparing and submitting a petition to modify.

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0458]

Agency Information Collection Activity Under OMB Review: Certification of School Attendance or Termination

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: 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. Refer to ''OMB Control No. 2900–0458.''

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0458'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 U.S.C. 101 (4).

Title: Certification of School Attendance or Termination (VA Forms 21–8960 and 21–8960–1).

OMB Control Number: 2900–0458.

Type of Review: Reinstatement of a previously approved collection.

Abstract: VA compensation and pension programs require current information to determine eligibility for benefits. VA Forms 21–8960 and 21–8960–1 solicit information that is needed to determine continued benefit eligibility for schoolchildren between the ages of 18 and 23. If the collection were not conducted or were conducted less frequently, VA would be unable to verify continued entitlement in a timely manner, and increased overpayments would result.

The burden estimate for VA Forms 21–8960 and 21–8960–1 has decreased as the number of respondent total has reduced over the past year.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 86 FR 35 on February 24, 2021, pages 11385 and 11386.

Affected Public: Individuals or Households.

Estimated Annual Burden: 1,543.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 9,259.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2021–10032 Filed 5–11–21; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 86 Wednesday,

No. 90 May 12, 2021

Part II

The President

Proclamation 10207—Mother's Day, 2021

Federal Register
Vol. 86, No. 90
Wednesday, May 12, 2021

Presidential Documents

Title 3—

The President

Proclamation 10207 of May 7, 2021

Mother's Day, 2021

By the President of the United States of America

A Proclamation

Each year on the second Sunday in May, we take time to thank and celebrate mothers across America—those who give us life and believe in us, so we can believe in ourselves. Throughout our history, even as they have nurtured and guided us, mothers have built, shaped, led, and sustained our Nation with selflessness and courage.

Like so many fellow Americans observing this day without their Moms with them, I will spend this Mother's Day missing my own mom, Catherine Eugenia ''Jean'' Finnegan Biden. She taught me about the importance of family, loyalty, and faith. Even now, I hear her voice reminding me that everyone is equal and that we are all defined by our sense of honor, duty, and courage. Her immeasurable strength lives on in all of her children, her grandchildren, her great-grandchildren, and the many other lives that she touched.

I will also spend this Mother's Day honoring the love of my life and the life of my love, Jill. In the many years of our marriage, she has healed our family, guided us through unimaginable hardships, and brought us untold joy and laughter. Her strength and determination have been our bedrock, and her warmth holds us all together.

Through their unconditional love, mothers shape our lives and help us become the people we hope to be. We especially thank the mothers who have led us through the COVID–19 pandemic. From the earliest days of this crisis, so many mothers across our country have worked essential jobs, borne the brunt of our caregiving crisis, and selflessly provided support and comfort in a time of anxiety and fear. For many families, mothers took on the full-time role of teacher and caregiver when our schools and child care facilities were closed or operating remotely. In fact, this year, millions of moms left the workforce or deferred their education in order to provide care. New mothers faced pregnancy and childbirth without family and friends to support them—exacerbating a preexisting maternal health crisis which disproportionately impacts Black and Native American families. On Mother's Day, we also honor those who have suffered the profound loss of the life of a child and those grappling with uncertainty in hopes of becoming mothers someday.

We also recognize that this will be the first Mother's Day for many families who lost their Mom due to COVID–19 and other diseases and cruel twists of fate of this past year. May God bless their memory and may this day fall gently on their loved ones left behind.

When we support mothers, we support the prosperity, security, and well-being of our entire Nation. That's why my Administration is committed to fighting for safe and equitable workplaces, addressing barriers women face at work, closing the gender wage and wealth gaps, and making quality child care affordable so parents can work, knowing their children are in good hands.

We've already begun this work through the American Rescue Plan's historic reductions in child poverty, ground-breaking investments in child care, and

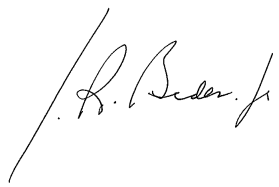
expanded support for families with children. Today, we are working to pass once-in-a-generation investments in our Nation's future through the American Jobs Plan and the American Families Plan. With these bills, we will modernize our schools, make it easier to care for aging loved-ones, create millions of good jobs, rebuild our country's infrastructure, and strengthen our economic competitiveness, so that all families have the opportunities they need to thrive.

Our Nation would not be where we are today without the foundations built by mothers. This Mother's Day, let us honor not only our own moms for their many contributions to our lives, but all mothers whose arms have cradled new generations and whose many gifts, unselfishly given, have blessed us all.

The Congress, by joint resolution approved May 8, 1914 (38 Stat. 770), has designated the second Sunday in May each year as ''Mother's Day'' and requested the President to call for its appropriate observance.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 9, 2021, as Mother's Day. I urge all Americans to express their love, respect, and gratitude to mothers everywhere, including the figures in our lives who nurture, guide, and sacrifice for us in the ways that mothers do. I call upon all citizens to observe this day with appropriate programs, ceremonies, and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this seventh day of May, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-fifth.



[FR Doc. 2021–10215
Filed 5–11–21; 11:15 am]
Billing code 3295–F1–P

Reader Aids

Federal Register

Vol. 86, No. 90

Wednesday, May 12, 2021

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6050**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.govinfo.gov.**

Federal Register information and research tools, including Public Inspection List and electronic text are located at: **www.federalregister.gov.**

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new**, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html and select** *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, MAY

23237–23576 3
23577–23842 4
23843–24296 5
24297–24474 6
24475–24696 7
24697–25798 10
25799–25942 11
25942–26148 12

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.

3 CFR

Proclamations:
10189 23843
10190 23845
10191 23847
10192 23849
10193 23851
10194 23853
10195 23855
10196 23857
10197 23859
10198 23861
10199 24297
10200 24301
10201 24477
10202 24479
10203 24697
10204 25799
10205 25943
10206 25945
10207 26147

Executive Orders:
14027 25947

Administrative Orders:
Presidential Determinations: No. 2021–06 of May 3, 2021 24475

Notices
Notice of May 6, 2021 25793
Notice of May 6, 2021 25795
Notice of May 6, 2021 25797

5 CFR

2611 25801

6 CFR

37 23237

7 CFR

3 24699

Proposed Rules:
205 25961
993 25975
1280 24513

8 CFR

Proposed Rules:
1 24750
103 ..... 24750, 25809
106 24751
204 24750
207 24750
208 24750
209 24750
210 24750
212 ..... 24750, 25809
214 24750
215 24750
216 24750
235 24750
236 24750
240 24750
241 24751
244 24750
245 24750
245a 24750
264 24750
274 25809
274a 24751
287 24750
316 24750
333 24750
335 24750

10 CFR

430 ..... 24483, 24484

Proposed Rules:
50 ..... 24362, 25977
51 24514
52 24362
429 24516
430 ..... 23635, 24538
431 ..... 23875, 24516, 24752

11 CFR

Proposed Rules:
113 23300

12 CFR

1242 23577

Proposed Rules:
30 24755
208 24755
328 24770
364 24755

13 CFR

126 23863

14 CFR

13 23241
39 ..... 23593, 23595, 23599, 24485
77 25801
244 23260
259 23260
383 23241
406 23241

Proposed Rules:
Ch. I 23876
39 ..... 23301, 24546, 24549, 24551, 24554, 24556, 24560, 24778, 24780, 24783, 24786, 24790, 25810, 25812
71 ..... 24562, 21782, 24792, 24794, 24795, 24797, 24798, 24800, 24801, 24803, 24805
Ch. II 23876
Ch. III 23876

15 CFR

Ch. XV 23271

16 CFR

Proposed Rules:
Ch. II 25817

17 CFR

232 25803
239 25803
249 25803
269 25803
274 25803
Proposed Rules:
240 24364

19 CFR

Ch. I 23277

20 CFR

Proposed Rules:
655 24368

21 CFR

1308 ..... 23602, 24487
1310 24703
Proposed Rules:
573 24564

22 CFR

228 24708

23 CFR

Proposed Rules:
Ch. I 23876
Ch. II 23876
Ch. III 23876

26 CFR

53 23865

29 CFR

780 24303
788 24303
795 24303

30 CFR

250 23606

31 CFR

Proposed Rules:
100 23877

33 CFR

100 ..... 23608, 23865, 24326, 24492
117 ..... 23278, 23609
165 ..... 23279, 23611, 23613, 23865, 24710, 25949
401 23241
Proposed Rules:
117 ..... 23639, 23880
165 ..... 24807, 25830

34 CFR

Proposed Rules:
Ch. II 23304

38 CFR

17 24494

39 CFR

3 24712
10 24712

40 CFR

9 24328
52 ..... 24499, 24500, 24502, 24503, 24505, 24507, 24713, 24715, 24717, 24718, 24726, 24728, 25951, 25954
62 24730
82 24444
180 ..... 24731, 25956
721 24328
725 24328
Proposed Rules:
52 ..... 24564, 24569, 24809, 24829, 24835, 25978
81 23309

42 CFR

37 24336
412 24735
510 23496
Proposed Rules:
412 25070
413 25070
425 25070
455 25070
495 25070

44 CFR

64 24739

45 CFR

147 24140
150 24140
153 24140
155 24140
156 24140
158 24140
184 24140

46 CFR

221 23241
307 23241
340 23241
356 23241
Proposed Rules:
Ch. II 23876

47 CFR

2 ..... 23281, 23614
15 23281
20 23614
68 23614
73 ..... 23866, 23868, 24339, 24510, 24741
90 23281
95 23281
Proposed Rules:
15 23323
73 ..... 23340, 24837, 25978, 25979
90 23323
95 23323

48 CFR

Proposed Rules:
Ch. 12 23876

49 CFR

107 23241
171 23241
190 23241
209 23241
213 23241
214 23241
215 23241
216 23241
217 23241
218 23241
219 23241
220 23241
221 23241
222 23241
223 23241
224 23241
225 23241
227 23241
228 23241
229 23241
230 23241
231 23241
233 23241
234 23241
235 23241
236 23241
237 23241
238 23241
239 23241
240 23241
241 23241
242 23241
243 23241
244 23241
272 23241
386 23241
578 23241
1570 23629
1582 23629
Proposed Rules:
Ch. I 23876
Ch. II 23876
Ch. III 23876
Ch. V 23876
531 25980
533 25980
Ch. VI 23876
Ch. VII 23876
Ch. VIII 23876
Ch. X 23876
Ch. XI 23876

50 CFR

17 ..... 23869, 25806
218 24340
622 24742
635 24359
648 ..... 23633, 24360, 24745
660 23872
665 24511
679 24746
Proposed Rules:
10 24573
17 ..... 23882, 25833
20 23641
32 23794
71 23794
224 23657
635 25992
660 23659

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 6, 2021

Public Laws Electronic Notification Service (PENS)

PENS is a free email notification service of newly enacted public laws. To subscribe, go to *https://listserv.gsa.gov/cgi-bin/wa.exe?SUBED1=PUBLAWS-L&A=1*

Note: This service is strictly for email notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.